

Injury Compensation Program² (Vaccine Program). 42 U.S.C. §§ 300aa-10 to -34 (2006). Petitioner alleges that the diphtheria, tetanus, and acellular pertussis (DTaP) vaccination administered to Emily on July 6, 2000, caused her to suffer an encephalopathy as defined by the Vaccine Injury Table (Table), 42 C.F.R. § 100.3(a)(2).³

Two fact hearings were conducted prior to the reassignment of this case to the undersigned. After reassignment, petitioner's counsel filed four motions for summary judgment. The original motion for summary judgment and supporting materials were filed on March 9, 2007, and denied on August 31, 2007. A renewed motion for summary judgment and in the alternative, for judgment on the record, was filed on October 31, 2008; petitioner's second renewed motion for summary judgment was filed on March 24, 2009; and petitioner's fourth (and third renewed) motion for summary judgment was filed on October 6, 2010. Except where indicated in this order, the undersigned refers to the various summary judgment motions collectively.

By status report filed on November 3, 2010, respondent's counsel declined to present any additional evidence on entitlement. Status Report, Nov. 3, 2010.

During a subsequently conducted status conference, the undersigned observed that a review of the record and factual findings permitted certain inferences that, together with the opinion of causation provided by petitioner's expert, Dr. Wheless, would support a finding in petitioner's favor.

By order of June 7, 2011, the undersigned provided the parties with a detailed overview of the fact and opinion evidence in the record that would support a finding in petitioner's favor. Nonetheless, as the undersigned did not have the opportunity to hear the testimony of the fact witnesses, and as expert evidence was limited to written reports,⁴ the parties were encouraged to informally resolve the matter. The parties then pursued mediation efforts.

² 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. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2006) (Vaccine Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

³ The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 2043 (31st ed. 2007).

⁴ An expert hearing to be held in May 2009 in Washington, DC was cancelled at petitioner's request. See June 7, 2011 Order at 10-11.

By request of the parties, the undersigned conducted another telephonic status conference on September 5, 2012. At that time, respondent's counsel represented that, in the view of the parties, the filing of an amended Rule 4 report, accompanied by a motion for ruling on the record, would be the most expedient method of resolving this matter. The parties indicated that because they were so close to a damages determination, a ruling on the record would permit a proffer on damages soon after issuance of a decision.

On September 6, 2012, respondent filed Respondent's Amended Vaccine Rule 4 Report and Motion for a Ruling on the Record (R's Amended Report). Respondent reports that medical personnel at the Department of Health and Human Services, Division of Vaccine Compensation ("DVIC"), have further reviewed this case, including the petition, the record, court filings and orders, the hearing transcripts, and the expert reports. R's Amended Report at 6. While maintaining the position that petitioner has failed to present preponderant evidence supporting her allegations or to establish a logical cause and effect relationship between the DTaP vaccine and Emily's encephalopathy, the Secretary has determined that no further resources will be expended to defend the case.⁵ Id.

Based on the record as a whole, as detailed below, petitioner is entitled to compensation under the Vaccine Program.

II. THE RECORD

A. Two Fact Hearings Were Held in 2005

On May 24, 2005, three members of the Lowrie family, Emily's mother (Jillian Lowrie), her grandmother (Myra Lowrie), and her grandfather (John Lowrie), testified before the previously assigned special master. Also testifying were two close friends of Emily's mother, namely Dara Ann Daniel and Stephanie Marie Yarbrough.

Three months later, on August 31, 2005, the then-assigned special master conducted a second hearing to take the testimony of Emily's pediatrician, Jean W. Bryant, M.D. Id.

⁵ Respondent stated in the Amended Report that the facts of this case are particularly unique, and will strongly object to any future attempt to interpret respondent's decision not to defend this matter as an acquiescence to any aspect of vaccine causation regarding any particular injury or fact pattern in another case. R's Amended Report at 6 n.4.

1. The Limited Scope of the Hearings

In support of the claimed Table injury, petitioner asserted that Emily showed certain symptoms of an injury that her medical records did not document. See Ruling Regarding Onset of Symptoms and Findings of Fact (Fact Ruling), *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *1 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Petitioner had previously filed affidavits from all five testifying witnesses describing symptoms of Emily’s injury. Fact Ruling at *5 (citing Pet. Exs. 15, 30-33).

Given the differences between the affiants’ statements and Dr. Bryant’s contemporaneous medical records, the special master conducted the fact hearings in order “[t]o determine whether [Emily’s] medical records were vague, incomplete, or otherwise susceptible to interpretation.” Id.

The special master did not consider a number of available medical records, as they were outside the “pertinent time period,” and thus did not require discussion. Fact Ruling at *4. These included filed “medical records . . . that document[ed] Emily’s treatment by various physicians, hospitals, and other health care professionals relating to her neurological problems.” Fact Ruling at *4 n.17 (listing in detail a “small sampling” of Emily’s records, including a record in which the special master said that “Dr. Wheless diagnosed Emily with ‘[e]ncephalopathy characterized by speech delay and probable global development delay that occurred in the setting of temporal association with immunizations as an acute encephalopathy.’”) (citing Pet. Ex. 10 at 12).

2. The Fact Ruling

On December 12, 2005, the previously assigned special master issued a Fact Ruling, in which she found—“[a]fter reviewing the medical records, affidavits, and testimony at both hearings, . . . that the medical records in this case [were] clear, internally consistent, and complete.” Id. Based on that finding and “the opportunity to observe the witnesses and evaluate their testimony,” the special master decided that petitioner could “not supplement the written record with contradictory testimony.” Id.

According to the special master, “with certain limited exceptions described [among the 22 enumerated findings of fact], petitioner’s explanations for the discrepancies between the medical records and her account of the events that occurred within 72 hours after Emily received her July 6, 2000 vaccinations [were deemed] to be insufficient to materially alter the contemporaneous medical records.” Fact Ruling at *24.

Included among the Findings of Fact were the following determinations:

Other than normal infant and young child ailments, Emily's development was essentially normal prior to her 15-month vaccinations.

Finding of Fact No. 2.

On July 18, 2000, [Emily's grandmother and mother] took Emily to see Dr. Bryant. They described Emily's symptoms subsequent to the July 6, 2000 vaccinations as inconsistent and [marked by] decreased response, irritability and crankiness, inconsolability, fever, decreased eye contact, blank stares, and walking and balance problems. In addition, they indicated that after Emily's four-month vaccinations, she experienced a limp.

Finding of Fact No. 14.

At the July 18, 2000 meeting, Dr. Bryant noted that Emily should not receive any further pertussis vaccines.

3. Request for Reconsideration of the December 12, 2005 Ruling

On June 1, 2006, petitioner filed a Motion for Reconsideration, and in the Alternative, for Certification to the Federal Circuit (Petr's Mot.). By a ruling issued on November 29, 2006 (November 29, 2006 Reconsideration Ruling), the undersigned denied petitioner's request for reconsideration of the December 12, 2005 Ruling. The undersigned found that contrary to petitioner's assertions, the applied legal standard was proper. Lowrie v. Sec'y of Health & Human Servs., No. 03-1585V, 2006 WL 3734216 at *16 (Fed. Cl. Spec. Mstr. Nov. 29, 2006).

The undersigned also declined to reconsider the factual findings set forth in the December 12, 2005 Ruling without first rehearing the testimony of the fact witnesses. Id. Deciding not to present Emily's family for another fact hearing, petitioner's counsel elected instead to seek a decision on the existing record.

B. Emily's Medical Records

On Thursday, July 6, 2000, Emily received her fourth DTaP and Hib vaccinations as well as her second MMR and Prevnar vaccinations. P's Ex. 3 at 1; P's Ex. 4 at 1. The DTaP vaccine was administered in her left anterior thigh. P's Ex. 3 at 1. See also Finding of Fact No. 4.

Dr. Bryant's records indicate that Emily suffered from a fever that lasted several days, beginning the day she received her vaccines, and spiking to 104 degrees (rectal reading). P's Ex. 3 at 19. On Sunday, July 9, 2000, at 9:13 a.m., Emily's mother called the on-call pediatrician to advise, according to the pediatric phone records, that Emily

had received vaccines the preceding Thursday, had developed “a temperature of 101 degrees,” and exhibited “bug bites on [her] legs.” P’s Ex. 3 at 19. Emily’s mother reported “no drainage” from Emily’s ear tubes, presumably evidence that Emily’s ears were not infected. Id.; see also Finding of Fact No. 11.

On Monday, July 10, 2000, at 8:40 a.m., Emily’s mother again called the pediatrician. The phone records reflect that Emily’s appetite had been poor since Saturday, and that since Sunday, she had been drinking poorly. Id. Expressed in Dr. Bryant’s notes was some “doubt” concerning the “longevity” of Emily’s fever after her vaccination. Id. But Dr. Bryant advised Emily’s mother to bring Emily into the office if her fever persisted another day. See id. Ignoring the counsel to wait another day, Emily’s mother arrived at Dr. Bryant’s office later that same day presenting Emily for examination. Id. Dr. Bryant’s records from that visit indicate that Emily was “crying but consolable by mom.” Id.; see also Finding of Fact Nos. 12 & 13.

Nearly one week later, on July 18, 2000, Emily’s mother and grandmother had a consultation with Dr. Bryant to address their ongoing concerns for Emily following her immunizations. See id. at 20. Dr. Bryant’s notes reflect reports from Emily’s family that after her vaccines, Emily exhibited an “inconsistent response,” was “irritable,” was “unable to console,” and had a “fever.” P’s Ex. 3 at 20. Emily was reported to have suffered from a 101 degree fever for three days and a 105 degree fever for three days. Id. Emily was reported to have also demonstrated a decreased response to her environment, decreased eye contact, and blank stares. Id. Her balance and walking were “bad since [her] imm[unizations].” Id. Dr. Bryant noted “no further pertussis,” id., and the billing records from that July 18, 2000 office visit provide additional support for a finding that Dr. Bryant had considered whether Emily suffered an adverse reaction to the pertussis vaccine. P’s Ex. 3 at 72. See also Finding of Fact Nos. 14 & 19.

On April 7, 2003, Dr. James Wheless, a pediatric neurologist at the University of Texas Health Science Center at Houston, evaluated Emily for treatment recommendations regarding her neurologic disorder. P’s Ex. 10 at 10; P’s Ex. 16 at 1. Dr. Wheless diagnosed Emily with “encephalopathy characterized by speech delay and probable global development delay that occurred in the setting of temporal association with immunizations as an acute encephalopathy” and “paroxysmal episodes” (on seizure-like event). P’s Ex. 10 at 12. Dr. Wheless recommended withholding any future immunizations from Emily. P’s Ex. 10 at 13.

C. Petitioner’s Expert Reports

On March 17, 2007, petitioner filed an expert report from Dr. Wheless. Dr. Wheless asserted that Emily’s irritability and decreased eye contact after her receipt of the DTaP vaccine was evidence that an acute encephalopathy had occurred. Id. at 3. Dr. Wheless further asserted that Emily’s initial acute encephalopathy “progressed to a

chronic encephalopathy that was characterized by dysfunction in her cognitive and social skills and also by [a] seizure disorder.” Id. Dr. Wheless opined that Emily’s chronic encephalopathy resulted from her pertussis vaccination. Id. at 4.

On March 2, 2009, petitioner filed a supplemental declaration from Dr. Bryant, who was Emily’s treating pediatrician at the time the vaccines were administered on July 6, 2000. See P’s Ex. 57. Dr. Bryant stated that Emily was developing normally at her 12-month well baby check on March 29, 2000, and that she had met “all her growth and developmental milestones.” Id. at 2. Dr. Bryant also observed that the family was “sufficiently worried and alarmed” by Emily’s symptoms following the administration of the vaccines in question, that they scheduled an appointment to discuss. Id. at 3. Dr. Bryant opined that Emily’s documented gait problems, and inconsistent response as well as Dr. Bryant’s own medical recommendation against any further pertussis vaccines, were supportive of a finding that the onset of Emily’s encephalopathy occurred in the days following her July 6, 2000 vaccinations. See id.

By filing dated March 12, 2009, petitioner’s counsel provided Emily’s medical records from a January 27, 2009 evaluation by Ian Butler, M.D., a pediatric neurologist. Dr. Butler’s assessment was that Emily’s previous medical history was “strongly suggestive of a vaccine-induced encephalopathy with seizures” and there was “no clinical evidence that Emily has a progressive disorder of the central nervous system that would negate consideration of a diagnosis of vaccine-related encephalopathy.” P’s Ex. 58 at 1-2.

D. Respondent’s Expert Reports and Petitioner’s Correlative Responses.

1. Dr. Kehrman’s Report

On May 19, 2008, respondent filed an expert report and curriculum vitae from Michael H. Kehrman, M.D., a pediatric neurologist. Dr. Kehrman challenged petitioner’s theory of causation asserting that absent the “temporal association [between the vaccine and] the onset of the alleged encephalopathy, no evidence of causation in fact” existed in this case. R’s Ex. A at 5. Dr. Kehrman posited that Emily’s “receptive and expressive language delay resulted from “her chronic and persistent ear infections, the most common cause of speech and language delays in children.” R’s Ex. A at 6. In support of his position, Dr. Kehrman referenced the 1987 edition of Nelson’s Textbook of Pediatrics. The 1987 edition of Nelson’s states, in relevant part: “[C]hronic otitis media can cause mild to moderate hearing loss, speech problems, language retardation, learning dysfunction, and inattention.” See R’s Ex. A at 6 (citing Nelson’s Textbook of Pediatrics 95-101 (1987)).

In Dr. Kehrman’s view, Emily exhibited symptoms of at least two distinct disorders having separate etiologies. First, he concurred with Dr. Wheless that Emily had suffered an encephalopathy, id., but he disputed any connection between Emily’s brain

injury and the vaccines she received. Second, he asserted that Emily developed a speech and language disorder as a result of her frequent bouts of otitis media. R's Ex. A at 5.

a. Dr. Wheless's Response

On September 11, 2008, petitioner filed additional exhibits, including an affidavit from Dr. Wheless that were responsive to Dr. Kohrman's expert report. Dr. Wheless averred that "all of Emily's problems [were] the expression of her static encephalopathy, which manifested within a day of her vaccinations." P's Ex. 46 at 2. Dr. Wheless added that Emily's seizures were "clearly a feature, [and] an additional manifestation, of her acquired brain injury, and the speech and language problems are likewise associated with the encephalopathy." P's Ex. 46 at 2.

Dr. Wheless strongly disagreed with Dr. Kohrman's opinion that Emily's speech and language problems resulted from the ear infections she had during infancy and as a toddler. Asserting that "the sine qua non of any deficit in speech development or language skills as the result of an ear infection is the temporary or permanent loss of hearing," Dr. Wheless pointed out that the records in this case affirmatively demonstrate that Emily has suffered no permanent hearing loss. Id. Nor is there evidence of any temporary loss of hearing. P's Ex. 46 at 2-3. To the contrary, Emily's medical records indicate that her hearing was normal. P's Ex. 46 at 3 (citing P's Ex. 5 at 28).

Dr. Wheless also questioned Dr. Kohrman's reliance on the 1987 edition of Nelson's because the more recent 2007 edition of the same text shows that medical understanding about ear infections has evolved over the intervening twenty year period. Contrary to Dr. Kohrman's position, the more current understanding is that neither "frequent ear infections... [nor] serious otitis media in early childhood result[s] in language disorder[s]." Id.

Dr. Wheless found factual support for Emily's encephalopathy claim in the pediatric record dated July 18, 2000. Id. In particular, Dr. Wheless referenced the litany of symptoms reported to Dr. Bryant on the date of the conference between Emily's mother and grandmother and Dr. Bryant. At that time, Emily's mother and grandmother reported that in the days immediately following Emily's vaccination, she experienced decreased response to environment, decreased eye contact, blank stares, crankiness, and a measure of inconsolability— symptoms Dr. Wheless described as consistent with the onset of an encephalopathy. See P's Ex. 46 at 3 (citing P's ex. 3 at 20).

Based on these reported symptoms, Dr. Wheless challenged Dr. Kohrman's assertion that the medical records showed "no evidence of an acute immunization-related encephalopathy." P's Ex. 46 at 5 (emphasis added). Dr. Wheless explained that the "blank stares recorded on July 18, 2000, [we]re consistent with seizures." Id. Dr. Wheless further explained that Emily's problems with walking and balance also recorded

at the time of the July 18, 2000 consultation (and noted in the billing records, P's Ex. 3 at 72), were suggestive of the type of motor disturbances that accompany an adverse neurological event. P's Ex. 46 at 5.

Dr. Wheless argued that as documented in the medical records, evidence of an acute encephalopathy can be found to have occurred a few days after the July 6, 2000 administration of the vaccines. Id. Moreover, he argued, the acute encephalopathy occurred within a time frame after Emily's vaccinations that has medical significance. He contended that Emily's fever, irritability, decreased responsiveness, and motor problems were observed within the time period after immunization during which children face an increased risk for encephalopathy. Id. As evidence that Emily's own pediatrician appreciated the significance of Emily's symptoms after vaccination and the time period in which they occurred, Dr. Wheless pointed to the notation in Emily's records made during the July 18, 2000 conference between Dr. Bryant and Emily's family counseling against receipt of "further pertussis" vaccines. Id.; see also Finding of Fact No. 19.

Insistent that Emily's symptoms of fussiness and sluggishness were not inconsistent, Dr. Wheless urged that periods of serious irritability as well as decreased consciousness can occur in an infant suffering from an acute encephalopathy. Id. at 5.

b. An Affidavit from Emily's Treating Otolaryngologist, Dr. Shoss

To further rebut Dr. Kohrman's claims regarding the injurious impact of Emily's numerous ear infections, petitioner filed an affidavit on October 31, 2008, from Stanford M. Shoss, M.D., the otolaryngologist who began treating Emily on February 29, 2000, four months prior to her receipt of the July 6, 2000 vaccines. See P's Ex. 47.⁶ Dr. Shoss averred that Emily's "speech and language disorder was not caused by her history of recurrent otitis media." P's Ex. 47, Attach. at 1. Dr. Shoss explained that Emily's "recurrent otitis media was aggressively treated both medically and surgically. . . . and that [n]ormal hearing sensitivity in both ears was documented on audiograms [between] September 18, 2002, and January 5, 2003. Id. Agreeing that Dr. Wheless appropriately relied on the 2007 edition of Nelson's, instead of the 1987 version cited by respondent's expert, Dr. Shoss discounted the impact of Emily's ear infections. Id. at 2.

⁶ Attached to Dr. Shoss's affidavit was a letter, designated here for purposes of reference as Attachment. The Attachment did not contain page numbers. The citation refers to the first and second pages of the unnumbered Attachment.

2. The Supplemental Opinions of Respondent's Expert, Dr. Kohrman, and Petitioner's Offered Response

On December 12, 2008, respondent filed a supplemental report from Dr. Kohrman and additional medical literature. See R's Exs. C-F. Dr. Kohrman maintained his view, based on the contemporaneous medical records and the Fact Ruling, that "there [was] no evidence of an acute encephalopathy" following Emily's receipt of the immunizations on July 6, 2000. R's Ex. C at 1. Dr. Kohrman posited instead that Emily's encephalopathy was "progressive in nature." R's Ex. C at 2. As evidence of her progressive encephalopathy, Dr. Kohrman pointed to the records from a pediatric visit that occurred six months prior to the vaccinations at issue documenting Emily's mother's expressed concern about Emily's development. See P's Ex. 3 at 7. That concern does not appear to have been shared by Emily's pediatrician, however, because in the same medical record, Dr. Bryant documented her own impression that Emily's development was appropriate. Id.

Almost one year later, on November 30, 2009, respondent filed another supplemental opinion from Dr. Kohrman proposing yet another theory of alternate causation. He opined that Emily's condition was caused by a prenatal injury. Dr. Kohrman's theory of prenatal injury emerged after he reviewed imaging of Emily's brain. R's Ex. G at 5.

On July 1, 2010, petitioner filed Dr. Wheless's response to Dr. Kohrman's prenatal brain injury theory. Dr. Wheless insisted that Dr. Kohrman's most recent hypothesis was inconsistent with the facts of this case—specifically with the April 22, 2003 MRI report that Dr. Wheless himself had ordered as part of his investigation of Emily's injury. See P's Ex. 52 at 19, P's Ex. 64 at 2-4. In Dr. Wheless's view, the lesion seen on Emily's April 22, 2003 MRI failed to explain any of Emily's impairments, and the impairments that the lesion would explain, Emily did not have. See P's Ex. 64 at 2-4.

By filing dated September 9, 2010, Dr. Kohrman responded that he and Dr. Wheless were in agreement that the MRI ordered by Dr. Wheless was abnormal and appeared to be consistent with ischemic white matter disease or periventricular leukomalacia (PVL). Dr. Kohrman referenced the textbook Neurology of the Newborn authored by Joseph Volpe, M.D.⁷ to explain the significance of these abnormal brain findings. R's Ex. I. Dr. Kohrman quoted Dr. Volpe's discussion of the long-term correlates of PVL: "The major long-term sequela of infants with PVL is cognitive disturbance." Id. at 435. Dr. Volpe added, in that same discussion, that the severity of the cognitive disturbance anticipated in children with PVL bore some relationship to the prominence of the motor deficits observed in the children.

⁷ Joseph Volpe, Neurology of the Newborn (Saunders Elsevier, 5th ed. 2008).

Although Emily's cognitive disturbance is pronounced, her motor deficits are less so. See P's Ex. 8 at 6-7 (motor skills returned, but speech skills did not); P's Ex. 10 at 3-5 (Dr. Kalsner notes that Emily has "developmental delay in all realms, possibly with the exception of gross motor skills"); P's Ex. 4 at 6,8 (Dr. Brennan assessed Emily at her three-year well child visit as a well child other than her developmental delay). Accordingly, by supplemental affidavit filed dated October 6, 2010, Dr. Wheless reiterated his view that the abnormal findings in Emily's brain failed to provide a biological "explanation for [her] condition." P's Ex. 67 at 2.

III. DISCUSSION

Petitioner alleges that Emily's July 6, 2000 DTaP vaccine caused Emily to suffer a Table encephalopathy. The Vaccine Act provides that in the circumstance in which petitioner establishes that a Table encephalopathy has occurred, a rebuttable presumption of causation attaches to petitioner's claim. 42 U.S.C. § 300aa-14(a). Among the persuasive factors supporting petitioner's vaccine claim here are: (1) Emily's documented symptoms over the days immediately following vaccination, (2) Emily's family's efforts to address Emily's condition and the response of the pediatrician's office within the week following the vaccination; (3) Emily's pediatrician's response to her post-vaccinal presentation, and (4) petitioner's expert filings in support of causation. Respondent challenged petitioner's claim and offered several theories of alternate causation. Petitioner effectively responded to each proposed theory of alternate causation. These factors together with respondent's election not to expend further resources to challenge petitioner's claim inform the undersigned's decision that petitioner is entitled to compensation under the Vaccine Program in this peculiarly unique set of circumstances.

IV. CONCLUSION

For the foregoing reasons, petitioner is entitled to an award of Program compensation. Counsel for the parties have indicated they expect to file a proffer on damages shortly after resolution of the merits. See September 18, 2012 Order. Accordingly, the parties are directed either to file a proffer on damages or to file a joint status report indicating when the proffer will be filed **on or before October 31, 2012**.

IT IS SO ORDERED.

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