IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

JOHN DOE 21,	)	
	)	No. 02-0411V
Petitioner,	)	
	)	Entitlement; DTaP; Developmental
v.	)	Delay; Sequella; Remand
	)	
SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	Filed: January 16, 2009
	)	
Respondent.	)	
	)	

John H. McHugh, New York, N.Y., for petitioner;
Michael P. Milmoe, United States Dep't of Justice, Washington, D.C., for respondent.

DECISION ON REMAND DENYING ENTITLEMENT [*]

Mr. John Doe alleges that the diphtheria - tetanus - acellular pertussis (DTaP) vaccine caused an injury to his son, Child Doe. Mr. Doe seeks compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 et seq. (2006). A preponderance of the evidence establishes that Mr. Doe is not entitled to compensation.

Child Doe received the DTaP vaccine on July 20, 1999. A preponderance of the evidence establishes that Child Doe started to show some signs of developmental delay in January 2000, which was diagnosed in March 2000. Mr. Doe has failed to establish that Child Doe's developmental delay was caused by the vaccination, which he received months earlier. Alternatively, Mr. Doe failed to establish that any adverse reaction to the July 20, 1999 DTaP vaccine lasted more than six months. Consequently, he is not entitled to compensation.

[*] Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

Previously, the Honorable Susan G. Braden ordered that the name of the petitioner be redacted in a decision available to the public. In accord with Judge Braden's October 9, 2008 order, this decision is being issued without the petitioner's name. See 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

The following outline is provided as a convenience to the reader and to facilitate review.

I. Factual History

Two earlier decisions describe Child Doe's medical history in great detail. Doe 21 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 19 (2008); Doe 21 v. Sec'y of Health & Human Servs., 02-0411V, 2008 WL 4679501 (Fed. Cl. Spec. Mstr. Oct. 14, 2008). Familiarity with these decisions is presumed. The following presentation of facts provides context for the analysis that follows.

A. From Birth Through Date of Vaccination

On May 11, 1999, Child Doe was born. See 10/2/02 Gov't Ex. B at 2-25. Some evidence suggests that Child Doe was born with a structural deformity in his brain known as a Chiari I malformation. Regardless of whether he had a Chiari I malformation, Child Doe's history for the first two months was normal. See 10/2/02 Gov't Ex. B at 30; 7/11/06 Pet. Ex. A at 5-7.

Child Doe had his two-month well-baby examination on July 20, 1999. Child Doe's pediatrician assessed him as "healthy." 10/2/02 Gov't Ex. B at 34. On this date, Child Doe received the DTaP vaccine. He also received other vaccines. 10/2/02 Gov't Ex. B at 32. However, there is no claim that these other vaccines caused Child Doe's injury.

Later that evening, Child Doe had crossed eyes, was moaning, and acting unusual. His mother brought him to the North Shore University Hospital Emergency Room. Upon admission, Child Doe's rectal temperature was 101.3 degrees. A review of his neurological system was negative. The resident described Child Doe as alert and in no acute distress. 10/2/02 Gov't Ex. B at 34B.

The doctors discharged Child Doe approximately 75 minutes after he was admitted to the emergency room. His mother was instructed to give him Tylenol for his fever and to follow up with the pediatrician in the morning. Child Doe's condition at discharge was "satisfactory." Id. at 34D.

It is important to interject into the chronology that respondent concedes that what happened to Child Doe on July 20, 1999, was an adverse reaction to the DTaP vaccine. Doe 21, 84 Fed. Cl. at 46-47; Doe 21, 2008 WL 4679501 * 26; tr. 1006-8. Respondent specifically identifies Child Doe's adverse reaction as a hypotonic-hyporesponsive event (HHE), although assigning a label to the reaction is not necessarily significant. What is significant is whether any adverse reaction caused any effects that lasted longer than six months. 42 U.S.C. § 300aa–11(c)(1)(D)(I); accord Song v. Sec'y of Health & Human Servs., 31 Fed. Cl. 61, 65 (1994), aff'd 41 F.3d 1520 (Fed. Cir. 1994) (table).[1] Thus, Child Doe's condition for the six months after his vaccination is described in the following section.

B. From Date of Vaccination Until Six Months Later

After the July 20, 1999 vaccination, which was given as part of the two-month health maintenance visit, Child Doe was seen three times before the next health maintenance visit, which was at four months. On July 21, 1999, the day after Child Doe was vaccinated and seen in the emergency room, his mother reported that his temperature was 101 degrees Fahrenheit. 10/2/02 Gov't Ex. B at 45. On July 28, 1999, Child Doe saw his pediatrician again. The doctor

[1] Although paragraph (D) in the statute provides alternative ways to measure the severity of the injury, Child Doe did not die, was not hospitalized, and did not have a surgical intervention.

reported that he was "alert [and] awake." However, Child Doe's eyes had "no tears" and were "crusty." 10/2/02 Gov't Ex. B at 48; see also tr. 1029.

Approximately three weeks later, Child Doe again saw his pediatrician. His temperature was 101°F and he was "cranky." The doctor described him as "alert" and "active." The doctor believed that Child Doe was suffering from a viral syndrome because his sister, who was four years older than he, was also ill. 10/2/02 Gov't Ex. B at 48; see also tr. 1029.

Child Doe had his four-month well-baby check up on September 14, 1999. The doctor determined that Child Doe was "well." Specifically, Child Doe could sit, hold up his head, and babble. The only area of concern was a "discharge" from the left eye that could possibly be from an obstruction in a tear duct. 10/2/02 Gov't Ex. B at 51.

As part of this visit, Child Doe received several more vaccinations. The doctor did not give Child Doe another dose of the DTaP vaccine because the doctor believed that the July 20, 1999 incident was a "hypotonic-[illegible] episode." Id. at 52; see also(wrong cite?) Use 10/2/02 Gov't Ex. B at 51. Instead of giving the DTaP vaccine, the doctor gave only the diphtheria and tetanus vaccines.

Child Doe suffered from an ear infection and thrush from September 23 to October 7, 1999. He saw a doctor at least five times during these two weeks. See 10/2/99 Gov't Ex. B at 53-55. During one of these visits, which was on October 4, 1999, Dr. Turow, the pediatrician, noted a "l[eft] strabismus" or "pseudostrabismus," and recommended an ophthalmologic consultation. Id. at 54. The significance of this visit is explained in section III.A.1.c(2), below.

On November 8, 1999, Child Doe was brought to the doctor's office. The doctor diagnosed him as having an upper respiratory infection and nasal congestion. The doctor noted that he was a "well infant," who had good head control and could grab objects well. However, Child Doe could not roll over and could not sit up without support. 10/2/02 Gov't Ex. B at 56. The pediatrician referred Child Doe to another doctor for left eye "deviation medially." Id. at 57.

As part of the November 8, 1999 examination, Child Doe received another dose of the diphtheria - tetanus vaccine. Again, Child Doe did not receive the acellular pertussis component of the DTaP vaccine. Id.; 7/11/06 Pet. Ex. A at 1; see also tr. 1042 (Dr. Turow describing the elimination of pertussis).

The examination by a pediatric ophthalmologist took place on November 10, 1999. Dr. Steven Rubin found Child Doe to be a "healthy 6 month old baby" for whom esotropia was suspected. Dr. Rubin found no evidence of strabismus and believed that any esotropia "would probably resolve spontaneously over the next several months." See 10/2/99 Gov't Ex. B at 59.

On November 15, 1999, November 22, 1999, and December 4, 1999, Child Doe was seen by doctors because he was experiencing illnesses that are relatively routine for childhood. See 10/2/99 Gov't Ex. B at 58, 61. During the December 4, 1999 visit, the doctor also observed that

Child Doe's head was slightly twisted. He recommended an appointment to review Child Doe's head circumference and development. Id. at 61.

In December 1999, Child Doe continued to experience various routine illnesses of childhood. The doctors prescribed various antibiotics. Id. at 62-63. Child Doe was still sick in the beginning of January 2000. However, on January 19, 2000, the pediatrician noted that Child Doe's ear infection had improved. Id. at 64.

On January 31, 2000, Child Doe had another well-baby examination. The doctor described him as "well." Child Doe could sit without support, use a "pincer grasp," speak, wave, and play "peek-a-boo." On the other hand, Child Doe could not pull "to stand" or "cruise."

This January 31, 2000 visit is slightly more than six months after Child Doe's adverse reaction on July 20, 1999. Therefore, for Child Doe to receive compensation, he must be suffering from a sequella at this date. Because events after January 31, 2000, may shed some light on Child Doe's condition, these are discussed briefly in the following section.

C. Events After January 31, 2000

In February 2000, Child Doe experienced some illnesses. The treating doctors do not note any concerns about his development. 10/2/99 Gov't Ex. B at 66-67.

In a follow up visit for an ear infection, on March 8, 2000, Dr. Turow noted a concern about Child Doe's "developmental progression." Dr. Turow thought that there was possibly an increase in tone, with Child Doe having the functional level of a 6-7 month old. 10/2/99 Gov't Ex. B at 68. On March 17, 2000, Child Doe also had an ultrasound because of concerns that his head size was enlarged. The ultrasound revealed "[p]rominent extra-axial spaces" consistent with "benign external hydrocephalus." Id. at 70. This condition did not affect Child Doe's development. Tr. 1023.

Dr. James Fagin from the Nassau County Early Developmental Intervention Program, examined Child Doe on March 27, 2000. Dr. Fagin determined that Child Doe had "fine & gross motor developmental delay." 10/2/02 Gov't Ex. L at 240.

A more in-depth examination of Child Doe's development occurred on March 29, 2000 at the Louise Oberkotter Early Childhood Center. Among different categories of development, Child Doe's gross motor functioning was the weakest. Child Doe was rated as performing between 5.5 and 7.0 months even though he was slightly more than ten months at the time. In other respects, he was between 7 and 8.5 months. In still other skills, he was between 8.5 and 10 months. Physical therapy and monitoring were recommended. Id. at 219-23.

On March 29, 2000, an ophthalmologist examined Child Doe. The doctor recorded a "vertical nystagmus." Id. at 69. This notation was the first time that a medical professional observed any nystagmus.

The next day, Child Doe's mother told the pediatrician that Child Doe's vertical nystagmus seemed to be worsening. The pediatrician referred them to a pediatric neurologist, Dr. Robert Gould. Dr. Gould tried to see, but did not observe, the vertical nystagmus. 10/2/02 Gov't Ex. B at 71; see also 10/2/02 Gov't Ex. F at 179.

On April 5, 2000, Child Doe again was seen by Dr. Rubin, a pediatric ophthalmologist who had examined him in November 1999. Dr. Rubin also did not observe any nystagmus. 10/2/02 Gov't Ex. B at 72.

Another pediatric neurologist, Dr. Pavlakis, examined Child Doe on April 28, 2000. The reason for the referral to Dr. Pavlakis was Child Doe's "up and down eye fluttering" and "upper eyelid fluttering," without "alteration of consciousness." Dr. Pavlakis noted that Child Doe regularly was alert, active, and interactive for someone his age, but also was delayed "in regard to motor milestones." Dr. Pavlakis concluded that Child Doe had mild hypotonia, but had "trembling in both arms" and "mild tremors." Dr. Pavlakis was not overly concerned with Child Doe's eye and eyelid fluttering and, after reviewing a video of Child Doe's "atypical eye movements," did not believe they were "seizures." Dr. Pavlakis, however, referred Child Doe to a neuro-ophthalmologist to explore whether Child Doe suffered from epilepsy. 10/2/02 Gov't Ex. B at 78-79.

The details of most events in Child Doe's medical history after April 2000 are generally not relevant to determining whether the July 20, 1999 DTaP vaccination caused Child Doe's developmental delay. Respondent concedes that by March 2000, Child Doe was suffering from an encephalopathy. Furthermore, respondent concedes that whatever caused the encephalopathy, which was apparent by March 2000, also caused additional developmental delays. Tr. 1006.

Although details of Child Doe's medical history after April 2000 are not set forth in this decision, these details appear in the two previous opinions and have been considered. Doe 21, 84 Fed. Cl. at 25-33; Doe 21, 2008 WL 4679501 *11-*13; see also Medtronic, Inc. v. Daig Corp., 789 F.2d 903, 906 (Fed. Cir. 1986) (indicating that the fact-finder is presumed to consider all evidence); Guillory v. United States, 59 Fed. Cl. 121, 126 (2003) (stating "The court is not aware of, and petitioner does not cite to, any requirement that the special master must reference in his decision each item of evidence presented during the proceedings before the special master."). Opinions from treating doctors about whether the July 20, 1999 vaccination caused Child Doe's development are discussed in section III.B.1.b below.

II. Procedural History

The two previous published decisions provide some procedural history of this case through October 2008. Thus, section A., below, reviews this history summarily. Section B, below, details the procedural history after the remand by Judge Braden.

A. From Petition to Remand

On April 30, 2002, Mr. Doe filed a petition seeking compensation for Child Doe's injuries. Mr. Doe asserted two different theories of recovery. First, he alleged that Child Doe suffered an injury (an encephalopathy) that appears on the Vaccine Injury Table in association with the DTaP vaccine. See 42 C.F.R. § 100.3 ¶ II. This cause of action was premised upon information not contained in medical records. Mr. Doe also asserted a second theory of recovery. Pet., introductory paragraph. Pursuant to this theory, Mr. Doe alleged that the DTaP vaccine "caused in fact" his son's injury. For this second theory, Mr. Doe did not rely upon the presumption of causation granted by the Vaccine Act and codified in the Vaccine Injury Table.

Mr. Doe filed medical records periodically from October 2002 through April 2004. (As the notations in the factual history suggest, the way Mr. Doe labeled exhibits was less than ideal. Mr. Doe used both letters and numbers and repeated letters and numbers.)

Because Mr. Doe was relying upon assertions that came from sources other than the contemporaneously created medical records, Special Master Edwards held a hearing to receive testimony from three witnesses on October 27, 2005. Tr. 1-147. On the next day, the Special Master heard testimony from a doctor retained by Mr. Doe, Dr. Eugene Spitz, and a doctor retained by respondent, Dr. Max Wiznitzer. Tr. 201-380. See Order, dated September 19, 2005.

In the October 28, 2005 hearing, Mr. Doe did not present testimony from Dr. Spitz in which Dr. Spitz expressed a medical theory causally connecting the July 20, 1999 DTaP vaccination to Child Doe's developmental delay. This omission may have occurred because Mr. Doe may have believed, erroneously, that the hearing was only on his claim pursuant to the Vaccine Injury Table. See tr. 385-86. Dr. Spitz primarily testified about whether Child Doe suffered the features of an encephalopathy as "encephalopathy" is defined at 42 C.F.R. § 100.3(b)(2). See tr. 212-18. Dr. Spitz also testified why he believed that Child Doe did not suffer from a Chiari I malformation. Tr. 341 et seq. In doing so, Dr. Spitz indicated that he reviewed films from an MRI. However, Mr. Doe had not filed the report of the radiologist who interpreted the MRI initially. See tr. 364-66. Therefore, the October 28, 2005 hearing did not conclude the development of evidence.

Eventually, Mr. Doe filed the reports of the MRI. However, before the next scheduled hearing, Dr. Spitz died. Mr. Doe retained another doctor, Dr. John Shane. Dr. Shane prepared a report, dated September 3, 2006, that Mr. Doe filed on November 13, 2006 as exhibit B. This report discusses, primarily, Dr. Shane's interpretation of the MRIs and whether Child Doe suffered a Chiari I malformation.

In preparation for another hearing, Mr. Doe filed a witness list on July 10, 2007. This witness list indicated that Dr. Shane would testify about a Chiari I malformation and Dr. Spitz's reputation.

Special Master Edwards convened another hearing on July 20, 2007, to complete the record. Tr. 381-479. At the beginning of the hearing, Mr. Doe indicated that he wanted to

present "another theory." Tr. 385. However, Special Master Edwards limited the July 20, 2007 hearing to testimony relating to the MRIs because that was the issue left open at the October 28, 2005 hearing. Tr. 395-96, 422-27.

On May 22, 2008, Special Master Edwards issued a decision, denying compensation. For Mr. Doe's first theory, which was that Child Doe suffered an on-Table encephalopathy, the Special Master found that facts that did not support Mr. Doe's theory. Specifically, Special Master Edwards found that the testimony of the three witnesses who testified on October 27, 2005, was not persuasive. Instead, Special Master Edwards credited the medical records that were created contemporaneously with the events described in the witnesses' testimony. Doe 21, 2008 WL 4679501 *20, *22.

Special Master Edwards's May 22, 2008 decision also denied compensation pursuant to Mr. Doe's alternative theory that the DTaP vaccine caused in fact Child Doe's injury. Here, the Special Master reasoned that Child Doe did not suffer an adverse reaction that persisted for more than six months. Doe 21, 2008 WL 4679501 *26.

Mr. Doe filed a motion for review of Special Master Edwards's May 22, 2008 decision. This motion was assigned to Judge Braden of the United States Court of Federal Claims.

Judge Braden issued a very detailed decision on October 6, 2008, which was reissued for publication on October 21, 2008. Judge Braden found that Special Master Edwards did not commit any reversible errors as argued in Mr. Doe's motion for review. Doe 21, 84 Fed. Cl. at 46, 49-50. However, Judge Braden did hold that Special Master Edwards committed three legal errors. First, Special Master Edwards erroneously placed the burden of disproving HHE on Mr. Doe. Second, Special Master Edwards erred when determining that a record created by Dr. Eviatar was not credible when Special Master Edwards did not observe her personally. Third, Special Master Edwards erred when he prevented Dr. Shane from completing his testimony. Id. at 46-49. Consequently, Judge Braden vacated Special Master Edwards's May 22, 2008 decision and remanded the case. Judge Braden instructed the undersigned to reopen the case to allow Dr. Shane to complete his testimony, to obtain testimony from Dr. Eviatar, and to allow the respondent to present any testimony in rebuttal. Judge Braden remanded the case with instructions to complete these tasks and to issue a decision within 90 days. Id. at 50.

B. After Remand

After Judge Braden remanded the case, an on-the-record status conference was held on October 16, 2008, and another hearing was scheduled. Following this status conference, Mr. Doe was ordered to file a supplemental report from Dr. Shane. The purpose of the supplemental report was to ensure that both respondent and the undersigned were aware of the scope of Dr. Shane's anticipated testimony. Mr. Doe was also instructed to contact Dr. Eviatar about testifying. Order, filed Oct. 16, 2008.

Mr. Doe filed a supplemental report from Dr. Shane on October 30, 2008 (stamped as filed on November 5, 2008). Exhibit 101. Dr. Shane's October 30, 2008 report discusses how a

vaccine containing pertussis can cause neurological injuries. Exhibit 101 at 5-9, 13-15. Dr. Shane also opined that HHE may have sequella. Id. at 7-8.

Mr. Doe was also attempting to obtain a report from a pediatric neurologist. Despite respondent's objection that a report from a new expert was beyond the scope of Judge Braden's remand order, Mr. Doe was permitted to obtain a report from a new expert. Order, filed Nov. 6, 2008. Mr. Doe actually filed a report from Dr. Mary Norfleet Megson on November 21, 2008. Dr. Megson's expertise is discussed below.

For his part, respondent filed a supplemental report from Dr. Wiznitzer on November 21, 2008. Exhibit F. This report responded to Dr. Shane's October 30, 2008 report. Dr. Wiznitzer could not respond to Dr. Megson's report because Dr. Megson's report was filed the same day as respondent filed Dr. Wiznitzer's report.

In a status conference on November 26, 2008, Mr. Doe stated that Dr. Eviatar had answered, in writing, questions jointly proposed by the parties. Mr. Doe stated that these answers obviated the need for Dr. Eviatar to testify in person. Respondent agreed and later filed Dr. Eviatar's letter as exhibit I.

A hearing was held on December 2, 2008, in New York, New York. During this hearing, Mr. Doe called four witnesses. The primary witnesses were Dr. Turow, Dr. Shane, and Dr. Megson.[2] Mr. Doe, himself, testified only briefly. Respondent called one witness, Dr. Wiznitzer.

After the hearing, the parties filed briefs on an expedited basis. They also submitted additional medical articles. Exhibits 146 through 172 and exhibits I through V. The case is ready for adjudication.

III. Analysis

Two general findings underpin the analysis. These are findings regarding Child Doe's development between July 1999 and March 2000. Child Doe was developing at a normal pace. This finding strongly suggests that the dose of the DTaP vaccine given on July 20, 1999 did not cause a delay in Child Doe's development. The second finding, which is related to the first, is that petitioner's experts were not persuasive.

After these two general points are discussed, the specific theories of recovery are examined. Largely for the reasons set forth in the general points, Mr. Doe's claim is denied.

[2] Mr. Doe called Dr. Turow because Dr. Eviatar had indicated that he was the source of information about Child Doe's condition. Respondent did not object to the calling of Dr. Turow.

A. General Points

1. Child Doe's Developmental Status from July 1999 to March 2000

There is no doubt that Child Doe was developing normally in his first two months, until July 20, 1999. There is also no doubt that Child Doe's development is impaired currently. Respondent maintains that the developmental delay was first evident in March 2000. Respondent further concedes that Child Doe's current condition is linked to the developmental delay apparent in March 2000. Thus, a critical question is what was Child Doe's developmental status between July 1999 and March 2000.

An abundance of evidence indicates that Child Doe was developing normally, at least through December 1999. Between July 20, 1999 and February 2000, a pediatrician saw Child Doe for health maintenance visits at four months of age (September 14, 1999), at six months of age (November 8, 1999), and at nine months of age (January 31, 2000). During these visits, a pediatrician concluded that Child Doe was healthy and did not refer Child Doe for any therapy.

During these routine appointments, which are sometimes referred to as "well-baby visits" or "health maintenance visits," the pediatrician examined Child Doe. Dr. Megson, generally complimented the work done by Dr. Turow and his colleagues. Tr. 1128 (Dr. Megson stating the pediatricians "documented things very well"), 1205-206 (Dr. Megson stating that Dr. Turow is "a wonderful pediatrician. I think they did a pretty good job.").

Child Doe's developmental progress was specifically reflected in these examinations. As records created contemporaneously to the events being observed by a treating doctor, they are presumed to be correct. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). While all these records are entitled to a substantial amount of weight by themselves, they are not the only form of evidence about Child Doe's condition. The testimony of Dr. Victor Turow, a pediatrician who cared for Child Doe during this time, adds to their value. As a witness, Dr. Turow appeared sincere and honest.

Because the well-baby visits establish that Child Doe was developing normally until at least December 1999, these visits are discussed in detail in the following sections. Although this review necessarily highlights the well-baby visits, Child Doe was seen by his pediatrician between visits. These intervening appointments were because Child Doe was sick, usually suffering from an ear infection. During these appointments, the pediatrician examined Child Doe briefly and also would have noted any other significant health problems that a parent raised. Tr. 1016-7. One example of this practice occurred when Dr. Turow saw Child Doe as a follow up for an ear infection and also noted concerns about Child Doe's developmental progress. 10/2/02 Gov't Ex. B at 68 (note from March 8, 2000).

a. Two-month-old Visit

On July 20, 1999, Child Doe was seen for a two-month-old health maintenance visit. 10/2/02 Gov't Ex. B at 34. Dr. Earhardt, the pediatrician on that day, assessed Child Doe as

"healthy." Dr. Earhardt noted that Child Doe "roll[ed] side to side, lifts head very well, coos vocalizes, focuses on face, turns to voice, smiles." Id.; see also tr. 1030.

Both experts retained by Mr. Doe offered the opinion that Child Doe was advanced at two-months. Tr. 1205 (Dr. Megson), 1295 & 1318 (Dr. Shane). This conclusion is overstated. The ability to turn to a voice is usually found in children two and a half to three-months-old. Tr. 1031 (Dr. Turow). So, Child Doe is slightly accelerated in this skill. Although Dr. Megson may have suggested that this ability is more commonly found in children who are four-months old, her testimony is not clear. Tr. 1125, 1205. Furthermore, even if Dr. Megson disagreed with Dr. Turow about the appropriate milestone for a two-month-old, Dr. Turow's opinion is more persuasive because Dr. Megson has relatively little experience in examining two-month-old children. Tr. 1168, 1214-15. The relative experience may be considered in determining which expert is more persuasive. Waleryszak v. Sec'y of Health & Human Servs., 45 Fed. Cl. 573, 578 (1999) (affirming decision of special master), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2000) (table); see also Guilliams v. Barnhart, 393 F.3d 798, 803 (8th Cir. 2005) (stating that in cases seeking benefits pursuant to the social security act, opinions of specialists within their field of expertise are generally entitled to more weight than opinions of nonspecialists). (Additional comments about the persuasiveness of Dr. Megson are set forth in section III.A.2.b, below.)

For his part, Dr. Shane premised his opinion that Child Doe was advanced on an assumption that Child Doe was rolling over. Tr. 1319. Dr. Megson shares this assumption. Tr. 1126. However, the notation actually reads that Child Doe "rolls to side," not rolling over. 10/2/02 Gov't Ex. B at 34; see also tr. 1350 (testimony of Dr. Wiznitzer noting this distinction).

Rolling side to side is different from rolling over. Even so, rolling side to side is an advanced ability for a two-month-old. Tr. 1030, 1039. Whether this ability truly augured an advanced development for Child Doe is not clear. Sometimes, a child may develop one skill earlier than expected, but then lose it for a period of time and not display this same ability until the "normal" time. Tr. 1104-05.

Thus, at two-months, Child Doe was slightly advanced in his ability to roll from side-to-side. Dr. Earhardt, the examining pediatrician, did not note anything particularly advanced or delayed. 10/2/02 Gov't Ex. B at 34.

During this visit, Child Doe received his first (and only) dose of the DTaP vaccine. Later, on this date, he was brought to the emergency room. The details of this visit are not relevant in describing Child Doe's development, which is primarily summarized in the sequence of records from health maintenance visits.

b. Four-month-old Visit

The next health maintenance visit occurred on September 14, 1999, when Child Doe was four-months. Dr. Barrone determined that Child Doe was "well." Specifically, Child Doe could sit, hold his head, reach for toys and babble. Dr. Barrone checked "normal" for neurological examination. The only area of concern was a "discharge" from the left eye that could possibly

be from an obstruction in a tear duct. 10/2/02 Gov't Ex. B at 51; see also tr. 1064, 1075. Dr. Turow noted that, in some respects, Dr. Barrone's notes could have contained more details that would aid in understanding what Dr. Barrone observed. Tr. 1085-86.

For example, the notation that Child Doe "sits" is vague. According to Dr. Turow, a four-month-old baby is unlikely to sit, if "sit" is understood to mean without support. On the other hand, some four-month-olds can remain in a seated position if they are placed there and supported. Tr. 1085-86. Dr. Megson agrees that trying to determine a child's developmental progress by looking at whether they were "sitting" without more information can be tricky. Tr. 1127, 1198. Dr. Wiznitzer, too, believes that the reference to "sit" must mean sits without support. Tr. 275, 321.

Dr. Barrone's notation that Child Doe could hold his head provides little information about his developmental progress. At his two-month check up, Child Doe could "lift[] [his] head up well." 10/2/02 Gov't Ex. B at 34. Thus, holding his head at four-months may not be much of a change depending upon how Child Doe was holding his head. Tr. 1085-86.

In contrast to the somewhat indefinite entries about sitting and holding his head, the report that Child Doe was reaching for toys and babbling does provide more details. Reaching for toys is a function typically performed by four- or five-month-olds. Babbling, if understood to mean monosyllabic babbling, is also more advanced than what a four-month-old can usually do. Tr. 1086.

The doctors who were retained in this litigation agree that Child Doe was not showing developmental delays at the four-month-old health maintenance visit. Dr. Spitz, the doctor whom Mr. Doe originally retained, indicated that Child Doe was making appropriate milestones at this visit. Tr. 238. Dr. Wiznitzer also thinks that Child Doe was making adequate progress. Tr. 274-76. Dr. Megson did not see anything to indicate to her that Child Doe was developmentally delayed. However, Dr. Megson did note that the pediatrician was a general pediatrician, not a specialist in development. Tr. 1198-99.

The only qualified exception to this general agreement about Child Doe's developmental progress at four-months came from Dr. Shane. Dr. Shane's opinion as to whether Child Doe was developmentally delayed at four months was unclear. Like Dr. Megson, whose testimony Dr. Shane heard, Dr. Shane believes that Dr. Barrone did not conduct a complete neurodevelopmental examination. However, Dr. Shane could not explain how a complete neurodevelopmental examination for a four-months-old child would differ. Dr. Shane's demeanor at this point in his testimony suggested that Dr. Shane was relying on the lack of a "neurodevelopmental examination" without understanding what one was. Tr. 1316-18. His testimony, therefore, lacks credibility. Instead, it appears that Dr. Shane stated that Child Doe was suffering from an encephalopathy during his four-month health maintenance visit solely to be consistent with his theory that Child Doe began suffering an encephalopathy on July 20, 1999. Therefore, it follows that, Dr. Shane believes that at the four-month visit, Child Doe was falling behind. Tr. 1316-18.

Dr. Shane's opinion and testimony are not persuasive for at least three reasons. First, Dr. Shane's demeanor during this testimony indicated that he was, at a minimum, uncertain how to respond. This uncertainty, in turn, is reflected is his evasive testimony about Child Doe's developmental status. Tr. 1316-18.

Second, Dr. Shane's opinion that Child Doe was falling behind is premised upon an assumption that Child Doe was "ahead of the curve at age two months." Tr. 1318. As discussed in section III.A.1.a, above, Dr. Shane appears to overestimate Child Doe's abilities at two months. Contrary to Dr. Shane's opinion, there is not a dramatic change in the progress of Child Doe's development during this time. For example, reaching for toys and babbling in monosyllables are functions typically performed by infants older than four-months. Therefore, at least as much evidence indicates that Child Doe was advanced at four months as evidence indicates that Child Doe was advanced at two months.

Third and most important, Dr. Shane is not as qualified as the other doctors who opined on this topic. Five other doctors (Dr. Barrone, Dr. Turow, Dr. Spitz, Dr. Megson, and Dr. Wiznitzer) all believed that Child Doe was normal at four-months. All of these doctors have much more experience in treating infants than Dr. Shane. Dr. Barrone and Dr. Turow were practicing pediatricians. Dr. Spitz was a pediatric neurosurgeon with some experience in pediatric neurology. Tr. 207-09. Dr. Wiznitzer is a pediatric neurologist. Tr. 258. Dr. Megson's specialty is in childhood development. Tr. 1109. In contrast, Dr. Shane is trained in pathology with some work focusing on neuropathology. Tr. 397-403. He is not a specialist in pediatric neurology. Tr. 1317. Thus, to the extent that Dr. Shane's opinion about Child Doe's developmental progress at the four-month visit conflicts with the opinions of other doctors, Dr. Shane's opinion must be rejected.

All of the persuasive evidence indicates that Child Doe was developmentally normal at four-months. This evidence includes the three visits to his pediatrician between the vaccination and the health maintenance visit. 10/2/02 Gov't Ex. B at 45, 48. Although the primary focus of these visits was not to evaluate Child Doe's developmental progress, the visits presented more opportunities for a pediatrician to assess Child Doe and for his parents to raise any concerns with the doctor. Tr. 1016, 1098 (Dr. Turow stating if a parent's concern "sounds more suspicious, we'll make a note of it."). Consequently, a preponderance of the evidence supports a finding that Child Doe was developmentally normal at four-months.

c. Six-month-old Visit

On November 8, 1999, Dr. Barrone saw Child Doe for a six-month health maintenance visit. Dr. Barrone's overall assessment was that Child Doe was a "well infant." 10/2/02 Gov't Ex. B at 56; accord tr. 1038.

In terms of development, Dr. Barrone provided a few details. Dr. Barrone evaluated Child Doe's neurological system as "normal." The doctor noted that he was a "well infant," who had good head control and could grab objects well. Child Doe could not roll over and could not sit up without support.

For acute problems, which are listed in the "Interval History" portion of the form, Dr. Barrone diagnosed Child Doe as having an upper respiratory infection and nasal congestion. Dr. Barrone noted that Child Doe had a four-year-old sibling with the same symptom, which indicate a potential cause of Child Doe's infection as nasal congestion.

As a plan for going forward, during his visit Dr. Barrone made two statements of significance in this case. Dr. Barrone stated that Child Doe should receive a dose of the diphtheria - tetanus vaccine. Child Doe did not receive the acellular pertussis component. Id.; 7/11/06 Pet. Ex. A at 1; tr. 1042. In addition, Dr. Barrone referred Child Doe to another doctor for left eye "deviation medially." Id. at 57.

(1) Developmental Status

The testifying doctors offered different views about Child Doe's developmental progress at six-months. A preponderance of the evidence establishes that Child Doe was showing signs of normal development, although the doctors wanted to follow his progress on certain points. Tr. 1053 (Dr. Turow); see also tr. 279 (Dr. Wiznitzer), 321 (Dr. Wiznitzer).

The areas of concern were that Child Doe had not rolled over and was not sitting up without support. Most babies can roll over completely by seven-months. Some babies can roll over completely by six-months. Tr. 1039-40 (Dr. Turow); see also tr. 279 (Dr. Wiznitzer). Similarly, most babies can sit without support by six to seven-months. Tr. 1040-41 (Dr. Turow); see also tr. 279 (Dr. Wiznitzer), tr. 321 (Dr. Wiznitzer), tr. 1200 (Dr. Megson), tr. 1319 (Dr. Shane).

The fact that Child Doe was not performing these activities at six-months does not mean that his development was abnormally slow. Generally, infants develop at different paces. "Each child follows their own developmental trajectory." Tr. 330-31. Sometimes, one function (such as language) develops more quickly in relation to the child's peers, but another function (such as gross motor control) in the same child progresses relatively slowly. These different rates of development can be normal. Tr. 1090. Additionally, in regard to Child Doe specifically, the milestone for rolling over and sitting without support appears to be seven months. Because Child Doe was examined at six-months, he could have met the milestone if he had been

examined one month later. In fact, Child Doe was sitting up without support at eight-and-a-half -months. 10/2/02 Gov't Ex. B at 65.

The different rates of development among infants explain why Child Doe was not referred for any therapy at the six-month mark. Tr. 1041. Dr. Turow explained that doctors look to see if a child is two standard deviations from the mean. Tr. 1040. If so, these children could be sent for additional evaluation. Although Dr. Turow was aware that Child Doe was not rolling over and was not sitting up without support at six months, Dr. Turow could not express any opinion as to whether Child Doe was developmentally delayed at six months. Tr. 1053. Instead, Dr. Turow would have followed Child Doe's progress.

Dr. Wiznitzer also took a "wait and see" attitude. Dr. Wiznitzer believed that a six-month-old child who is not rolling over completely and is not sitting without support should be monitored. Tr. 279, 321.

A contrary view came from the doctors retained by Mr. Doe. Dr. Megson and Dr. Shane opined that Child Doe was not normal at six months. Dr. Megson believes that not rolling over is "a problem." Tr. 1199. She would have referred him for physical therapy. Tr. 1200-01. Dr. Shane thinks that most six-month-old babies can sit up without support. Tr. 1319.

On this issue, the opinions of Dr. Megson and Dr. Shane are not persuasive. Both opinions rest on the predicate that six-month-old babies should be able to sit without support. However, a preponderance of the evidence indicates that most babies achieve this milestone at seven-months. Tr. 1040-41 (Dr. Turow); see also tr. 279 (Dr. Wiznitzer); but see tr. 1200 (Dr. Megson), tr. 1319 (Dr. Shane).

In establishing the milestone for when a baby should be able to sit without support, Dr. Turow's opinion is entitled to more weight than the opinions of Dr. Megson and Dr. Shane. Dr. Turow spoke with confidence appropriate for someone who has practiced pediatric medicine since 1981. Tr. 1012. It is likely that he has more experience in evaluating the developmental status of six-month-old infants than the other doctors who testified. Dr. Turow's opinion is enhanced by his personal characteristics, reflected in his demeanor and experience. Dr. Turow's demeanor while testifying suggested that he was expressing his sincere opinions as forthrightly as possible. He appears to have testified without any bias or prejudice.

Neither Dr. Megson nor Dr. Shane has a similar amount of experience in evaluating the developmental status of six-month-old infants. As discussed, Dr. Megson has relatively little experience with caring for children less than one-year-old. Although she specializes in the development of children, most of her patients are approximately two years old. Tr. 1214-15. Dr. Shane did not explain, persuasively, why a pathologist or a neuropathologist is qualified to present the opinions Dr. Shane presented. Tr. 1312-14. Dr. Shane is not a pediatric neurologist. Tr. 1317.

Consequently, a preponderance of the evidence supports a finding that the appropriate time to measure sitting without support is seven months. Tr. 1040-41 (Dr. Turow); see also tr. 279 (Dr. Wiznitzer).

This finding, in turn, leads to a rejection of Dr. Megson's opinion and Dr. Shane's opinion that Child Doe was developmentally delayed at six-months. Their opinions are based on the erroneous belief that a "normal" six-month-old infant can sit without support. When experts base their opinions on assumptions contrary to the record, these opinions may be rejected. Perreira, 33 F.3d at 1377 n.6 ("An expert opinion is no better than the soundness of the reasons supporting it."); see also Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (stating "[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert.")

Dr. Shane's opinion that Child Doe was developmentally delayed at six-months rests upon various errors. Dr. Shane stated that Child Doe "was rolling over at two months." Tr. 1319. However, the record actually states that he "rolls to side," not rolled over. 10/2/02 Gov't Ex. B at 34. Dr. Shane also thinks that Child Doe's developmental delay was manifest by his "abnormal eye movement." Tr. 1319-20. The determination that Child Doe's eye movements in November 1999 were not a sign of developmental delay is set forth in the following section. For the present, it is sufficient to note that Dr. Shane's reliance on "abnormal eye movements" as a sign of Child Doe's developmental delay undermines the value of his opinion.

The finding that Child Doe was not developmentally delayed at six-months is further supported by Dr. Barrone's determination and Dr. Wiznitzer's opinion. Dr. Barrone examined Child Doe at the six-month evaluation. 10/2/02 Gov't Ex. B at 56; tr. 1038. Dr. Barrone found him to be a "well" infant with "normal" neurological development. Although a conclusion of a treating doctor is not binding, 42 U.S.C. § 300aa–13(b); a treating doctor's assessment of the patient's current status is entitled to some deference. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). It is difficult for outsiders, who have not examined the child, to second guess the opinion of a treating doctor.

For these reasons, a preponderance of the evidence supports a finding that Child Doe was developmentally normal at six-months. However, as discussed in section III.B.1.c(2), this finding is not critical to the outcome of the case.

(2) Condition of Eyes

In addition to assessing and describing Child Doe's developmental progress on November 8, 1999, Dr. Barrone also referred Child Doe to a pediatric ophthalmologist for a left "eye deviation medially." 10/2/02 Gov't Ex. B at 57; tr. 1013-14. The doctor was concerned that Child Doe may have a lazy eye. Tr. 1014. A lazy eye is usually a problem in the muscles around the eye. Tr. 1034-35. The medical terms for lazy eye include strabismus and esotropia. Tr. 1015, 1035; see also Dorland's at 644 (defining esotropia) and at 1766 (defining strabismus).

Dr. Barrone's notation about a left "eye deviation medially" followed an entry made by Dr. Turow on October 4, 1999. Dr. Turow recorded that Child Doe was possibly suffering from a strabismus or pseudostrabismus. 10/2/02 Gov't Ex. B at 54. These two notations, which were made approximately one month apart, show that the parents were concerned about some problem with Child Doe's eyes and were reporting the problem to the doctors. The two entries also indicate that the doctors were recording the parents' concerns.

The condition of Child Doe's eyes between the end of September 1999 and the beginning of November 1999 is a strongly debated aspect. Mr. Doe's theory that Child Doe began suffering a permanent encephalopathy on July 20, 1999 rests, in part, upon a premise that the encephalopathy is manifest in the form of abnormal eye movements noted in the October 4, 1999 and November 8, 1999 medical records.

For example, Dr. Shane stated that Child Doe suffered a nystagmus in November 1999. Tr. 1289, 1312. The nystagmus is significant because without the alleged nystagmus in November 1999, almost nothing shows that Child Doe was suffering from an encephalopathy from August 1999 to December 1999. See Pet'r Post Hearing Memorandum at 57. When asked to assume that the nystagmus did not occur in November 1999, Dr. Shane identified the statements of Child Doe's parents and other care givers as evidence of an ongoing encephalopathy. Tr. 1322. However, these statements have already been determined not to be accurate. Doe 21, 84 Fed. Cl. at 46.[3] Eliminating the later-given statements means that Dr. Shane's opinion depends upon the existence of a nystagmus in November 1999.

Nystagmus is different from strabismus. Tr. 1362-63 (Dr. Shane). In November 1999, Child Doe was referred for a "l[eft] eye deviation medially." 10/2/02 Gov't Ex. B at 57. It is absolutely clear that a medial deviation differs from nystagmus. A medial deviation means that an eye is pointed to the person's nose. Nystagmus means that the eyes bounce either up-and-down or side-to-side. Nystagmus is usually associated with a neurological problem. Tr. 218 (Dr. Spitz); see also tr. 1034 (Dr. Turow). If parents report nystagmus, then a pediatrician is likely to have memorialized the problem in a note and also referred the child to a specialist. See tr. 1074-5 (Dr. Turow). This is what happened in March 2000. See 10/2/02 Gov't Ex. B at 68.

Despite the difference between a strabismus and nystagmus, petitioner's counsel repeatedly confuses the left eye deviation with nystagmus. For example, in the context of discussing Dr. Ruben's April 5, 2000 report, 10/2/02 Gov't Ex. B at 72-73; petitioner's counsel asked Dr. Turow "Is there a relationship between the nystagmus that you saw earlier and the nystagmus [reported to Dr. Ruben in April 2000]?" However, Dr. Turow clarified counsel's question by asking "Between the – you mean the lazy eye and the nystagmus?" With that clarification, Dr. Turow explained that the two conditions are "different entities." Tr. 1034-5. Another example of confusion occurs in Mr. Doe's brief. It states: "Eye movements were seen in September and were recorded in the medical record in October. They were not seen by any

[3] Dr. Shane did not review the decision by Special Master Edwards, which made findings of fact. Dr. Shane also did not review the decision by Judge Braden, which affirmed those findings of fact. Tr. 1362.

doctor until March." Pet'r Post Hearing Memorandum at 67. This statement is misleading because it equates the two types of eye movements. In fact, Child Doe displayed one type of eye movement, strabismus, in October 1999, and another type of eye movement, nystagmus, in March 2000.

As far as determining when the eye condition began, a preponderance of the evidence establishes that Child Doe's eyes deviated to his nose in early October 1999 or, perhaps, late September 1999. First, the medical record created by Dr. Turow in October 1999 notes "strabismus vs. pseudostrabismus." 10/2/02 Gov't Ex. B at 54. Second, Mr. Doe's own testimony suggests that the problem could have begun in "September, October, [or] November." Tr. 93. Mr. Doe's testimony, therefore, is consistent with Dr. Turow's October 4, 1999 record. Thus, there is little support for Mr. Doe's argument that the pediatricians were not recording concerns made by Child Doe's parents. See Pet'r Post Hearing Memorandum at 6, 8-9.

The more important issue is how Child Doe's eyes were acting in October and November 1999. As mentioned, Mr. Doe's experts maintain that Child Doe was suffering from nystagmus. However, no credible evidence supports a finding that Child Doe was suffering a nystagmus in October and November 1999.

The primary evidence contradicting Mr. Doe's theory that Child Doe was suffering a nystagmus in October and November 1999 is the medical records created by Dr. Turow and Dr. Barrone. Dr. Turow indicates that he saw strabismus or pseudostrabismus on October 4, 1999. 10/2/02 Gov't Ex. B at 54; see also tr. 1103-104 (Dr. Turow's testimony about this note). Similarly, Dr. Barrone notes a left eye deviation medially. 10/2/02 Gov't Ex. B at 57. This condition is different from nystagmus. Tr. 1333. As medical records created contemporaneously with the event being described, Dr. Turow's October 4, 1999 note and Dr. Barrone's November 8, 1999 notes are presumed to be correct. Cucuras, 993 F.2d at 1528 .

Further support for the determination that Child Doe was not having nystagmus comes from Dr. Rubin, a pediatric ophthalmologist who examined Child Doe on November 10, 1999. Dr. Rubin did not detect anything wrong with Child Doe's eyes. He "found no strabismus." More importantly, Dr. Rubin did not indicate that Mr. Doe or Mrs. Doe told him that their son was having nystagmus. 10/2/02 Gov't Ex. B at 59. If the parents had observed Child Doe's eyes fluttering or bouncing up and down, the parents are very likely to have reported their observations to Child Doe's doctor. (Child Doe's parents actually closely monitored his nystagmus after the nystagmus was detected in March 2000. See 10/2/02 Gov't Ex. B at 78-79.) The likelihood of a report of nystagmus to Dr. Rubin is even more likely because Dr. Rubin specializes in eye disorders in children. The omission of a parental report of suspected nystagmus in Dr. Rubin's letter strongly implies that Child Doe was not suffering nystagmus.

Despite the clarity in Dr. Rubin's November 17, 1999 letter, Dr. Rubin arguably modified his statement in a subsequent letter. On October 26, 2000, Dr. Rubin reported that he had seen Child Doe for a follow-up on October 12, 2000. Dr. Rubin stated that his "examination confirmed the presence of an infrequent, intermittent upbeat nystagmus which had apparently evaded detection at many prior examinations by me and other ophthalmologists as well."

10/2/02 Gov't Ex. B at 106.[4] Dr. Rubin's April 18, 2000 letter and October 26, 2000 letter indicate that when a patient sees Dr. Rubin for nystagmus, Dr. Rubin uses that term in his reports. Thus, the April 18, 2000 letter and October 26, 2000 letter are consistent with an inference that Child Doe's parents did not tell Dr. Rubin that Child Doe was suffering from a nystagmus in November 1999.

The omission of any contemporaneous notation from Dr. Turow, Dr. Barrone and Dr. Rubin that Child Doe was having nystagmus in October or November 1999 compels the finding that Child Doe, in fact, was not having a nystagmus in October or November 1999. The general presumption, established by the Federal Circuit in Cucuras, is that medical records created contemporaneously with the event being described are accurate. Mr. Doe has not established a persuasive reason for deviating from this presumption.

Secondary support for the finding that Child Doe was not suffering a nystagmus in October or November 1999 is the absence of any reports about nystagmus between November 1999 and February 2000. During this four-month span, Child Doe saw several doctors. See Doe 21, 84 Fed. Cl. 23-24 (summarizing medical records). However, none of the records from these doctors record a parent's concern about nystagmus or bouncing eyes. It is likely that if Child Doe suffered from an intermittent nystagmus beginning in November 1999, his parents would have continued to raise this concern with doctors. But, there is no indication that they did.

Mr. Doe, again, relies upon the testimony of a witness to suggest that the medical records are incomplete. His brief states "[w]itness testimony establishes that [Child Doe's] condition had evolved to nystagmus by Christmas of 1999. TR 50." There are two problems with this argument. First, as already discussed, the testimony of the fact witnesses has already been rejected. Second, even if the testimony of fact witnesses could be considered, the transcript does not support the statement. On page 50, the witness testifies that she started noticing that Child Doe's head was growing around Christmas time. On page 51, although the witness talks about Child Doe's eyes rolling up, nystagmus is not the same.

Mr. Doe offers three reasons to justify a finding that Child Doe suffered a nystagmus in November 1999. First, Mr. Doe, himself, testified that his son's eye movements today are the same as the eye movements in October 1999. Tr. 1364; see also tr. 1299-1300, quoting Mr. Doe's earlier testimony. This testimony is not credible because Mr. Doe's ability to remember the details of his son's eye movements nine years earlier is quite questionable. In addition, if Mr. Doe observed his son's eyes fluttering, he would have brought his son to a doctor. Mr. Doe, in fact, followed this course of conduct in April 2000. 10/2/02 Gov't Ex. B at 78-79.

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[4] This letter could be interpreted as indicating that the nystagmus was present in November 1999, when Dr. Rubin first examined him. However, it is more likely that Dr. Rubin was referring to his evaluation on April 5, 2000, when Dr. Rubin looked for, but could not find, nystagmus. 10/2/02 Gov't Ex. B at 72. Similarly, a pediatric neurologist, Dr. Gould, also looked for any nystagmus but could not see it on March 30, 2000. 10/2/02 Gov't Ex. B at 71. A neuro-ophthamalogist, Dr. Kupersmith, examined Child Doe on June 7, 2000, and also did not see any irregular eye movements. 10/2/02 Gov't Ex. D at 168-69.

Second, Dr. Shane states – repeatedly – that a doctor's failure to observe an intermittent condition, such as nystagmus, in the doctor's office does not mean that the intermittent behavior does not actually exist. Tr. 1292, 1308, 1317. Some logic supports Dr. Shane's point. Due to the on-again, off-again nature of nystagmus, a doctor may not be observing the patient when the nystagmus appears. Tr. 1016, 1043-44. But, the problem is not that the doctors failed to see the nystagmus, it is that everyone failed to see nystagmus. Here, neither Dr. Turow, nor Dr. Barrone, nor Dr. Rubin, recorded that the parents were observing Child Doe having nystagmus. Thus, Dr. Shane's point that the doctors missed seeing the nystagmus because the nystagmus was intermittent is not tenable. The more logical inference is that Child Doe was not having nystagmus.

Third, Dr. Shane attempted to justify describing the symptoms in November 1999 as nystagmus because Child Doe was eventually diagnosed as having nystagmus in March 2000. Tr. 1290-91. This is mistaken reasoning. The two conditions – eye deviation medially and nystagmus – are so different that the presence of one cannot be considered to be the forerunner to the other.

In sum, in October and November 1999, a preponderance of the evidence supports a finding that Child Doe suffered from intermittent strabismus. This finding does not contradict the early determination that Child Doe was developmentally normal at six-months. For infants up to six-months, an occasional floating lazy eye can be normal. Tr. 1017. Moreover, strabismus would probably indicate a problem with muscles, not neurological development. Tr. 1034-35.

d. Nine-month-old Visit

On January 31, 2000, Child Doe was seen for his nine-month-old well-baby visit. 10/2/02 Gov't Ex. B at 65. This appointment was actually about two weeks early because Child Doe was born on May 11, 1999. Tr. 1102-103. A preponderance of evidence indicates that Child Doe was still developing normally at this time. However, some evidence indicates that Child Doe had not reached one milestone.

Dr. Earhardt described him as "well." His neurological status was "normal." For developmental milestones, Child Doe could sit indefinitely without support, use a "pincer grasp," wave, and play "peek-a-boo." Child Doe could articulate "mama, dada, and baba." On the other hand, Child Doe could not pull "to stand" or "cruise." 10/2/02 Gov't Ex. B at 65.

Not pulling to standing at nine-months is a sign of slow development in gross motor abilities. Most nine-month-old infants can pull themselves to standing. Child Doe's inability to cruise is a matter of less concern because most nine-month-old infants do not cruise, although some do. Tr. 1090 (Dr. Turow), tr. 1201 (Dr. Megson). Dr. Earhardt did not refer Child Doe for any additional evaluations.

The three doctors who testified at the December 2, 2008 hearing presented a range of opinions about Child Doe's developmental status at nine-months. Dr. Wiznitzer believes that

Child Doe was showing normal development, although Dr. Wiznitzer would continue to monitor Child Doe. Tr. 330-31, tr. 1248-49. Dr. Megson wanted to obtain information about Child Doe's muscle tone, which could give her insight into Child Doe's developmental status. Tr. 1201-02. Finally, Dr. Shane did not offer an opinion about Child Doe's development at nine-months. Dr. Shane believed that the examination was "limited." Tr. 1320. In response to a leading question asked by Mr. Doe's attorney, Dr. Shane also indicated that he would watch Child Doe's development with respect to not pulling to stand. Tr. 1324.

A preponderance of the evidence indicates that Child Doe's development was still within normal limits when he was eight and half months. The strongest evidence is the evaluation of Dr. Earhardt. He observed Child Doe and examined Child Doe. As the treating doctor, Dr. Earhardt's record is presumed to be correct. Cucuras, 993 F.2d at 1528. Against this evidence, the opinions of Dr. Megson and Dr. Shane are much weaker. Essentially, Dr. Megson and Dr. Shane did not contradict the conclusion reached by Dr. Earhardt after the examination. Dr. Megson and Dr. Shane seem to want more information, but, based upon the existing record, they have not opined that Child Doe was developmentally delayed at nine-months.

2. Persuasiveness of Petitioner's Experts

The second general point concerns the persuasiveness of the experts, Dr. Spitz, Dr. Megson and Dr. Shane, retained by Mr. Doe. On critical points, neither Dr. Megson nor Dr. Shane was persuasive. Dr. Spitz's testimony was generally not relevant to determining whether Child Doe suffered a developmental delay.

a. Dr. Spitz

Dr. Spitz testified during the hearing held on October 28, 2008. Tr. 205-57, 340-68, 376-78. His testimony, unfortunately, was not completed because he looked at an MRI when the report interpreting that MRI had not been filed. Tr. 363-64. Even more unfortunately, Dr. Spitz died before the hearing could be resumed.

Dr. Spitz's testimony primarily addressed topics that are generally not relevant to the present issue. Mostly, Dr. Spitz's testimony related to Mr. Doe's claim that Child Doe is entitled to compensation because Child Doe suffered an on-Table injury, an encephalopathy, which is defined at 42 C.F.R. § 100.3(b)(2). For example, Dr. Spitz explained why he believed that Child Doe suffered a loss of consciousness on July 20, 1999. Tr. 213, 233-38. Dr. Spitz discussed probable errors in records created by Child Doe's doctors. Tr. 216, 230-31. In addition, Dr. Spitz testified in rebuttal to respondent's theory that a factor unrelated to the DTaP vaccine, a Chiari I malformation, caused Child Doe's problems. Tr. 340-64.

Special Master Edwards determined that "Dr. Spitz's opinion does not assist" him in reaching a decision primarily because Dr. Spitz's opinion "lack[ed] an appropriate factual basis." Doe 21, 2008 WL 4679501 at * 23. Judge Braden, in turn, affirmed the factual findings made by Special Master Edwards relating to Mr. Doe's on-Table claim. Doe 21, 84 Fed. Cl. at 46.

Dr. Spitz's testimony is generally not relevant to determining whether Mr. Doe has established that Child Doe is entitled to compensation based upon an off-Table theory. Mr. Doe's post-hearing brief does not mention Dr. Spitz at all. It would appear that the failure to present an argument based upon Dr. Spitz's testimony constitutes a waiver of any possible argument. See Vaccine Rule 8(f).

b. Dr. Megson

Dr. Megson is a "developmental pediatrician." Tr. 1109.[5] She has seen approximately 4,400 children. Tr. 1111. Of these, approximately 90 percent are children who appear on the autism spectrum. Tr. 1168. Because Dr. Megson's practice focuses primarily on autistic children, she usually begins seeing children when they are between 18 and 30 months. Tr. 1215. Her practice includes approximately 100 infants who are less than one year. Id.

The main flaw in Dr. Megson's testimony is that she did not explain her opinion in such a way to demonstrate that her opinion is reliable. Dr. Megson attempted to support her opinion with several medical articles. Exhibits 131-172. However, the medical articles submitted are not easily understood without years of schooling in medicine and Dr. Megson's attempts to explain some of the articles were generally not successful.

The presentation of Dr. Megson's opinion was poor. Frequently, Dr. Megson did not answer questions as they were asked. For example, early in her testimony on direct examination, Mr. Doe's counsel asked Dr. Megson to describe what happened to Child Doe after the vaccination. Dr. Megson's answer, which lasted approximately two pages, referred to her experiences in treating children with night blindness, G proteins, calcium channels, and how the acellular pertussis vaccine is detoxified. Dr. Megson did not provide any information about Child Doe. Tr. 1112-14.

In another example, Dr. Megson opined that a defect in calcium channels depressed TH1 cells, which are usually activated to fight viral infections. This opinion is an attempt to explain why Child Doe suffered so many ear infections. In the course of explaining her opinion, Dr. Megson jumped to another topic – that the vaccines contain metals that further compound the problem with calcium channels. Then, Dr. Megson returned to the issue of TH1 cells and stated that she did not have any articles to support her opinion. Tr. 1128-31. Although Dr. Megson submitted articles about TH1 cells after the hearing, exhibits 169-172; they do not make Dr. Megson's testimony more comprehensible.

[5] Respondent challenged whether Dr. Megson may describe herself as being board-certified in developmental pediatrics. Respondent's exhibit J, tr. 1168-74 (Dr. Megson), tr. 1222-23 (Dr. Wiznitzer). A misrepresentation of an expert's credentials may impair the expert's veracity. However, it appears that there may be some confusion as to whether existing practitioners were grandfathered. Therefore, if Dr. Megson presented herself inaccurately, this error appears not to be intentional.

These examples — and they are not an exhaustive list — are provided to demonstrate the challenges in understanding Dr. Megson's opinion. The parties were informed that they should take time to discuss any articles that the parties believed supported their case. Tr. 1009-10. But, Mr. Doe did not elicit testimony on many of the articles that Dr. Megson submitted before the hearing.

To some degree, this problem in presentation may reflect Dr. Megson's relative inexperience in testifying. Previously, she testified approximately eight times, usually in family court. She has not testified, before this case, in a case in the Vaccine Program. Tr. 1189. Although Dr. Megson's inexperience in testifying as an expert witness explains why her testimony was not presented as well as it could have been, this inexperience does not excuse the problems in her testimony.

c. Dr. Shane

Dr. Shane testified on July 20, 2007, before Special Master Edwards. Tr. 397-444. In accord with Judge Braden's remand order, he also testified at the most recent hearing. Tr. 1287-1327, 1362.

Dr. Shane's background is in pathology with experience in neuropathology. Doe 21, 84 Fed. Cl. at 41.

In some respects, Dr. Shane's demeanor was the inverse of Dr. Megson's. While Dr. Megson's presentation suffered from too little certainty, Dr. Shane's opinions were overstated. The general impression was that Dr. Shane was adamant in winning the case by expressing something helpful to Mr. Doe's theory, even if his opinion was not well supported. Two examples illustrate how Dr. Shane's presentation was not credible.

The first example concerns Dr. Shane's statement that Child Doe suffered a nystagmus in October or November 1999. Tr. 1259. As explained in section III.A.1.c(2), above, Child Doe did not suffer nystagmus in 1999. Dr. Shane's statement that Child Doe suffered a nystagmus in November 1999 would have been more informed if he had read the findings of fact by Special Master Edwards and the affirmance of those findings by Judge Braden. See tr. 1362. Without this basis, Dr. Shane's opinion is not persuasive. See Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it.")

Dr. Shane's use of selective literature about HHE is the second example of how Dr. Shane's testimony was misleading. Dr. Shane cited a Canadian study on HHE that recommended evaluating additional cases because few cases had been analyzed. Exhibit 101 at 8, citing exhibit 128 (Public Health Agency of Canada, Hypotonic-Hyporesponsive Episodes in Children Hospitalized at 10 Canadian Pediatric Tertiary-Care Centres, 1991-1994, 23-10 Canada Communicable Disease Report (May 15, 1997)). Dr. Shane accurately recounts what the authors of this study stated, in part. However, Dr. Shane did not note that the study also says "There do not appear to be any long-term neurologic sequelae." Exhibit 128 at 3. Dr. Shane also did not

appreciate that the recommendation for additional study was made in 1997. After that, other studies about HHE have involved a greater number of cases. See Exhibit 126 (Tracy DuVernoy et al., Hypotonic-Hyporesponsive Episodes Reported to the Vaccine Adverse Event Reporting System (VAERS), 1996-1998, 106 Pediatrics 52 (2000) (215 cases studied); see also tr. 1358 (testimony of Dr. Wiznitzer).

Another disadvantage with Dr. Shane was that his background seems to give him little basis for most of his testimony. Most of Dr. Shane's testimony on December 2, 2008, addressed whether and when Child Doe was showing signs of an encephalopathy or other neurological problem. E.g. tr. 1291-21, 1295, 1301 (stating "subsequent to that [episode on July 20, 1999], September, October, this child is beginning to exhibit a neurodevelopmental defect."). On December 2, 2008, Dr. Shane did not discuss whether Child Doe suffered from a Chiari I malformation and Dr. Shane did not discuss any of Child Doe's MRIs. Tr. 1301.

Dr. Shane's ability to opine about the developmental status of infants is not clear. Dr. Shane is a pathologist with an expertise in neuropathology. Doe 21, 84 Fed. Cl. at 41. This background may qualify him to interpret MRIs, although MRIs are more frequently interpreted by neuroradiologists, radiologists, or neurologists. Dr. Shane did not explain, persuasively, why a pathologist or a neuropathologist is qualified to present the opinions Dr. Shane presented. Tr. 1312-14. Dr. Shane is not a pediatric neurologist. Tr. 1317. To the extent that Dr. Shane offered opinions beyond the scope of his expertise, his testimony is not reliable. Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1268 (Fed. Cir. 2008); Nimely v. City of New York, 414 F.3d 381, 399 n. 13 (2d Cir. 2005) (stating "it is worth emphasizing that, because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields.")

To summarize the previous two sections, an abundance of evidence establishes that Child Doe was developing normally through at least December 1999. A preponderance of evidence also establishes that Child Doe's normal development continued until January 31, 2000. In addition, the testimony of Dr. Spitz, Dr. Shane, and Dr. Megson was either not relevant or not persuasive. These findings underlie the analysis of the specific theory presented by Mr. Doe.

B. Specific Theories

Mr. Doe does not present clearly his legal theory (or legal theories) for why he is entitled to compensation. See Pet'r Post Hearing Memorandum at 64-76. It appears that Mr. Doe's legal theory is that the July 20, 1999 DTaP vaccination caused an encephalopathy that was manifest as early as September 1999 and no later than November 1999. Id. at 66-67. To be entitled to compensation, pursuant to this theory, Mr. Doe must establish, by a preponderance of the evidence, the factors listed in Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). See Pet'r Post Hearing Memorandum at 65-66, citing Althen.

Alternatively, Mr. Doe's brief could be construed as presenting an argument that Child Doe's current condition constitutes a sequella to the adverse reaction Child Doe experienced on

July 20, 1999. See id. at 31-32, 71. Although this argument could have been presented more directly, it is addressed in an attempt to resolve all possible theories.

1. Encephalopathy

a. Standards for Adjudication

To prove causation in fact, a petitioner must establish three elements. The petitioner's

> burden is to show by preponderant evidence that the vaccination brought about [the] 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 vaccination and injury.

Althen, 418 F.3d at 1278; accord Doe 21, 84 Fed. Cl. at 45, quoting Althen. Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Here, Mr. Doe has not met his burden with regard to prongs two and three. (No finding is made with regard to prong one.) His failure is most apparent with regard to the second prong, logical sequence. Therefore, it is discussed first.

b. Logical Sequence of Cause and Effect

In determining whether petitioners have established "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," reports from treating doctors, testimony from treating doctors, and opinions from experts should be considered. Capizzano, 440 F.3d at 1326; 42 U.S.C. § 300aa–13(a)(1); see also Adams v. Sec'y of Health & Human Servs., 76 Fed. Cl. 23, 40-41 (2007). The facts, as found, do not support Mr. Doe's proposed explanation of what happened to Child Doe.

A brief summary of the facts, as established by a preponderance of evidence in this litigation, is that at two-months, Child Doe was healthy and possibly slightly advanced in his development. He received the DTaP vaccine on July 20, 1999, and experienced an adverse reaction that evening.

At four-months, Child Doe was developmentally normal. He did not show any signs of damage to his brain. When Child Doe was six-months, his pediatrician evaluated him as "well." The only potential problem – and this was a relatively small concern – was that Child Doe had not yet rolled over and was not sitting up without support. The parent's report of potentially unusual movements in Child Doe's eyes was determined to be within the usual limits for a six-month-old. 10/2/99 Gov't Ex. B at 59 (Dr. Ruben's report).

A more substantial concern about Child Doe's development was noted during his nine-month-old health maintenance visit. At this time, Child Doe was not pulling himself to standing, a task that most nine-months-olds should be able to perform.

By March 2000, when Child Doe was ten months old, doctors expressed concerns about Child Doe's failure to reach developmental milestones.

Given this chronology, there is little persuasive evidence to show that the July 20, 1999 DTaP vaccine caused Child Doe's failure to develop normally. The first well-baby checkup occurred two months after Child Doe received the DTaP vaccination. If Child Doe had been suffering from an encephalopathy, it is likely that he would have failed to meet many milestones. Yet, the pediatrician's report indicated that he was "well" and his neurological system was "normal." 10/2/02 Gov't Ex. B at 51.

The next well-baby visit, which was for six-months, shows possibly a slight decline in gross motor skills, specifically rolling over and sitting without support. It is difficult to attribute Child Doe's (lack of) ability as a manifestation of developmental delay, rather than the irregular rate of development. It is even more difficult to find that Child Doe's failure to roll over and to sit without support at six-months was a sign of an encephalopathy that allegedly began on July 20, 1999, approximately four months earlier. If Mr. Doe's theory were accurate, then Child Doe would have been suffering an encephalopathy for four months (of the six months that he had been alive), yet he only slightly missed two developmental milestones. He accomplished other tasks, such as grabbing objects and babbling.

In short, Child Doe's presentation at both the four-month and the six-month well-baby examinations is not consistent with a child who had developed an encephalopathy on July 20, 1999. The sequence advanced by Mr. Doe is not "logical," to quote from Althen.

Opinions expressed by treating doctors in letters written with hindsight do not assist Mr. Doe in meeting his burden of establishing this element by a preponderance of the evidence. Mr. Doe's post hearing memorandum fails to identify any statements in which treating doctors expressed an opinion that the doctor believed that the July 20, 1999 DTaP vaccine caused Child Doe's developmental delay. Nonetheless, a review of the record indicates that two doctors expressed some opinion about whether the vaccine caused Child Doe's developmental delay. These two doctors are Dr. Eviatar and Dr. Turow.

The record contains three statements from Dr. Eviatar. The earliest comment was made in a letter written by Dr. Eviatar on August 27, 2002. In this letter to Dr. Turow, Dr. Eviatar recounted Child Doe's medical history, as she understood it. She diagnosed Child Doe as suffering from "generalized gross motor and fine motor delay, as well as speech and language delay and some very mild persuasive developmental disorder features." Dr. Eviatar continued: "the onset of eye movements immediately after the Pertussin [sic] shot is puzzling. We do see episodes of flutter or opsoclonus and developmental delay as a result of autoimmune encephalitis known as encephalopathy." Dr. Eviatar recommended additional testing to learn more information about the possible cause of Child Doe's condition. 10/2/02 Gov't Ex. B at 136.

Approximately two years later, Dr. Eviatar expressed another opinion in a note written on a prescription pad. Dr. Eviatar stated "vertical nystagmus on straight page exaggerated on gaze to the [right]. [M]ost likely secondary to post DPT encephalopathy." 10/31/05 Pet'r Filing, Exhibit 1.

As recognized by Judge Braden, Dr. Eviatar's comments, especially the second one, could constitute evidence that could support Mr. Doe's proof on the second Althen element. Judge Braden ordered a remand, in part, to obtain more information from Dr. Eviatar.[6]

To comply with Judge Braden's order, the parties were authorized to subpoena Dr. Eviatar to a hearing. Order, filed Nov. 6, 2008. Counsel for petitioner was also encouraged to attempt to communicate with Dr. Eviatar informally to ascertain whether Dr. Eviatar's appearance at a hearing would be worthwhile. Within the Vaccine Program, the general practice is to require an in-court appearance of treating doctors when necessary. Sometimes, a doctor's testimony provides no information beyond what is contained in the medical records because the doctor does not recall anything apart from what is recorded. When doctors can contribute to an understanding of their medical records, then the parties or the special master will seek additional information using the least burdensome, least adversarial method. Cooperation among the parties and the special master often leads to obtaining more information from a treating doctor without resorting to a subpoena. But, subpoenas are authorized and have been issued when the doctor possesses important information and has not responded to less intrusive requests for information. In this case, counsel for Mr. Doe and counsel for respondent jointly drafted a set of written questions. Dr. Eviatar answered those questions. The parties agreed that her written statement obviated the need for her to testify. See order, filed Nov. 26, 2008.

In a letter dated November 21, 2008, Dr. Eviatar confirmed that she wrote the note, quoted above. However, Dr. Eviatar stated that her statement that the nystagmus was "most likely secondary to DPT encephalopathy" was actually a quote from Dr. Turow. Dr. Eviatar stated "This seemed extremely unlikely to me and I had no way of verifying it because I never saw [Child Doe] before or during the DPT reaction nor did I hear of such reaction to DPT." Dr. Eviatar concluded that "It is my medical opinion that [Child Doe's] developmental delay and immature eye movements are the result of congenital hydrocephalus and Arnold Chiari malformation . . . and are not related to DPT encephalopathy." Resp't Exhibit I.

Taken collectively, the statements of Dr. Eviatar do not support a finding that there is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Her three statements seem to express three different ideas. In the August 27, 2001 letter, Dr. Eviatar seemed to express the idea that the DPT vaccine can cause an encephalopathy without stating that the DPT vaccine did cause the encephalopathy for Child Doe. Furthermore, even if Dr. Eviatar's August 27, 2001 letter did express this causation, the conclusion would be

[6] Consistent with Dr. Eviatar's use of the term "autoimmune encephalitis," Judge Braden invited Mr. Doe to develop this theory. Doe 21, 84 Fed. Cl. at 47-48 & n.49. However, Mr. Doe stated that Child Doe did not suffer an autoimmune reaction. Order, filed October 16, 2008; tr. 1330.

questionable because Dr. Eviatar believed that Child Doe developed the "onset of eye movements immediately after the Pertussin shot." 10/2/02 Gov't Ex. B at 136 (emphasis added). As discussed at length in section III.A.1.c(2), above, Child Doe developed nystagmus at least nine months after receiving the DTaP vaccine. Thus, the August 27, 2001 letter contains a mistaken assumption lessening its evidentiary value. See Perreira, 33 F.3d at 1377 n.6 ("An expert opinion is no better than the soundness of the reasons supporting it.")

Dr. Eviatar's second statement contains a direct statement about causation. Dr. Eviatar states that the nystagmus is "most likely secondary to post DPT encephalopathy." 10/31/05 Pet'r Filing, Exhibit 1. This note, however, does not explain the basis for Dr. Eviatar's conclusion. This omission is significant because if Dr. Eviatar continued to believe that Child Doe's nystagmus began "immediately after" the DTaP vaccination, then her conclusion would derive from a faulty premise. Therefore, weighing the evidentiary strength of Dr. Eviatar's October 26, 2004 statement is difficult. It is also unusual for a doctor to express significant findings or opinions on a prescription pad note.

When given an opportunity to explain her reasoning, Dr. Eviatar backed away from what she wrote. Dr. Eviatar ascribed the critical language "most likely secondary to post DPT encephalopathy" to Dr. Turow. In addition, Dr. Eviatar expressed a contrary opinion — she stated Child Doe's "developmental delay and immature eye movements . . . are not related to DPT encephalopathy." Resp't Exhibit I. Dr. Eviatar's involvement of Dr. Turow prompted the parties to seek his testimony at the December 2, 2008 hearing. The parties agreed that because the Dr. Eviatar said her statement came from Dr. Turow, Dr. Turow should testify.

Receiving testimony from Dr. Turow was helpful because he was the other treating doctor who made some statement about whether the vaccine caused Child Doe's developmental delay. In a letter dated June 19, 2007, Dr. Turow stated that Child Doe "may well have had a vaccine reaction with developmental ramifications." 7/10/07 Pet'r Filing. Dr. Turow expressed a similar idea, using different words, in a letter written on September 19, 2002. 10/2/02 Gov't Filing at 8.

Neither of Dr. Turow's letters constitutes evidence that Dr. Turow believed that the DTaP vaccine caused Child Doe's developmental delay. Both letters say a vaccine reaction was possible. This phrasing suggests that Dr. Turow is uncertain.

Dr. Turow's testimony was consistent with his letters. When asked about the letters directly, Dr. Turow was quite clear that he could not say that the DTaP caused the developmental delay. Tr. 1057-59. Dr. Turow believed that "it was not impossible," tr. 1058; but would go no further. Tr. 1101. Like Dr. Turow's written statements, his testimony falls short of the standard of evidence that supports a finding of "a logical sequence of cause and effect." Van Epps v. Sec'y of Health and Human Servs., 26 Cl.Ct. 650, 654 (1992) (stating the "consistently equivocal testimony [of petitioner's expert] that the mumps vaccine was a 'possible' cause or 'could' be a cause of petitioner's seizure disorder did not rise to the level of a reasonable degree of medical certainty"); Doe v. Sec'y of Health and Human Servs., 19 Cl.Ct. 439, 450 (1990) (stating "an assertion that something is 'highly possible' does not rise to the level necessary to establish

causation by a preponderance of the evidence").

In sum, neither the medical records, nor the statements of treating doctors, nor the opinions of the experts retained by Mr. Doe support a finding that Mr. Doe has established, by a preponderance of the evidence, "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." For the reasons set forth above, Mr. Doe has not met his burden of proof on this element. Therefore, he is not entitled to compensation.

c. Timing

Mr. Doe is also required to establish, by a preponderance of the evidence, "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. A petitioner's failure to establish this element means that the petitioner is not entitled to compensation. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358-59 (Fed. Cir. 2006).

This element contains two components. First, there must be some evidence about when medical science would expect an injury caused by a vaccine to be manifest. See Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (stating "the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in- fact.") Second, a preponderance of the evidence must establish that the onset of petitioner's symptoms occurred within this window.

In this case, Mr. Doe failed to meet his burden of proof for both components. In regard to the timing prong, Mr. Doe's brief is relatively sparse – approximately one page. See Pet'r Post Hearing Memorandum at 71-72.

(1) What Timing Is Medically Acceptable?

First, Mr. Doe appears not to have presented any evidence about the time frame that medical science would consider acceptable. Mr. Doe's brief does not identify any evidence and a review of the transcript does not reveal any passages in which Mr. Doe elicited testimony from any witness about the expected time frame. This omission, by itself, means that Mr. Doe has not met his burden on this issue.

Rather than rely upon evidence introduced in this case, Mr. Doe could have been intending to use outside sources – either the Vaccine Injury Table or other cases involving DTaP and developmental delay. Mr. Doe, however, does not make this argument in his brief. Even if Mr. Doe had made such an argument, it would not have been persuasive.

The association of "encephalopathy" with a vaccine containing pertussis on the Vaccine Injury Table, 42 C.F.R. § 100.3(a) ¶ II.B, does not eliminate Mr. Doe's obligation to establish the medically appropriate time. Mr. Doe pursued a claim based upon the Vaccine Injury Table and did not prevail. Doe 21, 84 Fed. Cl. at 46. "Encephalopathy," as used in the Vaccine Injury Table, is manifest by certain discrete behaviors. 42 C.F.R. § 100.3(b)(2). In contrast, Mr. Doe's

claim that Child Doe suffered an "encephalopathy" seems premised upon a broader definition of the term. As such, Mr. Doe may not borrow the time frame from the Vaccine Injury Table.

Moreover, findings from other cases cannot replace the requirement to introduce evidence in this case. Althen, 418 F.3d at 1281 (stating specials masters should adjudicate "the merits of individual claims on a case-by-case basis."). Additionally, a brief survey of other cases in which the DTaP was found to cause in fact an encephalopathy shows that the amount of time between the vaccination and manifestation of the encephalopathy was much less than the amount of time proposed by Mr. Doe here. E.g. Paulmino v. Sec'y of Health & Human Servs., 69 Fed. Cl. 1, 2-3 (2005) (six-month-old child suffered seizure within 24 hours of receiving third dose of DTaP).

(2) When Did Child Doe's Symptoms Begin?

In addition to determining how long after vaccination medical science would expect an injury caused by that vaccination to appear, Mr. Doe also must establish that Child Doe's symptoms fell within that time. Mr. Doe argues that "the symptoms of delay in [Child Doe] as reported by the fact witnesses, in late summer of 1999 and confirmed by the November and January well-baby reports and ultimately by the diagnosis of the static encephalopathy establish that the encephalopathy was present at all times after July 20." Pet'r Post Hearing Memorandum at 72. Mr. Doe's argument that Child Doe's case fits within the appropriate time frame (whatever that time frame is) is not supported by a preponderance of the evidence.

Determining the onset of Child Doe's problems is somewhat difficult. Clearly, he was diagnosed as having developmental delay in March 2000. However, this diagnosis means that onset of the developmental delay started sometime before March 2000. Determining the exact date that the developmental delay began is not necessary because even if Mr. Doe's proposed argument that the first manifestation occurred in November 1999 were accepted, Mr. Doe still would not prevail.

The strongest evidence that Child Doe was not suffering an encephalopathy in late summer 1999 is the health maintenance visit from September 14, 1999. Dr. Barrone determined that, at four-months, Child Doe was "well" and neurologically "normal." 10/2/02 Gov't Ex. B at 51. As discussed in section III.A.1.c(2), above, a preponderance of the evidence establishes that Child Doe was not experiencing a developmental delay on September 14, 1999.

In his post hearing memorandum, Mr. Doe does not address the September 14, 1999 evaluation with any meaningful analysis. At best, Mr. Doe seems to argue that the September 14, 1999 health maintenance visit is not accurate because the pediatrician failed to record all the complaints raised by the parents. See Pet'r Post Hearing Memorandum at 5-6, citing tr. 94-95; id. at 14 (no cite to transcript), id. at 16 (citing tr. 93, 98, 50), id. at 18 (citing tr. 1364), id. at 67 (no cite to transcript).

The transcript pages identified by Mr. Doe conflict with the medical records only in part. On page 94-95, Mr. Doe testified that he told the pediatrician who performed the September 14,

1999 examination, Dr. Barrone, that although Child Doe once performed things like reaching for toys and smiling, he had stopped performing them. Tr. 95. This testimony is not consistent with the record that Dr. Barrone created on that day. 10/2/02 Gov't Ex. B at 51.

Mr. Doe's testimony on this point was rejected by Special Master Edwards, who observed his demeanor while testifying. See Doe 21, 2008 WL 4679501 * 19 (citing tr. 93 and noting that Mr. Doe "wishes the special master to believe that a multitude of [Child Doe's] physicians neglected to include in their treatment summaries, evaluation reports and consultation correspondence important aspects of [Child Doe's] medical history that the parents provided.") This determination, in turn, was affirmed by Judge Braden. Doe 21, 84 Fed. Cl. at 46 & at 49-50 ("where parental observation is in conflict with medical opinions, it is entitled to 'little weight' or deference") (emphasis in original).

Other than this passage from transcript pages 94-95, the remaining portions of fact witness testimony is consistent with medical records. For example, on page 93-94, Mr. Doe testified that Child Doe had abnormal eye movements in October or November. This testimony is consistent with Dr. Turow's October 4, 1999 note, which does report a "strabismus vs. pseudostrabismus." 10/2/99 Gov't Ex. B at 54. This notation contradicts Mr. Doe's argument that the medical records are incomplete.[7]

In addition, two witnesses testified that the increase in Child Doe's head circumference started in December 1999. Tr. 50, 98. A record from December 1999 shows that the pediatricians recorded this concern and acted on it by seeking additional consults. 10/2/99 Gov't Ex. B at 61. For these reasons, there is no persuasive reason to accept Mr. Doe's argument that the doctor failed to record correctly Child Doe's condition during September 14, 1999 well-baby visit.

Mr. Doe appears to make one more attempt to avoid the significance of the September 14, 1999 record. In passing, his brief argues that Child Doe's encephalopathy was manifest perhaps as late as three months (October) after his vaccination and "due to his age he could not have manifested it earlier." Pet'r Post Hearing Memorandum at 69. Mr. Doe's brief does not provide any substantiation for this statement. In fact, it appears that no evidence supports the statement in Mr. Doe's brief. If Mr. Doe believed that Child Doe's encephalopathy could not be manifest due to Child Doe's relative youth, then Mr. Doe should have elicited such testimony from at least one of the various doctors who testified at the hearing. For example, Mr. Doe could have asked any of the experts to assume that Child Doe suffered an encephalopathy on July 20, 1999, and then to explain how Child Doe's condition would have appeared on September 14, 1999. Mr. Doe, however, did not. When the undersigned questioned Dr. Shane about this topic, Dr. Shane's answers were not helpful. Tr. 1315-18. This lack of evidence leaves Mr. Doe to

[7] To the extent that Mr. Doe testified that Child Doe's eye movements in October 1999, were the same as his eye movements now, tr. 1364; this testimony is not persuasive. It is very doubtful that Dr. Turow, who saw the strabismus (or pseudostrabismus) in October 1999, would confuse this condition with nystagmus. Dr. Turow is very aware of the differences between the two conditions.

argue, but argument is not a substitute for evidence. Gilda Industries, Inc. v. United States, 446 F.3d 1271, 1281 (Fed. Cir. 2006).

For these reasons, a preponderance of the evidence indicates that Child Doe was developing normal and not exhibiting any signs of developmental delay as of September 14, 1999. This finding, by itself, is virtually a finding that Child Doe did not suffer any long-term adverse consequences to the July 20, 1999 DTaP vaccination. As stated, Mr. Doe does not even attempt to argue that there was evidence of developmental delay on September 14, 1999. Instead, Mr. Doe relies upon the November 8, 1999 well-baby visit as evidence that Child Doe was developmentally delayed. Pet'r Post Hearing Memorandum at 72.

There are several problems with Mr. Doe's argument.

First, Mr. Doe's argument relies upon testimony that was not credited. The testimony of witnesses who asserted that Child Doe exhibited behaviors consistent with developmental delay in the late summer of 1999 cannot be the basis of a finding in Mr. Doe's favor. Special Master Edwards, who observed these witnesses, "determined that the bulk of the fact witnesses' hearing testimony is not correct." Doe 21, 2008 WL 4679501 * 23. This determination, in turn, was affirmed by Judge Braden. Doe 21, 84 Fed. Cl. at 46. Judge Braden's affirmance is binding. 42 U.S.C. § 300aa–12(e); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 869 (Fed. Cir. 1992).

Second, even if the fact witnesses were credited, Mr. Doe has not established that the behaviors they describe are linked to the developmental delay diagnosed later. Mr. Doe appears to argue that these behaviors constitute "subtle signs" of developmental delay.

Within the Vaccine Program, behaviors that a medical professional would recognize as the first symptom or manifestation of onset of a condition are used to establish the accrual date for purposes of statute of limitations. Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1358 (Fed. Cir. 2007) (interpreting 42 U.S.C. § 300aa–16(a)(2)). These behaviors may be useful in evaluating causation as well. Doe 21, 84 Fed. Cl. at 49.

Although his argument is not entirely clear, Mr. Doe appears to be arguing that Child Doe's failure to sit without support and failure to roll over completely at six-months is the first manifestation of the developmental delay, which was diagnosed in March 2000. Pet'r Post Hearing Memorandum at 67. However, the evidence does not support a finding that these failures were one part of a singular process that continues, through diagnosis in March 2000, until today.

Mr. Doe has not established, by a preponderance of the evidence, that Child Doe's inability to sit without support and inability to roll over completely were part of the same process that was diagnosed as developmental delay in March 2000. The evidence, here, is mixed. Certainly, Dr. Megson and Dr. Shane testified that Child Doe's encephalopathy started on July 20, 1999, and continued. However, their opinions have already been discredited by the September 14, 1999 well-baby evaluation, which found Child Doe was normal.

Apart from Dr. Megson's opinion and Dr. Shane's opinion, Dr. Turow provided inconclusive testimony. Dr. Turow agreed that it was difficult to determine when the encephalopathy starts and stops. Tr. 1053. Dr. Wiznitzer stated that the encephalopathy started between January and April 2000. Tr. 330.

This dispute between experts about the significance of (allegedly) observed behavior distinguishes this case from Markovich. In Markovich, it appears undisputed that the eye-blinking was a sign of Ashlyn Markovich's seizure disorder. Markovich, 477 F.3d at 1360. Thus, the question was whether these observations were sufficient to start the running of the statute of limitations. In contrast, here, there is a fair question as to whether Child Doe's inability to sit without support and inability to roll over completely at six-months are a manifestation of developmental delay. In light of the finding that Child Doe could accomplish these tasks a few months later, 10/2/02 Gov't Ex. B. at 65; it seems, more probable than not, that his lack of ability reflected the "normal" irregular pace of infant development.

Third, even if Mr. Doe had established that Child Doe were displaying signs of developmental delay in November 1999 (a questionable point), and even if Mr. Doe had established that any problems in November 1999 were linked to the developmental delay diagnosed in March 2000, Mr. Doe has yet another obstacle. Mr. Doe has not established that November is the time that medical science would expect an encephalopathy to be manifest. See section III.B.1.c(1). Mr. Doe argues that November "is just four months after [Child Doe's] initial reaction to the vaccine." Pet'r Post Hearing Memorandum at 67.

However, no medical expert testified that four months is the appropriate amount of time. Actually, four months is beyond the range of time in which special masters have commonly awarded compensation.

To establish the appropriate temporal relationship, the opinions of Dr. Shane or Dr. Megson that the DTaP vaccine caused Child Doe's developmental delay are not helpful. Evidence that the temporal relationship is appropriate is not implied from a general statement about causation as demonstrated in Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). In Pafford, the petitioners introduced evidence that a vaccine caused Still's disease through two experts, Dr. Levin and Dr. Geier. Id. at 1356. Dr. Geier's testimony was rejected as unpersuasive. Id. at 1359. Eliminating Dr. Geier left Dr. Levin's testimony. Presumably, Dr. Levin believed that the temporal sequence was appropriate. Otherwise, he could not have expressed an opinion about causation. However, he did not express an opinion about the appropriate temporal relationship. Id. at 1358. Consequently, in that case, the special master found that the petitioners did not satisfy their burden of proof "due, in part, to the absence of 'evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event.'" Id. (quoting special master's decision). The Federal Circuit held that the special master's reasoning complied with the test established in Althen. Id. at 1358-59.

Mr. Doe's case is comparable to Pafford in that here Dr. Shane and Dr. Megson expressed opinions about causation without testifying about the appropriate temporal

relationship. This omission is the same as Dr. Levin's testimony and opinion in Pafford. Consequently, the result is the same – a denial of compensation.

d. Medical Theory

Although the finding that Mr. Doe has not established the proximate temporal relationship between the July 20, 1999 DTaP vaccination and the onset of Child Doe's developmental delay and the finding that Mr. Doe has not established a logical sequence of cause and effect connecting the July 20, 1999 DTaP vaccination to Child Doe's developmental delay precludes an award of compensation, the remaining element from Althen warrants brief comment. As discussed below, Mr. Doe should have presented more information about his theory.

To establish a medical theory, Mr. Doe relies upon the testimony of Dr. Megson. Pet'r Post Hearing Memorandum at 69 (stating "Dr. Megson has offered a fully supported explanation of exactly how the pertussis factor in the DTaP vaccination [Child Doe] received on July 20, 1999 caused his current disabilities."); accord id. at 72-74.[8] Although Dr. Shane's October 30, 2008 report discusses how the pertussis toxin can cause various neurological injuries, exhibit 101 at 5-9, 13-15; Mr. Doe did not elicit testimony from Dr. Shane on this topic. Tr. 1287-303.

Dr. Megson's theory is that a portion of the acellular pertussis vaccine interferes with the functioning of calcium channels, which are regulated by a substance known as a G protein. Exhibit ___ at 1; tr. 1166-67; see also Pet'r Post Hearing Memorandum at 23 (summarizing Dr. Megson's testimony without citation to evidence). [9]

Dr. Megson's theory rests upon a comprehensive understanding of cellular biology. However, Dr. Megson did little to explain the foundations on which her opinion rests. Broadly speaking, respondent disagrees with many aspects of Dr. Megson's theory. Resp't Post Hearing Br. at 8-9; tr. 1220-42 (Dr. Wiznitzer's testimony addressing Dr. Megson's opinion). Given the findings for the third prong from Althen and the second prong from Althen, it is not necessary to determine whether Dr. Megson's theory is reliable and, therefore, fulfills Mr. Doe's burden for the first Althen prong. See Morse Diesel Internat'l, Inc. v. United States, 99-279C, 2007 WL 5177405 * 5 (June 29, 2007); Coltec Industries, Inc. v. United States, 62 Fed. Cl. 716, 743 n.23 (2004), vacated and remanded on other grounds, 454 F.3d 1340 (Fed. Cir. 2006), cert. denied, __ U.S. __, 127 S.Ct. 1261 (2007). Even if Dr. Megson's theory were credited, Mr. Doe would not

[8] The circumstances leading to the opinion from Dr. Megson are set forth in section II, above. Respondent presents a fair argument that the introduction of Dr. Megson's report and testimony exceeded the bounds of Judge Braden's remand order. Resp't Post Hearing Br. at 2-4. However, any error in allowing the introduction of Dr. Megson's opinion appears harmless because Dr. Megson's opinion does not assist Mr. Doe in establishing that he is entitled to compensation.

[9] Mr. Doe did not introduce any testimony proposing molecular mimicry as the method by which the acellular pertussis vaccine can cause developmental delay.

be entitled to compensation because he has not established a logical sequence of cause and effect and he has not established the appropriate temporal relationship. See Capizzano, 440 F.3d at 1327 (noting that the second Althen prong is "not without meaning").

In sum, Mr. Doe has not established, by a preponderance of the evidence, all three elements necessary for his primary theory — that the July 20, 1999 DTaP vaccination caused an encephalopathy leading to the diagnosis of developmental delay in March 2000. This theory is not persuasive for many reasons, the most prominent of which is that as of September 14, 2000, Child Doe was developmentally normal.

2. Sequella

Mr. Doe's alternative theory seems to be that Child Doe's condition is related to the HHE, which Child Doe experienced the evening of July 20, 1999. On this theory, too, Mr. Doe has not met his burden of proof.

a. Standards for Adjudication

At the beginning of this section, it is worthwhile to restate the issue – has Mr. Doe established, by a preponderance of the evidence, that Child Doe suffered an injury, caused by the July 20, 1999 DTaP vaccination, that lasted for more than six months? This issue is both narrow and relatively rare.

Whether Child Doe suffered a sequella from his adverse reaction for more than six months is a separate and tightly defined issue. It is not necessary to determine whether the DTaP vaccine caused an adverse reaction using the three-prong test set forth in Althen, 418 F.3d at 1278. Such analysis is not required because respondent concedes that the July 20, 1999 DTaP vaccination caused Child Doe an adverse reaction.

However, respondent maintains that Child Doe did not suffer the effects of this adverse reaction for more than six months. Compared to the numerous decisions addressing whether a vaccine caused an adverse reaction, cases discussing the duration of an injury are relatively few. Usually, there is little dispute about the severity or duration of a petitioner's injury. The question is whether a vaccine originally caused the injury.

But, this case — at least this theory — is different. Respondent has conceded that the DTaP caused an adverse reaction known as an HHE. To be entitled to compensation, Mr. Doe must establish that Child Doe suffered the "residual effects or complications of such . . . injury or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa–11(c)(1)(D)(I); accord Song, 31 Fed. Cl. at 65 (1994), aff'd 41 F.3d 1520 (Fed. Cir. 1994) (table). If Mr. Doe meets this burden, then he is entitled to compensation for various items that "result from the vaccine-related injury." 42 U.S.C. § 300aa–15(a). Thus, establishing the extent of the injury caused by the vaccine is critical for two reasons. First, the duration of the injury determines whether Mr. Doe is entitled to compensation at all – he is not entitled to any

compensation for an injury that does not last for more than six months. Second, the extent of the injury determines the scope of compensation.

A "sequela" is "[s]omething that follows, esp. a pathological condition resulting from a disease." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 872 (Fed. Cir. 1992) (quotation marks eliminated, emphasis in original). The burden of showing that a condition is a sequela to an injury caused by a vaccine rests with the petitioner. This burden is to present a preponderance of evidence. Gruber v. Sec'y of Health & Human Servs., 61 Fed. Cl. 674, 684 (2004); DeFazio v. Sec'y of Health & Human Servs., 40 Fed. Cl. 462, 463-64(1998); Hossack v. Sec'y of Health & Human Servs., 32 Fed. Cl. 769, 776 (1995) ("a preponderance of the evidence must show that some logical, direct causal link exists between the presumed Table injury and the alleged sequela."). Special Masters may not determine that a particular event is a sequella to an injury merely because the event happens after the injury. Abbott v. Sec'y of Health & Human Servs., 27 Fed. Cl. 792, 794 (1993), aff'd in relevant part, 19 F.3d 39 (Fed. Cir. 1994) (unpub.)

When petitioners fail to establish that a particular condition is not a sequela to an injury caused by a vaccine, they are not entitled to compensation for that condition. DeFazio, 40 Fed. Cl. at 469 (affirming special master's determination); Song 31 Fed. Cl. at 66 (affirming special master's determination that the petitioner failed to establish a connection between the child's encephalopathy and "later speech delay").

b. Examination of Evidence

Mr. Doe has not met his burden of establishing, by a preponderance of the evidence, that Child Doe's adverse reaction to the DTaP vaccine lasted longer than six months. Therefore, pursuant to this alternative theory, he is not entitled to compensation.

The detailed basis for this finding is set forth in section III.B.1.b, above. The brief explanation is that Child Doe was developing normally for several months after the July 20, 1999 vaccination. At the next health maintenance appointment, Dr. Barrone determined that Child Doe was neurologically "normal." 10/2/02 Gov't Ex. B at 51.

This health maintenance appointment occurred when Child Doe was four months. If the theory advanced by Dr. Megson and Dr. Shane were correct, then Child Doe would have been experiencing an encephalopathy for one-half of his life. Child Doe had normal development for two months. 10/2/02 Gov't Ex. B at 34. At two-months, Child Doe received the DTaP vaccine and experienced an adverse reaction. According to Mr. Doe's experts, the encephalopathy started on July 20, 1999, and continues until today. Tr. 1158 (Dr. Megson's describing Child Doe as "devastated"), 1301 (Dr. Shane). Thus, according to this theory, Child Doe was suffering from an encephalopathy from July 20, 1999 through (and continuing past) September 14, 1999 (the date of the four-month well-baby visit).

The facts do not support this theory. At four-months, Child Doe was normal and healthy. His ability to reach for toys and his babbling show that he was meeting his developmental

milestones. 10/2/02 Gov't Ex. B at 51. No persuasive evidence indicates that this development could have happened if Child Doe were suffering from an encephalopathy.

Mr. Doe's presentation of evidence generally ignored the four-month well-baby visit. For example, Mr. Doe did not ask Dr. Turow any questions about this visit. See tr. 1011-56. When respondent inquired from Dr. Turow, he said that Child Doe was not abnormal. Tr. 1066. Mr. Doe also did not ask Dr. Megson or Dr. Shane about this visit. Instead, Mr. Doe more frequently inquired about the six-month visit. See tr. 1013 (this is the first record discussed by Dr. Turow), 1038. This approach is not persuasive.

If Child Doe did suffer an encephalopathy beginning on July 20, 1999 and continuing for at least six months, some effects of this encephalopathy would have been observable in the next well-baby visit. Even if the doctor did not observe anything wrong with Child Doe, the doctor would have elicited information about Child Doe's health from the parent(s). The parents would have reported any problems. But, they did not.

Child Doe's history after the four-month examination confirms the finding that the July 20, 1999 adverse reaction did not last longer than six months. Child Doe suffered from an ear infection and thrush from September 23 to October 7, 1999. 10/2/99 Gov't Ex. B at 53-55. But, no persuasive evidence demonstrates that a DTaP-caused encephalopathy would cause an ear infection. Babies less than one-year-old frequently have three ear infections within six months. Tr. 1082; see also tr. 332 (testimony of Dr. Wiznitzer, explaining that children are sick at least 7 times a year with some sort of respiratory illness). So, although Child Doe may have had so many ear infections that the doctors eventually placed tubes in his ears to help drainage, the number of ear infections does not necessarily indicate that he was having an adverse reaction to the DTaP vaccine. Tr. 1135-36. At best, Dr. Megson states that a problem in calcium signaling leads to an impairment in the cells of the immune system that fight infection. Tr. 1128. But, like much of Dr. Megson's testimony, this portion was conclusory and not persuasive.

For these reasons, even if Mr. Doe had intended to argue that Child Doe's condition were a sequela to the July 20, 1999 HHE, he has not established that any reaction lasted more than six months. Therefore, he is not entitled to compensation pursuant to this theory.

C. Alternative Causes

At various points, Mr. Doe argues that because no alternative cause of Child Doe's developmental delay has been found, the cause must be the July 20, 1999 DTaP vaccination. E.g., Pet'r Post Hearing Memorandum at 60, 62, 64-65, 68; see also tr. 1295 (Dr. Shane). This argument is not persuasive for two reasons.

First, it is undoubtedly true that the cause of developmental delay is not always determined. Tr. 1323 (Dr. Shane). There are some cases in which medical science cannot determine the cause. Thus, even if doctors cannot say what caused Child Doe's developmental delay, this failure does not mean that the cause must be the vaccine. Grant v. Sec'y of Health &

Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (stating "[e]ncephalitis . . . can have causes other than the administration of a vaccine.").

Second, and more important, Child Doe's argument is legally irrelevant. For the reasons explained in section III.B, Mr. Doe has not met the elements that he is required to establish to be entitled to compensation. Therefore, exploring whether there are alternative causes for Child Doe's condition is not necessary. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1354 (Fed. Cir. 2008); Adams, 76 Fed. Cl. at 42.

IV. Conclusion

Mr. Doe appears to believe that the July 20, 1999 DTaP vaccine caused his son's developmental delay. But, the sincerity of his belief is not determinative. Instead, to be awarded compensation, Mr. Doe must present a reliable medical record or medical opinion. 42 U.S.C. § 300aa–13(a). Here, the various medical opinions are not persuasive and do not fulfill Mr. Doe's burden to prove his case. Consequently, he is not entitled to compensation.

The Clerk's Office is ordered to enter judgment in favor of respondent, if a motion for review is not filed. The Clerk's Office is also ordered to transmit a courtesy copy of this decision to Judge Braden. See Vaccine Rule 28A.

IT IS SO ORDERED.

_____
Christian J. Moran
Special Master