In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

M.D., a minor, by his mother and next friend, ROSEMARY DILASCIO,	*	No. 10-611V Special Master Christian J. Moran
Petitioner,	*	Filed: April 26, 2017 Reissued: August 22, 2017
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Diphtheria-tetanus-acellular-pertussis ("DTaP"), seizures
Respondent.	*	

Corey B. Kaye, Kaye & Lechner, Mineola, NY, for petitioner;
Glenn A. MacLeod, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

M.D., the son of petitioner Rosemary Dilascio, suffers from a severe form of epilepsy. He began having seizures shortly after his fifth birthday. The seizures started after he received a set of vaccinations, including the diphtheria-tetanus-acellular pertussis ("DTaP") vaccine. Ms. Dilascio's petition alleges that the DTaP vaccination caused his epilepsy and seeks compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 through 34 (2012). The petition sets forth two discrete causes of action: one based on the Vaccine Table and the other an off-Table claim.

[1] After this decision was issued on April 26, 2017, Ms. Dilascio filed a motion for redaction. The motion was granted in so far as it sought to replace her son's name with initials. The decision is now being made available to the public pursuant to the E-Government Act, 44 U.S.C. § 3501 note (2012).

For both causes of action, Ms. Dilascio has failed to present persuasive evidence. First, for the on-Table cause of action, the evidence overwhelmingly indicates that the onset of M.D.'s change in health occurred seven days after vaccination. Because the relevant regulation restricts presumptive causation to 0-72 hours, M.D.'s case does not fall within the Table.

Ms. Dilascio's second cause of action also fails. Under the facts of this case, she is required to present a persuasive opinion from an expert. The expert whom Ms. Dilascio retained, Robert Gould, M.D., presented a report with many deficiencies, outlined below.

For these reasons, Ms. Dilascio is not entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision.

Procedural History

As background, on April 27, 2009, Ms. Dilascio, represented by Attorney Corey Kaye, filed a petition on behalf of M.D., which was assigned docket number 09-266V. With the petition, Ms. Dilascio filed 11 exhibits. One of these exhibits revealed that Ms. Dilascio had also filed a medical malpractice claim. Pursuant to 42 U.S.C. § 300aa–11(a)(5), the special master entered an order concluding proceedings. Order, filed Aug. 17, 2009.

This case's procedural history formally began on September 10, 2010, when Ms. Dilascio, still represented by Mr. Kaye, filed another petition. Ms. Dilascio included a notice that this case (docket number 10-611V) related to the earlier case (docket number 09-266V). On February 18, 2011, the presiding special master ordered that exhibits 1-11 from case 09-266V be filed into this case. The Clerk's Office did so and sent copies to the attorneys for Ms. Dilascio and the Secretary.

Ms. Dilascio was required to submit updated medical records. The first order requiring the filing of medical records was issued on November 16, 2010, with a deadline of January 18, 2011. Ms. Dilascio sought and was granted additional time to file records. When the medical records were not submitted, the special master issued orders to show cause why the case should not be dismissed for failure to prosecute three times. Orders dated Apr. 18, 2012; July 23, 2012; and Feb. 7, 2013. On each occasion, Ms. Dilascio persuaded the special master that additional time was warranted and that she intended to continue her case.

On September 20, 2013, Ms. Dilascio filed a set of records on compact disc. She later represented that she believed that she had filed all the records. The process of gathering medical records took approximately three years.[2]

Because Ms. Dilascio had indicated that the records were complete, the Secretary examined the evidence and set forth his assessment in his report, filed pursuant to Vaccine Rule 4, on December 9, 2013. The Secretary maintained that Ms. Dilascio had not established that she was entitled to compensation.

The parties' views of the evidence were discussed during a January 10, 2014 status conference. In that status conference, Ms. Dilascio stated that she intended to obtain a report from an expert. To assist, the undersigned issued a set of instructions for the parties to provide to their experts. The undersigned also indicated that the experts' reports would constitute their direct testimony at any hearing. Order, filed Jan. 10, 2014. The initial deadline for the expert report from the petitioner was set as May 9, 2014.

More than one year later, on June 25, 2015, Ms. Dilascio filed a report from Robert J. Gould. Dr. Gould is a pediatric neurologist. Exhibit 22, tab A (curriculum vitae). Dr. Gould opined that "M.D.'sdevastating encephalopathy is, in fact, causally related to the administration of the DTaP vaccine." Exhibit 22 at 5. Ms. Dilascio also filed medical articles on which Dr. Gould relied. Exhibits 23-42.

With the filing of the petitioner's expert report, it appeared that the Secretary would obtain an expert report of his own. See order, filed July 10, 2015. But, the Secretary's expert discovered that the North Shore Hospital records from M.D.'s hospitalization beginning May 2006 were missing pages. Because May 2006 was shortly after the vaccination at issue, the Secretary requested that Ms. Dilascio obtain complete records. Ms. Dilascio agreed. She filed the records on December 28, 2015. These were subsequently assigned exhibit 43.

On March 1, 2016, the Secretary filed a report from John Zempel, also a pediatric neurologist, and his curriculum vitae. Exhibits A and B. Dr. Zempel stated: "I think it is extremely unlikely that the DTaP vaccine caused the onset of the catastrophic epilepsy in this case." Exhibit A at 11.

After only a brief interval, Ms. Dilascio filed a responsive report from Dr. Gould on April 29, 2016. Exhibit 44. The submission of this reply appeared to

[2] On September 23, 2013, the case was reassigned to the undersigned.

conclude the process of disclosing opinions from experts. Thus, the matter was set for a hearing.

A June 24, 2016 order scheduled a hearing for approximately five months later, on December 2, 2016, in New York. The June 24, 2016 order set intervening deadlines, including the submission of briefs before the hearing. An order issued on July 8, 2016, detailed the expected topics of the forthcoming briefs and expressly noted that the parties should adhere closely to the schedule for filing briefs. The contents of the expected briefs and the schedule were reviewed in a July 14, 2016 status conference.

Ms. Dilascio had considerable difficulty complying with the June 24, 2016 order. After much counseling, Ms. Dilascio filed an accurate table of contents listing exhibits on September 15, 2016. She also filed her pretrial brief on October 24, 2016. Her pretrial brief indicated that both of M.D.'s parents might testify. See Pet'r's Preh'g Br., filed Oct. 24, 2016, at 3.

The Secretary filed his pretrial materials on November 1, 2016. In addition to a brief, the Secretary submitted another report from Dr. Zempel, addressing some of the articles on which Dr. Gould had relied and citing additional articles. Exhibit D1. The Secretary also asked for clarification about any anticipated testimony from M.D.'s parents, especially his father, who is not a petitioner. Resp't's Preh'g Br., filed Nov. 1, 2016, at 2 n.1.

The petitioner was ordered to file an affidavit from Mr. Dilascio, ideally before the prehearing conference scheduled for November 16, 2016, and no later than November 28, 2016. Order, filed Nov. 9, 2016. On November 16, 2016, the parties represented that they were attempting to resolve the case. Therefore, the substantive aspects of the pretrial conference (see Vaccine Rule 5) were deferred until November 28, 2016.

By November 28, 2016, Ms. Dilascio had not filed an affidavit from Mr. Dilascio. In the prehearing status conference, which was digitally recorded, she requested that the case be submitted on the existing record. She did not want to proceed with the hearing scheduled for December 2, 2016. When asked whether either of M.D.'s parents wanted to testify, Mr. Kaye indicated that the parents' version of events was well documented, and that he had "more concerns about the other aspect of [Mr. Dilascio's] live testimony[.]" Status Conference, Nov. 28, 2016. The Secretary concurred with the petitioner's proposal to submit the case based upon the written record. The Secretary noted that the pretrial orders informed the parties that the experts' reports would constitute their direct testimony and the pretrial orders allowed the parties to set forth arguments in their

pretrial briefs. Thus, the Secretary believed that the record was sufficiently developed that a hearing was unlikely to affect the outcome of the litigation.

The undersigned accepted Ms. Dilascio's proposal to cancel the December 2, 2016 hearing. The case appeared ready for adjudication.

However, in reviewing the materials, the undersigned realized that the National Childhood Encephalopathy Study (NCES) could have possibly supported Ms. Dilascio's claim. Support from the NCES was only "possible" because the NCES examined adverse events following the whole cell pertussis vaccine and M.D. received the acellular pertussis vaccine. Special masters have taken different positions on the transferability of the NCES. Compare Grace v. Sec'y of Health & Human Servs., No. [redacted], 2006 WL 3499511 (Fed. Cl. Spec. Mstr. Nov. 20, 2006) with Romero v. Sec'y of Health & Human Servs., No. 07-671V, 2010 WL 2766761 (Fed. Cl. Spec. Mstr. June 22, 2010). The undersigned, therefore, provided this guidance to Ms. Dilascio, outlined how Ms. Dilascio could proceed, and instructed her to determine whether she wished to explore the NCES. Order, issued Feb. 16, 2017.

Ms. Dilascio stated that she did "not wish to submit further documentation or expert reports." Pet'r's Status Rep., filed Apr. 20, 2017. Thus, the case is now ready for adjudication.

Facts

M.D. was born in April 2001. Before receiving the vaccinations on April 24, 2006, he was in relatively good health. His pediatricians did not document any significant illnesses at any of the periodic visits. See exhibit 2, passim. On the date of the critical vaccinations, the pediatrician noted no health concerns, mentioning that M.D. was going into kindergarten. Exhibit 2 at 33 / pdf 38.[3] This visit included routine vaccinations. Exhibit 3 at 2 / pdf 43.

The day following the vaccination, according to Ms. Dilascio's log book, M.D. had a "rash at shot site, no fever." Exhibit 9 at 2 / pdf 35.[4] Ms. Dilascio also

[3] PDF page numbers are included for certain exhibits because of non-standard pagination within many of the submitted PDF exhibits.

[4] Ms. Dilascio submitted an affidavit in which she averred that "the logs and seizures logs which are attached as Exhibit 9 . . . were maintained by me contemporaneously with M.D.'s treatment and care and are true and accurate." Exhibit 8 ¶ 3. Despite this assertion, the date on which Ms. Dilascio began to create these logs is not entirely clear. The first page of the log book, which purports to present events from April 24, 2006 through April 30, 2006, contains numerous cross-outs, suggesting that the log book was not prepared on those dates.

wrote that she called the pediatrician on April 25, 2006. While the pediatrician's records do not contain any logs of telephone calls, the staff at pediatrician's offices do not always memorialize telephone conversations. Thus, the lack of a corroborating entry is not particularly surprising. Ms. Dilascio's log book states that on Wednesday, April 26, 2006, M.D. was "fine, no fever." Id.

On April 27, 2006, the log book states "M.D. wakes up [with] 2 lumps on neck: Take into pediatrician. Tests positive for strep. Starts antibiotics – Amoxicillin [with] Augmentin." Id. It appears that a record from the pediatrician for this record is not included with the exhibits. However, a lab test from April 27, 2006, indicates that M.D. was positive for group A streptococcus. Exhibit 5 at 83 / pdf 130.

According to the log book again, on Friday, April 28, 2006, M.D. was "fine." At 4:00 pm, he developed a fever for which he was given Motrin and Tylenol at the pediatrician's suggestion. Exhibit 9 at 2 / pdf 35. On the next day (Saturday), he was fine. He was also fine on Sunday. Ms. Dilascio also noted that the rash, which she had memorialized as appearing on Tuesday, April 25, 2006, was "fading." Id. at 2-3.

On Monday, May 1, 2006, M.D.'s health changed dramatically. May 1, 2006 is seven days after vaccination. During the day, he appears to have slept more than typical five year olds. At 11:00 pm, Ms. Dilascio found him in the bathroom, naked, standing at the sink with toothpaste on his toothbrush. He was covered in diarrhea. He was also groggy. Ms. Dilascio put M.D. in her bed and started to launder M.D.'s sheets. When she returned, he was "foaming at mouth, eyes wide open in catatonic state." Exhibit 9 at 3-4 / pdf 36-37; see also exhibit 7 at 7 (admission to Schneider's Children Hospital).

After Ms. Dilascio called 911, an ambulance transported M.D. to Syosset / North Shore Hospital. He arrived at approximately 11:45 pm on Monday, May 1, 2006. The history was relatively consistent with the recitation above. Exhibit 20 at 1, 13. He had a second seizure in the emergency room during which he became "fully unresponsive, eyes rolled back." Id. at 13. A brain CT without contrast showed "no evidence of acute intracranial pathology." Id. at 11.

At approximately 2:00 am on Tuesday, May 2, 2006, M.D. was transferred via ambulance from Syosset to North Shore / Schneider Children's Hospital. Exhibit 7 at 7 / pdf 33; see also exhibit 9 (log book) at 4 / pdf 37. He remained at Schneider until July 27, 2006. Exhibit 9 at 1 (log book); exhibit 7 at 123 / pdf 149 (transfer report). During these 86 days, medical personnel generated hundreds of pages of records.

On the first day of his hospitalization at Schneider, M.D. was "lethargic" and "responsive to painful stimuli." Exhibit 7 at 26 / pdf 52. Specialists in pediatrics and neurology consulted. Id. at 128 / pdf 154, 130 / pdf 156. M.D.'s seizures continued. By late on May 2, 2006, he had to be intubated. Exhibit 7 at 28 / pdf 54 (nurse's note); exhibit 9 at 4 / pdf 37.

The doctors struggled to explain the origin of M.D.'s seizures. On May 3, 2006, the attending doctor from the pediatric intensive care unit described M.D. as a "5 yr old new onset seizures, presumed viral encephalitis." Exhibit 7 at 37 / pdf 63. However, a specialist in infectious diseases indicated that encephalitis was not likely because testing had not revealed any inflammation in the cerebrospinal fluid and M.D. was not experiencing a fever. Exhibit 7 at 45 / pdf 71. The doctors ran many tests looking for organisms that could explain the fever but found none. Exhibit 7 at 142-52 / pdf 168-78; see also id. at 49 / pdf 75 (infectious disease specialist: "No etiology for encephalitis identified to date").

Despite being in a hospital and on medication, M.D. continued to have seizures. He was eventually placed in a phenobarbital coma. Exhibit 7 at 66-67 / pdf 92-93. EEG recordings, taken over multiple days, showed multiple seizures. See exhibit 7 at 166-89 / pdf 192-215.

After approximately 10 days of seizures, a nurse from the office of M.D.'s pediatrician submitted a notice to the Vaccine Adverse Event Reporting System ("VAERS"). She stated: "On May 2, 2006 patient admitted to hospital with status epilepticus. No encephalitis. [Patient] currently intubated continuing to have seizures. Etiology unknown at this time." Exhibit 10 at 6 / pdf 37.

A concise summary of M.D.'s nearly three-month stay at Schneider Children's Hospital is found in the transfer note. In addition to the events mentioned above, this note states: "Over the course of several months, the patient was weaned off of [phenobarbital] and then versed and controlled on his current regimen of medications. Patient has had document[ed] seizures on EEG. Often these seizures are subclinical but sometimes consist of staring episodes and apnea." Exhibit 7 at 123 / pdf 149.

From Schneider Children's Hospital, M.D. went to Blythedale Children's Hospital. He stayed at Blythedale until October 4, 2006 (69 days). Exhibit 9 (log book) at 1. The associated documentation exceeds 700 pages. See exhibit 18.1, passim.[5] This information is useful in determining M.D.'s condition on any

[5] Petitioner filed records from Blythedale in four parts, corresponding to four different admissions. This decision cites records from the first admission as exhibit 18.1. Records from the second admission are cited as exhibit 18.2, etc.

particular day and in noting the particular types of therapies that he received. However, these rehabilitation records shed negligible (if any) light on the cause of M.D.'s condition. See exhibit 18.1 at 5-11 (handwritten transfer note).

Ms. Dilascio's log book indicates that after Blythedale, M.D. went to New York University Medical Center ("NYU") from October 4, 2006 until November 15, 2006. Exhibit 9 at 1. While it appears that petitioner did not submit any records from NYU for this hospitalization, the log book fills this gap to some extent. See exhibit 9 at 60-90 / pdf 93-123.

The log book indicates that M.D. returned to Blythedale on November 15, 2006, exhibit 9 at 1, and records from Blythedale confirm that M.D. was admitted there on November 15, 2006. See exhibit 18.2 at 12-23. From Blythedale, M.D. went to NYU on January 23, 2007. Id. at 381-82.

M.D. stayed at NYU from January 23, 2007 to January 30, 2007. Exhibit 5 at 50 / pdf 97.[6] The history recounts the salient events in M.D.'s life:

> This is a 5 year old male with a history of refractory partial epilepsy and neurological impairments felt to be secondary to encephalitis. Seizure onset was approximately 9 months ago. The patient presented initially with change in mental status after fever. One week prior to the episode the patient had received DTaP vaccination and was treated with Augmentin for a throat infection. Fever workup (LP, serum and CSF cultures, chest x-ray, MRI) and metabolic workup revealed no etiology. Seizures described as eye rolling and arm stiffening associated with elevated blood pressures and desaturations were refractory to multiple antiepileptic therapies (steroids, IVIG, ketogenic diet, Depakote, Phenobarbitol and Tegretol) and initially required Pentobarbitol/versed coma for cessation of seizures. The patient was transferred to Blythedale in July 2006 after he underwent placement of a tracheostomy and [gastrostomy] tubes with continued daily seizures on Depakote, Phenobarbitol and Tegretol. He was recently discharged from the epilepsy monitoring unit at Tisch in

[6] This transfer record is included in the records of M.D.'s pediatrician. It appears that the records from NYU that the petitioner filed do not include records from this hospitalization. Entries in the log book for this time can be found in exhibit 9 at 155-57 / pdf 188-90.

> October 2006 after multiple antiepileptic medication adjustments. Current antiepileptic medications include Felbatol 600mg tid, Tegretol 400mg tid and Zonegran 300mg bid. He is now admitted due to persist[e]nce of seizures despite present antiepileptic regimen.

Id. M.D.'s status in January 2007 was that he was "nonverbal, unable to sit or ambulate." In addition, he had "tracheostomy and [gastrostomy] tubes in place." Id.

After NYU, M.D. again returned to Blythedale. See exhibit 18.3 at 8 / pdf 80; exhibit 9 at 157 / pdf 190. He stayed until May 8, 2007, when he returned to NYU. Exhibit 18.3 at 4 / pdf 76; exhibit 9 at 178 / pdf 211. Eventually, on June 4, 2007, M.D. was able to live at home. Exhibit 5 at 31 / pdf 78, 35 / pdf 82 (correspondence between pediatrician and agency providing care-at-home assistance); exhibit 9 at 185 / pdf 218.

M.D. continued to have seizures. See, e.g., exhibit 16c-2 at 51 (November 22, 2010 record of video EEG). He remained under the care of a pediatric neurologist. Exhibit 15, passim.

In September 2011, M.D. was admitted to NYU to explore whether surgery could assist with controlling his seizures. See exhibit 15 at pdf 8 (letter from pediatric neurologist recommending surgery). While hospitalized, M.D. underwent another MRI (exhibit 16c-4 at 58 / pdf 8) and a lengthy video EEG (exhibit 16c-7 at 205 / pdf 5). After exploring an operation, the doctors determined that surgery was unlikely to help M.D. See exhibit 16c-11 at 408 / pdf 8.

The NYU hospitalization records from September 2011 appear to be the most recent records filed as exhibits. In a status conference held in November 2016, Ms. Dilascio's attorney represented that M.D. was not doing well and had been in the hospital.

Analysis

Ms. Dilascio alleges two distinct causes of action. First, she asserts that she is entitled to compensation because M.D. suffered an injury listed on the Vaccine Table. More specifically, she argues that M.D. suffered an "encephalopathy" within 0-72 hours of receiving the DTaP vaccine on April 24, 2006. Second, and in the alternative, Ms. Dilascio asserts an off-Table claim, that the April 24, 2006 DTaP vaccination was the cause-in-fact of her son's seizure disorder.

1. On-Table Claim

Congress created the Vaccine Program to promote recovery for people injured by vaccinations. In doing so, Congress created a table that associates certain vaccines with certain conditions that arise in certain amount of time. When a petitioner establishes an on-Table injury, there is a presumption that the vaccine caused the injury. The Secretary may rebut this presumption with other evidence. Whitecotton v. Shalala, 514 U.S. 268, 270-71 (1995).

The current version of the table is found at 42 C.F.R. § 100.3(a). For the DTaP vaccine, the Vaccine Table lists "encephalopathy" within 0-72 hours. 42 C.F.R. § 100.3(a) ¶ II.B.

Through Qualifications and Aids to Interpretation, the Secretary has further defined "encephalopathy." An "acute encephalopathy" means "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). For children who are older than 18 months of age, including M.D.,

> an acute encephalopathy is one that persists for at least 24 hours and is characterized by at least two of the following:
>
> (1) A significant change in mental status that is not medication related, specifically a confusional state, or a delirium, or a psychosis;
> (2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and
> (3) A seizure associated with a loss of consciousness.

42 C.F.R. § 100.3(b)(2)(i)(B).

The Secretary has also excluded some factors from contributing to an "encephalopathy."

> The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a

> diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3(b)(2)(i)(E).

Under this regulatory definition, Ms. Dilascio has failed to demonstrate that M.D. suffered an "encephalopathy" within 72 hours of the DTaP vaccination. All evidence indicates that for the first three days after April 24, 2006, M.D. had a normal mental status. His mother's log book states that he had a rash and a sore throat. Exhibit 9 at 2 / pdf 35. He also tested positive for strep. Exhibit 5 at 83 / pdf 130. These are not symptoms of an encephalopathy.

When M.D. started having seizures, the doctors were consistently informed that his problems started on May 1, 2006, which is seven days after vaccination. See exhibit 20 at 1; exhibit 7 at 7 / pdf 33 (admission notes), 128 / pdf 154 (consult with pediatrician), 130 / pdf 156 (consult with pediatric neurologist). It seems likely that if M.D. had started experiencing any mental problems before May 1, 2006, one of the doctors would have recorded this information. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Ms. Dilascio has not presented an affidavit contesting the accuracy of the histories that place the onset of neurologic problems on May 1, 2006.[7]

In Dr. Gould's report, he asserted that M.D. could have had seizures that no one witnessed. Exhibit 22 at 2-3. The order for pretrial briefs requested that Ms. Dilascio identify any affirmative evidence that could support a finding that M.D. suffered an encephalopathy within 72 hours of vaccination. Order, filed July 8, 2016, at 2, 4. Ms. Dilascio did not actually cite any evidence from a percipient witness about M.D.'s behavior in the critical time. Rather, Ms. Dilascio relied upon the opinions of Dr. Gould. Pet'r's Preh'g Br. at 2.

Dr. Gould's opinion about M.D.'s condition in the 72 hours following vaccination is not based upon any evidence. At best, Dr. Gould is saying that something (like a seizure) could have occurred. Even if a seizure could be a manifestation of an acute encephalopathy (something the Aids and Qualifications

[7] In the petition, Ms. Dilascio asserted that M.D. suffered "'Table Injury' known as Disorder of the brain (Encephalopathy) within seven days of administration of the DTaP vaccine." Pet. at 1 (preamble). As discussed in the text above, the regulations restrict encephalopathy after pertussis vaccines to 0-72 hours. Thus, the petition's reference to "seven days" is erroneous.

to Interpretations proscribe (42 C.F.R. § 100.3(b)(2)(i)(E))), there is no evidence that a seizure did occur within 72 hours. Consequently, Ms. Dilascio has failed to present evidence that establishes, on a more-likely-than-not basis, that M.D. suffered an encephalopathy within 72 hours of the April 24, 2006 DTaP vaccination. Ms. Dilascio may not receive compensation based upon an on-Table cause of action.[8]

2. Off-Table Claim

When petitioners do not prevail on an on-Table claim, they may assert an alternative cause of action that a particular vaccination was the cause-in-fact of an injury. 42 U.S.C. § 300aa–11(c)(1)(C)(ii)(I); Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010).

The three elements of an off-Table claim are concisely stated. A petitioner must present preponderant evidence showing: "(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 v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

To prevail, Ms. Dilascio must present a medical record or a medical opinion supporting her claim that the DTaP vaccine was the cause-in-fact of M.D.'s seizure disorder. 42 U.S.C. § 300aa–13(a). With respect to any notations in the medical records, Ms. Dilascio recognized that none of the doctors treating her son "were trying to attribute the acute brain encephalopathy to a Vaccines event." Pet'r's Preh'g Br. at 2. Thus, these records do not assist Ms. Dilascio in proving her case.

Ms. Dilascio argues that the VAERS report holds "some probative value" because the filing of a VAERS reports indicates, in Ms. Dilascio's view, the pediatrician "considered the possibility of a vaccine related event." Id. Yet, Ms. Dilascio immediately and forthrightly undercuts her argument by commenting that "this VAERS reporting was required by statute." Id. In light of the requirement to report events that occur shortly after vaccination, it is difficult to draw any inference in favor of causation from the VAERS report in this case because the nurse who submitted the form said the "etiology [was] unknown at this time."

[8] Even further afield is Dr. Gould's argument that the Secretary was arbitrary in limiting the presumed causal association between DTaP and acute encephalopathy to those cases that arise within 72 hours. See exhibit 22 at 3; exhibit 44 at 1. Regardless of Dr. Gould's opinion, Congress granted the Secretary authority to modify the Vaccine Table. Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1312-15 (Fed. Cir. 1999). Therefore, there is no basis for a special master to extend the Table's timeframes.

Exhibit 10 at 6 / pdf 37. For these reasons, Ms. Dilascio cannot prevail based upon the "medical records." She must rely upon the "medical opinion" from Dr. Gould.

Dr. Gould's two reports contain many infirmities, leading to a conclusion that his opinion is not persuasive. Starting with the first prong from Althen, it is not entirely clear that Dr. Gould presented a coherent theory to explain how the DTaP vaccine can cause an encephalopathy and/or a seizure disorder. At best, in the context of arguing that the 72 hour limit for an on-Table encephalopathy is arbitrary, Dr. Gould states: "The mechanism of action of the presumed encephalopathy here is believed to be related to some type of body response/immune response." Exhibit 22 at 3. Although Ms. Dilascio was specifically directed to summarize Dr. Gould's theory, order filed July 8, 2016, at 5, the ensuing brief did not. See Pet'r's Preh'g Br. at 2.

An assertion that a vaccine can cause an illness through an unexplained "immune response" is far too simplistic to be persuasive. While petitioners and their experts are not expected to present theories backed with scientific certainty, see Althen, 418 F.3d at 1279-80, the expert must provide some details that allow the theory to be evaluated. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1360-61 (Fed. Cir. 2013) (holding special master was not arbitrary and capricious in rejecting petitioner's theory); Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1251-54 (Fed. Cir. 2012) (holding that Court of Federal Claims used an erroneous standard of review and reinstating special master's finding that petitioners failed to meet their burden of proof with respect to prong 1); Hines v. Sec'y of Health & Human Servs., 21 Cl. Ct. 634, 646 (1990) (ruling that a special master may give little weight to a doctor's conclusory affidavit), aff'd on nonrelevant grounds, 940 F.2d 1518 (Fed. Cir. 1991).

The lack of detail on the theory carries over to create a deficiency with respect to the third Althen prong, which concerns timing. This element requires a persuasive showing of a defined period of time during which an inference of causation may be drawn appropriately. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op. 503 Fed. Appx. 952 (Fed. Cir. 2013); cf. order, filed July 8, 2016, at 6. Here, Dr. Gould criticizes "the completely arbitrary nature of the 72 hour time frame." Exhibit 22 at 5; accord exhibit 44 at 1. However, Dr. Gould does not propose any temporal limit. The absence of a limit essentially and impermissibly renders the third prong of Althen a nullity. Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 142 (2010). Consequently, Ms. Dilascio has not met her burden regarding prong three.

Given that Ms. Dilascio has failed to present persuasive evidence on prong 1 and prong 3, it follows as a matter of logic that the evidence does not preponderate in her favor regarding prong 2. Dr. Gould notes that the doctors have not identified any cause for M.D.'s seizures. Exhibit 22 at 4; exhibit 44 at 2. However, the fact that doctors have not found another cause for M.D.'s seizure disorder does not mean that a vaccination is the cause of the disease. Althen, 418 F.3d at 1278 (stating that "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation"); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992). In an off-Table case, the Secretary's burden to present persuasive evidence that a factor other than a vaccine caused an illness arises only after the petitioner presents persuasive evidence on the three Althen prongs. LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014). Here, for the reasons explained above, Ms. Dilascio did not meet her initial burden. Therefore, she cannot be awarded compensation.

Conclusion

The evidence shows that M.D.'s case is tragic. He was healthy until approximately five years old. Then, he received a dose of the DTaP vaccine. Approximately seven days later, he started having seizures that drastically impaired his functioning. His health problems persist.

However, the evidence fails to establish a persuasive connection between the DTaP vaccination and M.D.'s seizure disorder. M.D. experienced the first symptoms of a brain disorder outside of the time listed on the Vaccine Table. For the off-Table claim, the report of Dr. Gould was not even minimally sufficient. Therefore, despite the sympathetic nature of Ms. Dilascio's status, she cannot be awarded compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master