In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 21, 2017

HAYTOR VEGA *and* LUCIA MARTINEZ, *Legal Representatives of a Minor Child,* D.V.M.,	*	PUBLISHED
	*	No. 13-183V
Petitioners,	*	
v.	*	Chief Special Master Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Diphtheria-Tetanus-acellular Pertussis ("DTaP") Vaccine; Encephalopathy; Table Injury.
Respondent.	*	

Howard Scott Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for petitioners.
Linda Sara Renzi, United States Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On March 11, 2013, Haytor Vega and Lucia Martinez ("petitioners"), as legal representatives of a minor child, D.V.M., filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petition ("Pet.") (ECF No. 1). Petitioners allege that D.V.M. suffered an acute encephalopathy within seventy-two hours of receiving a diphtheria-tetanus-acellular pertussis ("DTaP") vaccine on March 12, 2010. Pet. at 1, 4-5. Therefore, they allege that they are entitled to compensation under the Vaccine Injury Table ("Table").

[1] Because this decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute a clearly unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioners have met their legal burden. Petitioners have provided preponderant evidence that D.V.M. suffered a Table encephalopathy within 72 hours of the DTaP vaccination administered on March 12, 2010. Furthermore, respondent has not presented preponderant evidence that the encephalopathy had a cause unrelated to the vaccine. Accordingly, petitioners are entitled to compensation.

I. BACKGROUND

A. Procedural History

Petitioners filed their claim on March 11, 2013. Pet. On April 10, 2013, petitioners filed initial medical records on compact disc. Notice of Intent to file CD-ROMs of Exhibits (ECF No. 6). On April 25, 2013, the undersigned convened an initial status conference, during which she ordered petitioners to file all records and a Statement of Completion within sixty days, and ordered respondent to file his Rule 4(c) report within sixty days thereafter. Scheduling Order (ECF No. 7). Petitioners timely filed the remaining records and a Statement of Completion on May 22, 2013. ECF Nos. 8, 9. On July 22, 2013, respondent filed a motion for extension of time until September 30, 2013 to file the Rule 4(c) report. Motion (ECF No. 10). The motion was granted on the same day. Scheduling Order (ECF No. 11).

On September 30, 2013, respondent timely filed his Rule 4(c) report recommending against compensation. Respondent's ("Resp's") Report (ECF No. 12). Respondent attached an expert report from pediatric neurologist Max Wiznitzer, M.D. Resp's Exhibit ("Ex.") A. Respondent also attached Dr. Wiznitzer's curriculum vitae. Resp's Ex. B.

On January 7, 2014, the undersigned conducted a status conference and then ordered petitioners to file additional records, including all reports and films from D.V.M.'s MRIs, no later than April 7, 2014. Scheduling Order (ECF No. 14). Petitioners did not meet this deadline. Petitioners moved for and received several extensions of time, before filing the records on or about September 12, 2014. Statement of Completion (ECF No. 27).

Over the course of the next year, petitioners' original counsel withdrew from the case and the case was stayed until petitioners retained new counsel. ECF Nos. 34-36. On September 29, 2015, attorney Howard Gold replaced the *pro se* petitioners as the attorney of record. Consented Motion (ECF No. 40).

On October 7, 2015, the undersigned held a status conference with petitioners' and respondent's counsel. Order (ECF No. 44). The undersigned summarized the primary substantive issue in the case as being whether D.V.M.'s encephalopathy qualified as a Table injury. Id. at 1. In his initial report filed on September 30, 2013, respondent's expert Dr. Wiznitzer opined that D.V.M. suffered an acute encephalopathy within three days of vaccination, which would entitle him to compensation under the Table. Id. (citing Resp's Ex. A at 8). However, Dr. Wiznitzer opined that D.V.M.'s encephalopathy was most likely caused by a structural lesion unrelated to the administration of his vaccinations, which would disqualify him from compensation under the Table. Id. Dr. Wiznitzer's initial report was based on his review of D.V.M.'s medical records, but he had not reviewed D.V.M.'s actual CT and MRI films. Id. During the status conference, the parties and the undersigned agreed that petitioners should convey compact discs containing the

actual CT and MRI films to respondent for Dr. Wiznitzer's review. The undersigned ordered petitioners to do so no later than November 6, 2015. Id. at 2. Additionally, she ordered petitioners to file an expert report regarding whether the CT/ MRI images showed a structural lesion within thirty days thereafter. Id. After moving for and receiving several extensions of time, petitioners transmitted the CT and MRI images to respondent on or about January 24, 2016. Status Report (ECF No. 49). After moving for and receiving further extensions of time, petitioners filed a letter from Dr. Marcel Kinsbourne on April 15, 2016. Petitioners' ("Pet'rs'") Ex. 35 (ECF No. 56).

On June 14, 2016, the undersigned conducted a Rule 5 status conference. Order (ECF No. 57). After obtaining the consent of both parties, she summarized her preliminary views of the case. Id. at 1. She stated that based on her review of the medical records, statements by treating radiologists in their reports, and the expert opinions that had been filed, D.V.M.'s encephalopathy did not appear to fall under an exception to the Table presumption of entitlement due to a structural lesion or other reason. Id. at 2. Thus, her preliminary finding was that D.V.M. suffered a Table encephalopathy for which petitioners were entitled to prevail. Id. She encouraged the parties to discuss settlement. Id. She granted respondent's counsel's request to discuss the case with her client and Dr. Wiznitzer, and then file a status report indicating how respondent wished to proceed within thirty days, by July 14, 2016. Id.

On July 14, 2016, respondent requested that petitioners transmit the MRI studies, referenced in petitioners' expert report, for Dr. Wiznitzer's review. Status Report (ECF No. 58). That same day, the undersigned ordered petitioners to transmit the MRI studies to respondent by August 15, 2016. Order (ECF No. 59). On August 17, 2016, the undersigned granted the parties' request for additional time to determine whether original MRI films existed, or whether there were only digital images. Order (ECF No. 61).

On September 12, 2016, respondent confirmed that Dr. Wiznitzer had received the MRI studies. Status Report (ECF No. 63). On October 27, 2016, respondent filed Dr. Wiznitzer's supplemental expert report. Resp's Ex. C (ECF No. 64). On November 3, 2016, the undersigned ordered petitioners to file a supplemental expert report and updated medical records. Scheduling Order (ECF No. 65). On January 16, 2017, petitioners filed Dr. Kinsbourne's supplemental expert report and one additional medical article. Pet'rs' Ex. 36 (ECF No. 68).

On January 31, 2017, the undersigned held a second Rule 5 status conference. Order (ECF No. 69). Based on her review of the medical records and the expert reports, her preliminary opinion at that time, consistent with her initial opinion at the first Rule 5 status conference in June 2016, was that the records demonstrated that D.V.M. suffered an acute encephalopathy within seventy-two hours of vaccination, which supported compensation under the Table. Id. The medical records and diagnostic studies did not show any evidence of an alternative cause that would create an exception to the Table presumption. Id. She ordered respondent to file a status report informing the undersigned how she wished to proceed within thirty days, by March 6, 2017. Id. at 3. She ordered petitioners to file any additional medical records and a status report within forty-five days, by March 20, 2017. Id. at 3-4.

On March 6, 2017, respondent filed a motion for a decision on the record. Motion (ECF No. 70). Petitioners filed their response to the motion on March 19, 2017. Response (ECF No. 71). Respondent's reply was due by March 30, 2017. Respondent did not file a reply. Thus, this matter is now ripe for adjudication on respondent's motion for a ruling on the record.

B. Summary of Relevant Facts[3]

D.V.M. was born on January 12, 2010. Pet'rs' Ex. 1. At birth, he weighed 9 pounds, 5.8 ounces and had Apgar scores of 9 and 9. Pet'rs' Ex. 3 at 19. He was discharged from the hospital two days after birth, on January 14, 2010. Id. at 44. No issues were noted at a well-child visit at Southern Crescent Pediatrics on February 9, 2010, at which point, D.V.M. was three and one-half weeks old. Pet'rs' Ex. 4 at 1.

On March 12, 2010, D.V.M. returned for his two-month well-child visit. Id. at 2. Elimination and sleep were noted to be normal; there was no history of recent illness; and no concerns were reported. Id. Height and weight were in the 97th and 95th percentiles, respectively. Id. D.V.M. was noted to be "doing okay." Id. He met the following developmental milestones: "smiles responsively; coos and laughs; responds to loud sounds; follows past midline; holds head up 45 degrees when prone; head steady when sitting with support; grasps rattle and holds briefly (2-3 mos.); regards own hand (2-4 mos.)." Id. He had a normal physical exam. Id. His neurological exam was normal, indicating normal tone and reflexes. Id. D.V.M. received Prevnar, Hepatitis B, and Pentacel[4] vaccinations. Id. at 2, 4; Pet'rs' Ex. 5. The pediatric records do not specify the exact time the vaccine was administered during that appointment on March 12, 2010. Pet'rs' Ex. 4; Pet'rs' Ex. 5.

The next day, March 13, 2010, at approximately 6:00 a.m., D.V.M. presented to the emergency room at Piedmont Hospital. Pet'rs' Ex. 6 at 2. Because petitioners did not speak English, the hospital staff utilized a language line to translate and communicate with them. Id. at 3.[5] The emergency room report states that D.V.M. "got immunizations yesterday and did not eat well and beginning at about 9:00 last night, he started turning his head to the right and gazing to the right." Id. The chief complaint was "looking to the right." Id.

A CT scan was performed and Gillian Sherbourne, M.D., recorded the results at approximately 6:09 a.m. Id. at 13. Dr. Sherbourne's impression was "acute parenchymal, intraventricular and subarachnoid blood." Id. She did not exclude the "[p]ossibility of a vascular anomaly with bleed or even underlying brainstem lesion with bleed." Id.

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[3] In order to reach this decision, the undersigned fully reviewed all of the medical records. This section is a summary of the facts deemed most relevant to the present issue: whether D.V.M.'s encephalopathy qualifies as a Table injury or whether respondent has shown by a preponderance of the evidence that the encephalopathy was caused by a factor, such as a structural lesion, unrelated to the vaccine received on March 12, 2010.

[4] Pentacel is a trade name for a vaccine containing "Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed; Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate)." U.S. Food and Drug Administration, Vaccines – Approved Products – Pentacel, available at https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm172502.htm (last visisted April 20, 2017).

[5] A later record provides the "patient's language" (presumably meaning the parents' language) as Spanish. Pet'rs' Ex. 7 at 1.

Dr. Sherbourne discussed the results with James V. Robertson, M.D., who completed an emergency room report the next day, on March 14, 2010. Id. at 2. Dr. Robertson wrote that upon admission, D.V.M. was "basically unresponsive with a gaze to the upward outer right and is actively having a seizure." Id. The fontanel were "minimally distended and somewhat tense." Id. D.V.M. was intubated and was administered intravenous Ativan to control the seizure. Id. Dr. Robertson wrote that "CT scanning shows an intraparenchymal hemorrhage." Id. Dr. Robertson wrote that the intraparenchymal hemorrhage "extend[ed] to the subarachnoid space." Id.

Later in the morning on March 13, 2010, D.V.M. was transferred to Scottish Rite Hospital, where he remained for 18 days. Id.; Pet'rs' Ex. 7 at 1. The triage records provide that he "rec[ei]ved immunizations yesterday, during night right gaze and head to right noticed by parents." Pet'rs' Ex. 7 at 4. Another record made at 8:36 a.m. states that D.V.M. "seemed extra sleepy 2 hrs after" receiving the vaccine and that night at 6:00 p.m., he "took only 2-3 oz. [formula], usually takes 3-4 oz." Id. at 75.

That day, Virginia J. Greenbaum, M.D., of the Child Protection Team, with the aid of an interpreter, evaluated "this patient with IVH [intraventricular hemorrhage]/ SDH [subdural hemorrhage] for concerns of NAT [non-accidental trauma]." Pet'rs' Ex. 7 at 93-96. Dr. Greenbaum recorded that on the night of March 11, 2010, D.V.M. had "slept normally" and "woke and ate appropriately." Id. at 93. On March 12, 2010, D.V.M. woke at 8:00 a.m. and ate somewhat less than usual. Id. He was sleepy in the morning and slept on the way to his pediatrician appointment, which was at approximately 11:00 a.m. Id. After the appointment, D.V.M. was taken to his uncle's home for approximately one and a half hours. Id. During that visit, D.V.M. was not acting entirely normally. Id. He was sleepy, did not appear to be focusing normally, and preferentially held his head to the right. Id. Upon leaving the uncle's house, the family went to the grocery store, and "mom and baby slept in the car while dad shopped." Id. On the way home, D.V.M. ate approximately 2 ounces of food (compared to normally eating about 4 ounces). Id. After getting home and having his diaper changed, D.V.M. slept until about 6:00-7:00 p.m. Id. Petitioners characterized this as being unusual because D.V.M. was normally awake in the afternoon. Id. His mother stated that D.V.M. was in a "deep sleep" when she woke him to be fed. Id. During the feed, D.V.M. was "not happy" and "cried a bit." Id. Petitioners also observed that he turned his head and fixed his gaze to the right, beginning at about 9:00 p.m. Id. at 93-94; see also Pet'rs' Ex. 6 at 2. D.V.M. was then put to bed. In the middle of the night, his father observed D.V.M. was somewhat stiff and complained or moaned a bit. Pet'rs' Ex. 7 at 93. On March 13, 2010, at approximately 4:30-5:00 a.m., petitioners woke D.V.M. Id. They observed that his right eye would not open; the right side of his mouth drooped; his head was turned to the right and resisted manipulation; his body was stiff; and he was moaning. Id. at 93-94.

After collecting this history and examining D.V.M., Dr. Greenbaum found no history or evidence of trauma. Id. at 96. She also wrote, "[e]tiology of intracranial bleed not clear. Distribution of acute hemorrhage is unusual for AHT.[6] DDX[7] includes vascular anomaly and coagulopathy. Await results of MRI/ MRV/ MRA[8] and ophtho." Id.

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[6] "AHT" may be an abbreviation for "acute head trauma."

[7] "DDX" may be an abbreviation for "differential diagnosis."

[8] MRA stands for "magnetic resonance angiogram." It is "a form of magnetic resonance imaging .

Those additional tests were all conducted soon after. The MRI and the MRV/ MRA were both performed on the same day, March 13, 2010. Id. They both showed "approximately 1.5 cm in diameter area of hemorrhage in the region of the left ambient cistern/ dorsal brainstem." Id. at 121-22. "Follow up imaging [was] suggested to exclude possible underlying lesion, such as a vascular malformation or cavernous angioma." Id. at 122.

On March 14, 2010, Raymond Cheng, M.D., performed a neurology consult. Id. at 117. He noted that D.V.M. had received vaccinations the day before he was taken to the emergency room. Id. He wrote: "review of the MRI had shown about 1.5-cm-diameter hemorrhage in the left ambient cistern and left subdural fluid collections." Id. His impression was "seizures" and "intracranial hemorrhage in the ambient cistern, left subdural fluid collection, by formal examination suspected nonaccidental trauma." Id. Also on March 14, 2010, Christina L. Weeks, M.D., performed an ophthalmology consult. Id. at 118. She wrote: "the possible cause [of the intracerebral hemorrhage] is vascular anomaly." Id. Dr. Weeks was called to evaluate for retinal hemorrhages, but did not find any. Id. at 118-19.

On March 29, 2010, D.V.M. underwent a repeat head CT scan, which showed: "[i]nterval diminution in density of previous dorsal brain stem and ambient cistern hematoma, slightly smaller in size but with persistent mass effect upon the fourth ventricle." Id. at 60. "An underlying mass lesion [was] not excluded." Id. It was recommended that "[i]f any further evaluation is needed clinically, evaluation of subacute hemorrhage would be more sensitive by MR." Id.

D.V.M. was discharged on March 31, 2010. Id. at 54. The discharge diagnoses were: intraventricular hemorrhage; left facial nerve palsy; left abducens nerve palsy; right hemiparesis; feeding difficulty; seizure; and unspecified anemia. Id. at 62. A neurosurgeon, Dr. Brahma, recommended "further imaging to eval[uate] for vascular malformation; plan to repeat MRI in 3 weeks." Id. at 57. D.V.M. did not undergo the repeat MRI until June 15, 2010. Id at 128. The MRI impression on June 15, 2010, included "interval improvement," "no obvious underlying mass," and "no definite evidence for an underlying vascular malformation." Id.

Another MRI on December 14, 2010 found no change in the ventricles' size and configuration, but an interval decrease in the size of the extra-axial fluid spaces. Id. at 140-41. There was "no evidence of mass effect." Id. at 141. There was interval progression of myelination compared to the prior study; normal vascular flow voids; and hemosiderin deposition in the brainstem. Id. No vascular malformation or lesion was found. Id. Yet another MRI was performed on November 15, 2011. Id. at 151-52. The records do not note any major changes or any evidence of an underlying vascular malformation or lesion. Id.

The records created after this date do not appear relevant to determining the possible cause of D.V.M.'s injuries. They reflect that he continues to display global developmental delays which necessitate ongoing care.

. . used for detection of abnormalities in the vessels of the blood and neck." Dorland's Illustrated Medical Dictionary ("Dorland's") (32d ed. (2012)) at 85.

II. STANDARDS FOR ADJUDICATION

The Vaccine Act was established to compensate vaccine-related injuries and deaths. §300aa-10(a). "Congress designed the Vaccine Program… as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

A petitioner must prove that he is entitled to compensation under the Vaccine Program. The burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). A petitioner may demonstrate entitlement in one of two ways. The first way is to show that the vaccinee suffered an injury listed on the Vaccine Injury Table, beginning within the requisite time period set forth on the Table (a "Table injury"), in which case, causation is presumed. 42 C.F.R. § 100.3. The second way is to prove that the vaccine was the cause in fact of the vaccinee's injury. 42 U.S.C. § 300aa-11(C)(1)(c)(ii). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B). "Factors unrelated to the administration of the vaccine" do not include "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." § 300aa-13(a)(2)(A).

In the present case, petitioners allege that D.V.M. suffered an encephalopathy meeting the criteria of the Table, within the specified period of time. An encephalopathy is defined as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. § 300aa-14(b)(3)(A). The Table further provides, in relevant part, that "a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2). An acute encephalopathy, in turn, is defined as "one that is sufficiently severe as to require hospitalization (whether or not hospitalization occurred)." Id. at § 100.3(b)(2)(i). An acute encephalopathy in a child under the age of eighteen months is indicated by a "significantly decreased level of consciousness lasting for at least 24 hours." Id. at § 100.3(b)(2)(i)(A). A "significantly decreased level of consciousness" is indicated by the presence of one or more of the following signs: "(1) decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli; (2) [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things." Id. at § 100.3(b)(2)(i)(D). Petitioners also allege that D.V.M. experienced the onset of the condition within seventy-two hours of administration of the DTaP vaccine, as required for a Table injury. Petitioners contend that the medical records and diagnostic studies do not show any evidence of an alternative cause for the encephalopathy, which would create an exception to the presumption of causation.

Respondent argues that petitioners are not entitled to compensation because D.V.M.'s encephalopathy falls under an exception to the Vaccine Injury Table. "An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion, or genetic disorder is known." C.F.R. § 100.3(b)(2)(iii).

The undersigned notes that close calls are resolved in favor of the petitioner. Althen v. Sec'y of Health & Human Servs., 418 Fed. 3d 1274, 1280 (Fed. Cir. 2005). "If at the time a decision is made on a petition filed under Section 2111(b) of the Act for a vaccine–related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table." C.F.R. § 100.3(b)(2)(iii).

III. EXPERT OPINIONS AND CAUSATION ANALYSIS

As discussed below, the parties agree that D.V.M. suffered an encephalopathy meeting the Table criteria within the requisite period of time. Therefore, the issue is whether respondent has shown by a preponderance of the evidence, that D.V.M.'s encephalopathy was caused by an acute hemorrhage secondary to a structural lesion.[9]

A. Expert Opinions

1. Respondent's Expert Dr. Max Wiznitzer

a. Qualifications

Dr. Wiznitzer obtained his medical degree from Northwestern University in 1977. Resp's Ex. B at 1. He then completed a residency in pediatrics at Children's Hospital Medical Center in Cincinnati; a fellowship at the Cincinnati Center for Developmental Disorders; a fellowship in pediatric neurology at the Children's Hospital of Philadelphia; and a fellowship in higher cortical functions at the Albert Einstein College of Medicine. Id. He is a pediatric neurologist at University Hospitals of Cleveland, as well as an associate professor of several subjects at Case Western University. Id. at 2. He is board-certified in pediatrics; psychiatry and neurology (with a special qualification in child neurology); neurodevelopmental disabilities; and medical examination. Id. at 5.

b. Initial Report

Dr. Wiznitzer's initial opinion, dated September 29, 2013, was based on his review of the petition and petitioners' exhibits 1-21. Resp's Ex. A at 1. He noted that "some records, such as [D.V.M.'s] subsequent neurology and hematology/ oncology follow-up after the March 2010 hospital admission and his actual neuroimaging studies (CT scans and MRI scans from 03/13/10 to the present), would be useful to review." Id. at 9.

Dr. Wiznitzer conceded that D.V.M. suffered an encephalopathy "sufficient to meet the criteria of the Vaccine Injury Table." Id. at 8. Specifically, he had an alteration of consciousness resulting in a hospital admission well within 72 hours of a DTaP vaccine. Id.

Dr. Wiznitzer accepted the narrative recorded on March 13, 2010, by Dr. Greenbaum, the doctor evaluating D.V.M. for concerns of non-accidental trauma. Id. at 2-3 (quoting from Pet'rs' Ex. 7 at 93-96). Of note, this record states that the vaccine was administered on March 12, 2010 at

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[9] Throughout the decision, the phrases structural lesion; vascular anomaly; vascular malformation; vascular lesion; and structural anomaly are all used interchangeably and refer to a structural lesion.

approximately 11:00 a.m. and that afterwards, the parents and D.V.M. went to a maternal uncle's home for 1.5 hours, where D.V.M. was sleepy, did not appear to be focusing normally, and preferentially held his head to the right. Id. (quoting from Pet'rs' Ex. 7 at 93-96).

However, Dr. Wiznitzer opined that D.V.M.'s encephalopathy fell under an exception to the Table because it was caused by factors unrelated to the vaccine. Id. at 1. Namely, he thought that D.V.M.'s "intracranial hemorrhage was caused by an acute bleed from a vascular anomaly." Id. Dr. Wiznitzer opined that D.V.M. had a "structural lesion in the left pons." Id. He stated that the child protection team, the physical medicine and rehabilitation team, and the radiology reports all listed this as part of the differential diagnosis. Id. He stated that the clinical picture and the radiology findings were consistent with this diagnosis. Id.

Dr. Wiznitzer stated that "while the differential diagnosis of a vascular anomaly includes a cavernous angioma and aneurysm, the most likely lesion is an occult vascular malformation." Id. at 8-9. He opined that this explained "why there was no identifiable blood flow signal or residual lesion on MRI after the initial bleed." Id. at 9.

He also stated that vascular anomalies "are not affected or influenced by vaccines." Id. He did not opine about how old D.V.M.'s intracranial hemorrhage was. But he stated that D.V.M. "received vaccines, including DTaP, after the intracranial hemorrhage with no reported adverse event." Id. "Therefore, the intracranial hemorrhage from the vascular anomaly had no association with his 2 month old vaccination." Id.

c. Supplemental Report

In the fall of 2016, Dr. Wiznitzer reviewed the MRI studies and submitted a supplemental report, in which he maintained that D.V.M.'s encephalopathy fell under an exception to the Table. Resp's Ex. C. He stated:

> [The MRI] studies show an area of hemorrhage involving the left brainstem at the level of the lower midbrain/ pons and superior cerebellar peduncle with spread to adjacent CSF spaces on the MRI that disappears on subsequent studies with the presence of residual hemosiderin. This finding is consistent with an acute bleed from a small vascular malformation or cavernous angioma that destroyed the vascular lesion and resulted in the findings on the later MRIs. It is known that this can occur with no evidence of the vascular lesion on follow up neuroimaging…[10]
>
> [D.V.M.] had a localized hemorrhage in the brainstem (i.e., a structural lesion) that was a result of a small vascular lesion that was destroyed during the process of this hemorrhage (which is known to occur). Id. at 1.

[10] Dr. Wiznitzer did not provide any medical literature or other evidence to support this opinion that an acute bleed may destroy a vascular lesion such that there would be no evidence of it on neurology studies.

Dr. Wiznitzer also opined that this hemorrhage existed prior to the vaccination, and was not exacerbated by it. Id. He stated that this "evolving hemorrhage" likely caused the "change in mental status within 2 hours of [D.V.M.'s] immunizations." Id. He stated it was "not biologically plausible" for a vaccine to "have this type of effect in this short time period." Id. "Therefore, the brainstem hemorrhage had a temporal, but not causal, association with the 3/12/10 immunizations." Id. at 1-2. Dr. Wiznitzer also stated that the hemorrhage was responsible for D.V.M.'s "right sided weakness, left sixth and seventh nerve palsies, and left sensory neural hearing loss." Id. at 2. However, he found it "difficult to ascribe" D.V.M.'s global developmental delay to this condition. Id. Accordingly, Dr. Wiznitzer recommended getting more recent medical and educational records to further investigate this delay. Id.

2. Petitioner's Expert Dr. Marcel Kinsbourne

a. Qualifications

Petitioners did not file a curriculum vitae for their expert Dr. Kinsbourne. Like respondent's expert Dr. Wiznitzer, he is a pediatrician and neurologist, who frequently serves as an expert witness in the Vaccine Program. Internet research located Dr. Kinsbourne's current curriculum vitae.[11] He graduated from medical school at Oxford University in 1955. He is the director of the New School Cognitive Neuroscience Laboratory. He is also listed as an adjunct professor of neurology at Boston University School of Medicine and a research professor at the Tufts University Center for Cognitive Studies.

b. Initial Report

Dr. Kinsbourne summarized that D.V.M. had a normal birth and delivery. Pet'rs' Ex. 35. Dr. Kinsbourne stated: "He developed normally until he was due for his routine two month pediatric vaccinations, consisting of DTaP, IPV, Hib, PCV7, hepatitis B and rotavirus vaccinations, which he received at about 6:0 p.m. [sic] on March 12, 2010." Id.[12] Dr. Kinsbourne stated that "[t]hree hours later," D.V.M. "began to stare rightward." Id. The following morning, D.V.M. was brought to the E.R., where he was unresponsive; found to be having a seizure; and underwent an MRI which revealed a brainstem hemorrhage. Id.

Dr. Kinsbourne wrote: "In an attempt to locate the source of the bleeding, [D.V.M.] was studied with multiple brain MRIs on suspicion that the source of the hemorrhage was a structural anomaly in the posterior cerebral circulation, which supplies the brain stem, or a brain stem neoplasm." Id. However, "[m]ultiple MRIs did not reveal any structural basis for the brainstem hemorrhage." Id. Dr. Kinsbourne noted that in the process of writing his report, he

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[11] The New School Cognitive Neuroscience Laboratory (the "Kinsbourne Lab") - Marcel Kinsbourne, M.D. Curriculum Vitae, available at http://www.kinsbournelab.org/curriculum-vitae.html (last visited April 20, 2017).

[12] Dr. Kinsbourne did not cite to any medical records in this initial report. And his statement that D.V.M. received the vaccinations at approximately 6:00 p.m. is not supported by any of the medical records. All medical records addressing the time of the appointment say that it was approximately at 11:00 a.m. See, e.g., Pet'rs' Ex. 7 at 93.

reviewed the MRI images. Id. He "could not discern any structural brain abnormality in any of the films." Id.

c. Supplemental Report

In his second report, Dr. Kinsbourne again disagreed that there was any evidence of a structural lesion. He stated that the treating physicians initially considered this possibility, as part of the early differential diagnosis. Pet'rs' Ex. 36 at 1. However, the MRIs and the MRA conducted to further investigate this possibility did not find any supportive evidence. Id. at 2-3. Furthermore, "[n]one of [the] subsequent medical records feature arteriovenous malformation as a diagnosis, or any other category of medical disease." Id. at 4.

Dr. Kinsbourne also disagreed with Dr. Wiznitzer's statement that D.V.M.'s brain hemorrhage was "consistent with the rupture of a hitherto unsuspected arteriovenous malformation." Id. at 3. He provided an article by Sandberg et al.[13] in support of the propositions that spontaneous intraparenchymal hemorrhages are rare and that many cases remain unexplained. Id. at 4. He noted that Sandberg et al. described four infants who, like D.V.M., experienced spontaneous intraparenchymal hemorrhage without any evidence of vascular malformations or lesions. Id. These case reports undermine Dr. Wiznitzer's opinion that hemorrhage is "consistent with" a vascular malformation.

Dr. Kinsbourne challenged Dr. Wiznitzer's statement that the first manifestation of D.V.M.'s injury was a "change of mental status within 2 hours of D.V.M.'s immunizations." Resp's Ex. C at 1. Dr. Kinsbourne stated that D.V.M. was vaccinated at 11:00 a.m., and "after he was vaccinated he seemed sleepy and he was reluctant to feed, changes in behavior that are familiar as side effects of DTaP vaccination and do not indicate neurological injury." Pet'rs' Ex. 36 at 1. In other words, this was not the onset of his condition. Instead, "the first indication that [D.V.M.] was suffering a neurological injury" was "at 9:00 p.m.[,] 10 hours after the vaccinations, [when] his parents observed that D.V.M. was staring fixedly rightwards with his head and eyes turned right and that he was unresponsive." Id. Dr. Kinsbourne stated that this "10-hour time interval between the vaccinations and the onset is classical for pertussis vaccine encephalopathies." Id.

B. Analysis

After fully reviewing the parties' filings, the undersigned concludes that petitioners have met their burden of demonstrating that D.V.M. suffered a Table encephalopathy within 72 hours of receiving the DTaP vaccination. Respondent has not presented preponderant evidence that the encephalopathy had a cause unrelated to the vaccine.

As respondent's expert Dr. Wiznitzer has conceded, it is clear that D.V.M.'s injury meets the criteria for a Table encephalopathy. Resp's Ex. A at 8. Therefore, it is only necessary to analyze whether respondent has presented preponderant evidence of an alternative cause. The undersigned finds that respondent has not done so.

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[13] Sandberg et al., Spontaneous Intraparenchymal Hemorrhage in Full-Term Newborns, NEUROSURGERY 48: 1042-49 (2001) [Pet'rs' Ex. 36, Tab 2].

Dr. Wiznitzer argued that D.V.M. had an "occult vascular malformation" which caused an acute bleed (a hemorrhage), which then destroyed the malformation, leaving no evidence of malformation on follow up neuroimaging. Resp's Ex. C at 1.[14]

D.V.M.'s treating physicians did initially consider the possibility of a vascular anomaly or an underlying brainstem lesion. Pet'rs' Ex. 6 at 13 (Dr. Gillian Sherbourne's review of CT scan without contrast and her differential diagnosis, recorded March 13, 2010). However, repeated imaging never found any evidence of any such lesion. See, e.g., Pet'rs' Ex. 7 at 41 (March 13, 2010, MRI); id. at 122 (March 13, 2010, MRA); id. at 48 (March 17, 2010, MRI); id. at 120 (March 29, 2010, CT); id. at 126 (June 15, 2010, MRI); id. at 140-41 (December 14, 2010, MRI); id. at 151-52 (November 15, 2011). Thus, serial diagnostic studies do not support Dr. Wiznitzer's opinion that D.V.M. had a vascular malformation. Moreover, D.V.M. was never diagnosed with a vascular malformation or lesion.

Dr. Kinsbourne opined that hemorrhages in post-natal, young infants are extremely rare and are not caused by vascular lesions. Pet'rs' Ex. 36 at 4. He provided the Sandberg et al. article which reported eleven infants with hemorrhages over the course of forty years at a busy children's hospital. Pet'rs' Ex. 36, Tab 1. No evidence of vascular malformations was found in these cases. Therefore, the Sandberg article suggests that vascular malformations do not cause this kind of hemorrhage in an infant such as D.V.M.

Based on her review of the record, the undersigned does not agree with Dr. Wiznitzer's opinion that the infant's hemorrhage occurred prior to vaccination. D.V.M. was a healthy, normal infant when he presented to his pediatrician on March 12, 2010. No signs or symptoms of acute hemorrhage were reported or documented in the record from that visit. Instead, D.V.M. had a normal physical and neurological exam. The first evidence of neurological injury, as consistently reported by the parents and documented in the medical records, began several hours after the vaccinations, in the evening, when D.V.M. turned his head and fixed his gaze to the right. See Pet'rs' Ex. 6 at 2; Pet'rs' Ex. 7 at 93-94. Thus, the undersigned finds there is no evidence that D.V.M.'s hemorrhage occurred before vaccination.

IV. CONCLUSION

For all of the reasons discussed above, the undersigned finds that petitioners have established entitlement to compensation. A separate damages order shall issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[14] Of note, factors unrelated to vaccine administration do not include "undocumentable cause[s]." See § 300aa-13(a)(2)(A).