

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-220V

Filed: September 23, 2014

Not for Publication

DAVID STACHLEWITZ, on Behalf of H.G.S., *

*

Petitioner, *

*

v. *

Table encephalopathy;
positional asphyxia;
failure to rebut respondent's
defeat of the presumption
of causation

*

*

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

*

Respondent. *

*

Anne C. Toale, Sarasota, FL, for petitioner.

Ryan D. Pyles, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on March 28, 2013, under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10-34 (2006). Petitioner alleges that the DTaP, IPV, HiB, Prevnar, and rotavirus vaccines his son H.G.S. received on May 17, 2010, caused him to suffer a Table encephalopathy on May 19, 2010.

¹ Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision 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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

An encephalopathy is a Table injury if it occurs within three days of the vaccinee's receipt of DTaP vaccine, and the vaccinee had a significantly decreased level of consciousness lasting more than 24 hours. 42 C.F.R. §§ 100.3(a)(II)(B), 100.3(b)(2)(i)(A) (2011). For this reason, in her Orders on June 24, 2013 and July 24, 2013, the undersigned posited that this was a Table injury case. In a Table case, causation is presumed. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Therefore, in her July 24, 2013 Order, the undersigned ordered respondent to file a Rule 4(c) Report by August 23, 2013.

On August 23, 2013, respondent filed her Rule 4(c) Report, stating that H.G.S.'s encephalopathy was due to his sleeping position that resulted in suffocation or near suffocation, leading to a lack of oxygen to his brain, i.e., hypoxic ischemic encephalopathy documented on MRI. Resp't's Rep. at 5.

On September 10, 2013, respondent filed her expert report by Dr. Rachel Y. Moon. Resp't Ex. A. Dr. Moon is a specialist in sudden infant death syndrome or SIDS. See Ex. B. Dr. Moon writes that, on May 19, 2010, H.G.S. was placed on the family bed to go back to sleep after having been fed eight ounces of formula. Ex. A, at 2. He was propped up on a pillow. Id. When petitioner went back into the bedroom to check on H.G.S., the child was prone, face down on the bed, unresponsive, cyanotic, and breathing shallowly. Id. Petitioner could not rouse H.G.S. and called 911. Id. H.G.S. was brought to Arrowhead Hospital and transferred from there to St. Joseph's Hospital. Id. Numerous tests, including a brain MRI, were done. Id. The brain MRI showed diffuse ischemia in all vascular areas and other findings consistent with hypoxic ischemic encephalopathy. Id. The brain MRI did not show any inflammation. Id. There was no mention of bulging of the fontanelle. Id. Dr. Moon's opinion is that H.G.S. experienced an episode of positional asphyxia after rolling into a prone, face-down position on the bed. Id. She notes that because H.G.S. was born five to seven weeks prematurely, his developmental capabilities were those of a ten- to twelve-week-old infant and that, having rolled into a prone position, he would not have been able to move spontaneously out of that position. Id. at 2-3. Dr. Moon further notes that the severe blood acidemia shown in the first capillary blood gas suggested that H.G.S.'s positional asphyxia was prolonged, resulting in severe hypoxic injury. Id. at 2.

On September 24, 2013, the undersigned held a telephonic status conference with counsel and discussed respondent's expert Dr. Moon's report. The undersigned said that this report refuted the presumption of causation from the vaccination, and petitioner would need to file an expert report criticizing Dr. Moon's opinion. Petitioner's counsel said she would need a SIDS specialist. On September 24, 2013, the undersigned issued an Order giving petitioner until December 11, 2013, to file an expert report.

On December 11, 2013, petitioner filed a Motion for Enlargement of Time, asking for 120 more days (or four months in addition to the two and one-half months that had already elapsed) to file an expert report. Petitioner's counsel said she had not yet found an expert. Pet'r's Mot., ECF No. 21.

On December 13, 2013, the undersigned issued an Order granting petitioner's motion, setting a new deadline of April 10, 2014, for petitioner to file an expert report.

On April 10, 2014, petitioner filed a second Motion for Enlargement of Time, asking for another 120 days, saying she had not yet retained an expert but had spoken to one who did not want to review the case until all of the records were available. Pet'r's Mot., ECF No. 24. Petitioner's counsel wrote she was seeking fire and police department records. Id. She reported that she could not obtain the fire department records without a copy of H.G.S.'s birth certificate, and petitioner had not responded to her requests for the birth certificate. Id.

On April 16, 2014, the undersigned held a telephonic status conference with counsel. The undersigned clarified for petitioner's counsel that the issue in the case was the interpretation of H.G.S.'s May 20, 2010 brain MRI. Respondent's expert Dr. Moon's interpretation was identical to that of the radiologist at the hospital. The fire department and police department records would not be relevant to what happened inside H.G.S.'s brain. Petitioner had still not provided an expert report, which was necessary to refute Dr. Moon's conclusion that H.G.S.'s brain MRI of May 20, 2010 was consistent with hypoxic encephalopathy and not a vaccine reaction.

On April 17, 2014, the undersigned issued an Order to Show Cause, ordering petitioner to show why this case should not be dismissed by May 16, 2014. On May 16, 2014, petitioner responded to the undersigned's April 17, 2014 Order to Show Cause, stating the necessity of obtaining all outstanding records to adequately explore alternative theories of causation-in-fact.

Petitioner filed Exhibit 14 on June 5, 2014, consisting of the obstetric records for H.G.S. On July 3, 2014, petitioner filed Exhibit 15, consisting of records of the Glendale Fire Department EMS. These records are consistent with the previously-filed records, i.e., petitioner found H.G.S. lying supine and unresponsive. Ex. 15, at 7. H.G.S.'s breathing was shallow, and he had occasional decerebrate posturing. Id.

On July 7, 2014, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel stated she had an expert, and he was reviewing the records. In an Order dated July 7, 2014, the undersigned set a deadline of September 5, 2014 for petitioner to file an expert report.

On July 23, 2014, the court received two CDs from petitioner marked Exhibits 16 and 17 which consist of over 6,000 pages of records from Banner Thunderbird Hospital. The undersigned reviewed them and found no different information from the records petitioner previously filed.

On August 27, 2014, petitioner filed Exhibit 18, consisting of records from Rural/Southwest Ambulance. The information in this exhibit is consistent with the information petitioner previously filed.

On September 5, 2014, petitioner's counsel filed a Status Report, stating that she was reviewing the expert report with petitioner in order to discuss how petitioner wished to proceed.

On September 12, 2014, the undersigned issued a second Order to Show Cause, ordering petitioner to respond during the telephonic status conference set for September 23, 2014.

During the telephonic status conference on September 23, 2014, petitioner's counsel stated she would not file petitioner's expert report, and she had nothing further to file except a statement in response to the undersigned's Order to Show Cause. Directly after the telephonic status conference, petitioner filed a response to the Court's Order to Show Cause, stating, "Petitioner is unable to provide the Court with an expert report to rebut the report of Respondent's expert Dr. Moon."

The undersigned therefore **DISMISSES** this case. While petitioner initially had a presumption of causation for a Table encephalopathy, respondent successfully defeated that presumption by identifying a known factor unrelated. Petitioner has failed to offer any proof to rebut respondent's identification of a known factor unrelated.

FACTS

H.G.S. was born on January 15, 2010. Med. recs. Ex. 3, at 33.

On May 17, 2010, at his four-month check-up, H.G.S. was noted to be a healthy baby. Id. He received DTaP, HiB, IPV, Prevnar, and rotavirus vaccines. Id.

On May 19, 2010, H.G.S. was taken to Arrowhead Hospital ER. Med. recs. Ex. 7, at 9. According to H.G.S.'s father, H.G.S. was found that morning with an altered mental state, lying supine on a couch. Id. at 9, 13.

From May 19, 2010 to June 10, 2010, H.G.S. was at St. Joseph's Hospital and Medical Center. Med. recs. Ex. 6, at 5. Dr. Patricia Avila wrote the discharge summary. Id. at 6. The discharge diagnosis was hypoxic ischemic encephalopathy secondary to near-sudden infant death syndrome event, dysphagia, developmental regression, and gastroesophageal reflux disease. Id. The history was that H.G.S. had recently been treated for a urinary tract infection and finished his antibiotics two days prior to presentation. Id. He was given a bottle of eight ounces at 5:30 a.m. and another of two ounces at 8:15 a.m. Id. He was put down to sleep on the family bed. Id. His father said H.G.S. was propped up with a pillow and left in the room. Id. When the father returned to check on the baby, H.G.S. was lying face down, cyanotic with shallow breaths, and unresponsive. Id. The father gave him rescue breaths and called 911. Id. Initial lab findings were concerning for acidosis. Id. at 7. The conclusion was that H.G.S. likely had a severe hypoxic injury. Id. H.G.S.'s brain MRI was consistent with a hypoxic event. Id.

The May 20, 2010 brain MRI report indicates that there were regions of abnormal T2 signal seen in the left frontal region as well as the basal ganglia bilaterally consistent with hypoxic ischemic encephalopathy. Med. recs. Ex. 6, at 140. There was diffuse ischemia seen in

all vascular territories on the apparent diffusion coefficient maps as evidenced by restricted diffusion, including the posterior circulation/cerebellar hemispheres. Id.

On March 9, 2011, H.G.S. was evaluated for speech/language and oral-motor/feeding due to developmental delay. Med. recs. Ex. 2, at 1. His history was that he was born prematurely at 35 weeks, weighing four pounds six ounces, via planned Caesarean delivery due to maternal hypertension. Id. H.G.S. was in neonatal intensive care for eight days after birth and was discharged without complications. Id. H.G.S. had typical development for four months. Id. At four months, he was found without oxygen after rolling over in his sleep. Id. He suffered a hypoxic ischemic event and was hospitalized at St. Joseph's Hospital for 22 days. Id. After his accident, H.G.S. had difficulty reaching his developmental milestones. Id.

DISCUSSION

To satisfy his burden of proving causation in fact, petitioner must prove by preponderant evidence: “(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 HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Althen, 418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioner’s affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

The Vaccine Act does not permit the undersigned to rule for petitioner based on his claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa–13(a)(1) (2006).

Although petitioner started with a Table encephalopathy in which causation is presumed, he lost the presumption of causation when respondent filed the expert report of Dr. Moon, whose analysis of H.G.S.’s brain MRI was consistent with the analysis of the reviewing radiologist at St. Joseph’s Hospital. The Federal Circuit has emphasized the importance of the conclusions of treating physicians in evaluating whether or not an individual suffered a vaccine injury. Andreu v. Sec’y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009); Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The medical records here are consistent in diagnosing H.G.S. with

positional asphyxia. Respondent successfully carried her burden of showing that a known factor unrelated to the vaccination caused H.G.S.'s encephalopathy. 42 U.S.C. § 300aa-13(a)(1)(B); see also § 300aa-13(a)(2)(B) (A known factor unrelated "may, as documented by the petitioner's evidence . . . [be shown to be] the agent or agents principally responsible for causing the [vaccinee's] illness, disability, injury, [or] condition . . ."). Respondent has successfully shown, through H.G.S.'s medical records, the interpretation of his medical tests including the brain MRI, and Dr. Moon's expert report, a known factor unrelated to the vaccination that caused H.G.S.'s encephalopathy—asphyxia which came from his position, lying supine on his face.

Petitioner had one year to find a medical expert and file an expert report to refute the opinion of respondent's expert Dr. Moon and the opinions of the reviewing radiologist and other physicians at St. Joseph's Hospital. Petitioner hired an expert whose report was obviously not in petitioner's favor; otherwise, petitioner would have filed the expert report. Petitioner admits in his latest response to the undersigned's second Order to Show Cause that he is unable to find an expert to rebut respondent's expert's conclusion that H.G.S. experienced positional asphyxia, resulting in lack of oxygen to his brain and encephalopathy.

This is indeed a tragic case, and the undersigned expresses her sympathy to petitioner. However, the fact remains that petitioner has not met his burden of proof. This case is **DISMISSED** for petitioner's failure to prove by a preponderance of the evidence that a vaccination caused H.G.S.'s encephalopathy. 42 U.S.C. § 300aa-13(a)(1)(A).

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: September 23, 2014

s/Laura D. Millman

Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.