

OFFICE OF SPECIAL MASTERS

JODY NORDWALL,
as trustee for the next of kin of,
MATEO TORI, deceased,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

No. 05-123V
Special Master Christian J. Moran

Filed: February 19, 2008

Diphtheria – Tetanus – acellular
Pertussis (DTaP) vaccine; entitlement;
death; positional asphyxia.

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

PUBLISHED DECISION

Ms. Nordwall filed a petition seeking compensation pursuant to the National Vaccine Injury Compensation Program ("the Program"). 42 U.S.C. §§ 300aa-1 et seq. (2006). Ms. Nordwall alleges that the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine caused the death of her son, Mateo "Mat" Tori, when he was approximately 10 weeks old.

1 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).

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 clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Ms. Nordwall did not establish that she is entitled to compensation. Consequently, the Clerk's Office is ordered to enter judgment in favor of respondent.

I. Procedural History

Ms. Nordwall, acting pro se,² filed a petition on January 18, 2005.³ She filed 15 exhibits with her petition. Approximately three months later, Mr. McHugh filed a motion to appear as counsel. Mr. McHugh has acted as the attorney of record since that time.

Ms. Nordwall filed a report from Dr. John Shane, a pathologist, on March 16, 2006. As discussed more extensively below, Dr. Shane opined that the DTaP vaccine caused Mat's death.

On May 19, 2006, respondent filed his report pursuant to Vaccine Rule 4. Respondent maintained that Ms. Nordwall did not establish that she was entitled to compensation for Mat's death. In support of his position, respondent submitted a report from Dr. Lucy Rourke-Adams, a pediatric neuropathologist. Later, respondent supplemented his report with a statement that he believed that the evidence did not establish that Mat suffered an encephalopathy, as defined in the Program. 42 C.F.R. § 100.3(b)(2).

The parties were given an opportunity to resolve this case. When the fruitlessness of settlement discussions became evident, the case was scheduled for a hearing. This hearing was held in Philadelphia, Pennsylvania, on May 9, 2007. During this hearing, Dr. Shane and Dr. Rourke-Adams were called as expert witnesses. Ms. Nordwall and Dr. Tori also testified. The testimony of Mat's parents was required, because they asserted facts that were not reflected in the contemporaneously created records. An evaluation of their testimony and findings of fact are discussed in the following section.

² Initially, the petition listed both Ms. Nordwall and José Tori, Mat's father, as petitioners. However, on January 11, 2007, a motion to change the caption to eliminate Dr. Tori as a petitioner was filed. This motion was granted on January 22, 2007. This alteration does not affect the outcome of this case.

³ Initially, the Clerk's Office docketed the petition as filed on January 19, 2005, a date that was outside of the statute of limitations by one day. However, Ms. Nordwall established that the Clerk's Office actually received the petition on January 18, 2005. An order, dated June 2, 2005, determined that the date of filing was January 18, 2005.

Thus, the filing on January 18, 2005, was within the statute of limitations. 42 U.S.C. § 300aa-16(a)(3) (stating that no petition seeking compensation for a death caused by a vaccine may be filed after "24 months from the date of death."). The deadline for filing within the statute of limitations considers that January 17, 2005, was a legal holiday, and the Clerk's Office was closed. Rule 6(a) of the Rules of the Court of Federal Claims.

A review of the transcript from the May 9, 2007 hearing revealed the need for supplemental information from Dr. Shane and Dr. Rourke-Adams. Both parties presented supplemental articles, and a supplemental hearing was held on October 23, 2007. The matter is now ripe for adjudication.

II. Facts

Mat was born on November 7, 2002. Exhibit 1. Although Ms. Nordwall experienced some complications during this pregnancy, respondent has not argued that any issue that arose before Mat's birth contributed to his death. See Resp't Rep't, filed May 19, 2006; Resp't Supp. Rep't, filed September 8, 2006.

At two weeks old, on November 21, 2002, Mat was seen by a doctor. The chief complaint was that when Mat was nursing, his lips turned blue for a few moments. Mat displayed no shortness of breath, gasping, or wheezing. He also cried vigorously and moved all his extremities well. Exhibit 4A at 2. The doctor's assessment was that this was a normal newborn examination. Id. at 1. The doctor prescribed Zantac® because he had acid reflux and was spitting up regularly. Id. at 9; exhibit 15 at 3.

On November 29, 2002, Mat had another examination. The doctor did not note any concerns. Exhibit 4A at 3.

On January 17, 2003, Mat returned for his two-month well-child examination. Other than adjusting the Zantac®, no problems were identified in this visit. Id. at 5. At this stage of development, Mat could raise his head when he was placed on his stomach. However, he could not roll over. Exhibit 6, affidavit of Ms. Nordwall, ¶ 10; tr. 24. Mat received his first dose of the DTaP vaccine. He also received two other vaccines: his first dose of inactivated polio and his first dose of COMVAX®, a vaccine against both hemophilus influenzae type B and hepatitis B. Exhibit 4A at 7. He received the vaccinations around 4:15 P.M. Mat's good health on this day was confirmed by Dr. Milagros Santiago in a letter dated July 28, 2003. Exhibit 4B.

When Mat and his family returned home, they went about their usual activities. Ms. Nordwall fed Mat. They napped. Ms. Nordwall left for work around 6:30 P.M. Tr. 19, 41, 67-69.

Through this point in the chronology, the parties agree that the contemporaneously created records set forth the facts accurately. At this point, the parties' assertions diverge. Ms. Nordwall maintains that the records created shortly after Mat's death are inaccurate and also omit information that is important to her case. Respondent, instead, maintains that the contemporaneously created records are accurate and complete. Resp't Supp. Rep't at 3.

The dispute concerns Mat's health from the evening of January 17, 2003, the date he was vaccinated, until the morning of January 18, 2003, when his mother found him not breathing in

his bed. Mat's parents assert that Mat was crying, uncomfortable, and had a fever. Mat's condition is important because the expert Ms. Nordwall retained, Dr. Shane, bases his opinion, in part, on an assumption that Mat was fussy in the middle of the night. Tr. 147. In contrast, his state does not affect the opinion offered by respondent's expert, Dr. Rourke-Adams. Tr. 222.

A preponderance of the evidence supports the following findings:

In the early evening, Mat exhibited an elevated temperature and his father gave him ibuprofen. Tr. 21. During his testimony, Dr. Tori did not recall whether he specifically took his son's temperature. If Dr. Tori did take his temperature, he did not remember what Mat's temperature had been. Tr. 37. Between 8:00 P.M. and midnight, Mat was fussy; Dr. Tori had difficulty consoling him. Tr. 21. During this time, Ms. Nordwall called home to check in and to see how her son was doing. Tr. 58. Dr. Tori told her that he was doing fine. Dr. Tori may have presented the situation more positively than was warranted. Mat was crying, but his crying was something his dad believed he could handle. Tr. 58, 69-71.

When it was time for Mat's midnight feeding, Dr. Tori gave him a bottle. Although Dr. Tori testified that Mat did not drink his bottle, tr. 22; a preponderance of evidence establishes that Mat did drink his bottle. Other evidence persuasively establishes that Mat had no problems with his feeding. Dr. Tori told personnel at the emergency room, on the date of Mat's unfortunate death, that Mat drank his bottle "without difficulty." Exhibit 9 at 1. The police report also states that Ms. Nordwall told an investigating officer that her husband told her that Mat "had eaten." Exhibit 13 at 8.

Around midnight, Dr. Tori put Mat to sleep in an upstairs bedroom. Tr. 22, 25. Mat was swaddled in a blanket, meaning it was wrapped around him. Tr. 22, 31, 56; see also exhibit 21-2 (photograph of a doll demonstrating how Mat was wrapped). Mat was also propped between three pillows because being elevated helped with his reflux. Tr. 16. After Mat was in bed, Dr. Tori went to sleep with the aid of a sleep medicine. Tr. 25.

At approximately 4:00 A.M., Mat's two year old sister, Christina, woke her father to tell him that Mat was crying. Tr. 25. Dr. Tori checked on Mat. Exhibit 9 at 1; tr. 25. Mat was in the same position as when he was placed in bed at midnight. Tr. 32. Mat was crying and Dr. Tori attempted to console him. Whether Dr. Tori was successful in consoling him is disputed. Dr. Tori testified that Mat remained crying to the point of being hoarse. Tr. 32, 60. However, Dr. Tori reported to people in the emergency room that Mat "seemed to settle down fairly quickly." Exhibit 9 at 1. Because Dr. Tori provided information about his son when Dr. Tori's memory was fresh, a preponderance of the evidence establishes that Mat was consoled by Dr. Tori and went back to sleep. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).⁴

⁴ Although not entirely consistent in some details, the police reports support a finding that Mat was consoled after waking up around 4:00 A.M. Officer Barland states that Dr. Tori

Ms. Nordwall returned from working as a nurse at a hospital around 8:30 A.M. on January 18, 2003. When Ms. Nordwall first saw Mat, he was “covered up by a large blanket.” Exhibit 13 at 2. He was on his left side. In her testimony, she stated that she could see Mat’s mouth and one nostril, but that Mat was blue and not breathing. Exhibit 13 at 2; tr. 73, 85. She screamed for Dr. Tori. Ms. Nordwall and Dr. Tori began CPR and called for emergency assistance. Exhibit 6 at ¶ 9; exhibit 7 at ¶ 14; tr. 27, 72-75.

The details after Ms. Nordwall discovered Mat are not significant for resolving this case. Every effort was made to help Mat. His mother, his father, paramedics, and police officers performed CPR in a room close to the front door. People’s entrances and exits brought cold air into the room where Mat lay unclothed. (Dr. Tori estimated that the temperature on this January morning in Minnesota was between one and ten degrees Fahrenheit.) Exhibit 8; tr. 27-29.

Accompanied by his father, Mat went to a local hospital in an ambulance. In the emergency room, his rectal temperature was 99.0 degrees Fahrenheit. Doctors continued to attempt to resuscitate Mat until Ms. Nordwall arrived. Once she had a chance to observe Mat’s condition, efforts to revive Mat ceased. Exhibit 9 at 1. His time of death was recorded as 10:07 A.M. Exhibit 11 at 1.

Following Mat’s death, police officers interviewed Ms. Nordwall and Dr. Tori separately. Their statements were presented as exhibit 13 and provide an account created within hours of the tragic events they describe. Because these statements were created when Ms. Nordwall’s and Dr. Tori’s memories were strongest, they are presumptively accurate. See Cucuras, 993 F.2d at 1528. Therefore, they are the foundation for many factual findings presented above.

An autopsy was performed on Mat’s body. Exhibit 11. The work of the medical examiner is the foundation for the opinions of the two experts, Dr. Shane and Dr. Rourke-Adams. Tr. 99. Dr. Rourke-Adams, respondent’s expert, agrees with the medical examiner who found that the cause of Mat’s death was positional asphyxia. In contrast, Dr. Shane believes that the DTaP vaccine caused an impairment in Mat’s brain function, known as an encephalopathy, and this encephalopathy caused Mat’s death.

III. Analysis

To receive compensation for Mat’s death, Ms. Nordwall must prove either: (1) that Mat suffered a “Table Injury”—*i.e.*, an injury falling within the Vaccine Injury Table – corresponding

told him that “Mateo was fine when [Dr. Tori] fed him formula at 0430 hours.” Exhibit 13 at 2. Officer Poyer recounts that Dr. Tori told him that Dr. Tori “tended to Mateo at about 0430. . . . Everything was fine at that time.” Id. at 4. Dr. Tori told the officers who interviewed him at the hospital that at approximately 4:00 A.M., Mat was crying, Dr. Tori checked on him, “did not notice anything unusual about the baby,” “did not feed the infant,” and “the baby stopped crying.” Id. at 9.

to one of his vaccinations, or (2) that Mat suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec’y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).

Ms. Nordwall asserts two methods of receiving compensation for Mat’s death. First, she claims that Mat suffered an “encephalopathy” as that term is used in the vaccine injury table. See Pet. at 7, exhibit 12. Alternatively, Ms. Nordwall contends that the DTaP vaccine caused Mat’s death “in fact.” Pet’r Post Trial Br., filed July 9, 2007, at 33-35. These two different theories of relief are discussed below, along with an analysis of Dr. Shane’s and Dr. Rourke-Adams’s opinions. The final section discusses positional asphyxia, a factor unrelated to the vaccination, that precludes an award of compensation for either a table injury or an off-table injury.

A. Table Injury

Ms. Nordwall claims that Mat suffered an encephalopathy within 72 hours of receiving the DTaP vaccine. Pet’r Post Trial Br. at 33-34. If Ms. Nordwall establishes that Mat suffered this condition within the appropriate time, then she is not required to prove causation. Rather, causation is presumed. Cucuras, 993 F.2d at 1528. She would, therefore, be entitled to compensation unless respondent established that a factor unrelated to the vaccine caused Mat’s encephalopathy.

Whether Mat suffered an encephalopathy is the decisive question. A preponderance of the evidence establishes that he did not.

Regulations set forth what Ms. Nordwall must establish. Initially, a regulation defines what constitutes an “encephalopathy”:

A vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the appropriate period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

42 C.F.R. § 100.3(b)(2).

The term “acute encephalopathy” is also defined:

An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours.

42 C.F.R. § 100.3(b)(2)(i).

Here, because no evidence shows that Mat suffered a seizure, tr. 137; the issue becomes whether he suffered “a significantly decreased level of consciousness.” The regulations define that term too:

A “significantly decreased level of consciousness” is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . .:

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2)(i)(D).

While subparagraph (D), quoted above, states what behaviors constitute signs of an encephalopathy, subparagraph (E) explains what behaviors do not constitute signs of an encephalopathy. This portion of the regulation provides:

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.

42 C.F.R. § 100.3(b)(2)(i)(E).

To summarize the regulatory definition, Mat suffered an acute encephalopathy if he had a decreased response to his environment, but this decreased response cannot be evidenced by fussiness or crying, among other behaviors.

Here, no evidence established that Mat had a decreased response to his environment. Thus, Ms. Nordwall has failed to meet her burden of proof.

The lack of evidence on this point is illustrated by the brevity of Ms. Nordwall’s post trial brief on this claim. This section, which is only two pages in length, fails to cite to the regulatory definition of encephalopathy. Instead, Ms. Nordwall argues that “inflammation of the brain and high temperature, as well as evidence of vasogenic edema . . . is direct evidence of encephalopathy.” The general medical community may — or may not — consider inflammation, high temperature, and/or vasogenic edema to be signs of an encephalopathy, as that term is

commonly used in the medical community. Cf. exhibit 6 ¶ 31 (stating “crying, irritability, elevated temperatures and motor seizure activity are characteristic findings of encephalopathy”); exhibit 7, affidavit of Dr. Tori, ¶ 28 (same). But, this point is not relevant because the regulations define “encephalopathy” as used in the Vaccine Injury Table. By this definition, Ms. Nordwall’s evidence is entirely lacking.

Ms. Nordwall also points to Mat’s death as evidence of his encephalopathy. Pet’r Post Trial Br. at 35. However, the Federal Circuit has rejected this logic. Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 960-61 (Fed. Cir. 1993).

Therefore, Ms. Nordwall has not established that Mat suffered a table injury. The analysis for her alternative theory of relief, that the vaccine was the cause in fact of Mat’s death, is set forth in the next sections.

B. Evaluation of Dr. Shane’s and Dr. Rourke-Adams’s Opinions

In regard to Ms. Nordwall’s claim that the vaccine in fact caused Mat to suffer an encephalopathy, Ms. Nordwall relies upon the testimony of Dr. Shane. Dr. Shane opines that three facts about Mat, which are discussed at length below, point to Mat having an encephalopathy. In contrast, respondent presented the testimony of Dr. Rourke-Adams, who opined that the cause of Mat’s death was positional asphyxia. In short, the experts view this case differently.

The persuasiveness of the experts must be evaluated and the testimony of one side’s expert may be rejected when a reasonable basis supports such a rejection. Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). A decision about the persuasiveness of an expert is virtually not reviewable on appeal. Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

In the Vaccine Program, an expert’s opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and,
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

The causation in fact claim turns on determining which expert was more persuasive. Here, Dr. Rourke-Adams more persuasively demonstrated that the verified facts fit her theory.

Ms. Nordwall marshals several points to support Dr. Shane's belief that Mat suffered an encephalopathy. These are: (1) the weight of his brain evidenced edema, (2) the autopsy slides evidenced edema, and (3) the lack of persuasive evidence about the condition of Mat's fontanelle. Ms. Nordwall also argues that the lack of petechiae shows that Mat did not die of positional asphyxia. Pet'r Post Trial Br. at 13-32. An analysis of these points reveals that Dr. Shane's opinion is less persuasive than Dr. Rourke-Adams's contrary opinion.

1. Edema - Demonstrated by Brain Weight

Mat's brain weighed 755 grams. Exhibit 11, autopsy report, at 3. Dr. Shane and Dr. Rourke-Adams draw different conclusions from this fact. To Dr. Shane, this weight far exceeds the weight of a healthy two-month-old baby. Thus, Dr. Shane reasons that Mat's brain weighs more because his brain was swollen with cells responding to an injury caused by the DTaP vaccine. Dr. Rourke-Adams believes that Mat's brain was not excessively heavy and, even if it were, a heavy brain did not cause Mat's death.

The implications from a finding that Mat's brain weighed 755 grams are important to this case. Dr. Shane relies upon a finding that Mat's brain was excessive to support his opinion that Mat suffered an encephalopathy. He reasons that Mat's brain was excessively large; the large size was caused by swelling; the swelling (called edema in the medical community) was caused by an encephalopathy; and, finally, the encephalopathy was caused by the vaccination. Exhibit 16; exhibit 18 (Dr. Shane's supplemental report, filed June 5, 2006);⁵ tr. 118, 144-45, 150; Pet'r Post Trial Br. at 19-21.

Mat's brain, however, was appropriate for his size. The average weight of a two-month-old male infant is 506 grams. Exhibit 27 (Dale M. Schulz, Weights of Organs of Fetuses and Infants, 74 Archives of Pathology 244 (1962)) at 248. While Mat's brain weighed more than the brain of most two-month-old infants, this difference is less meaningful for two reasons. First, Mat was actually ten-weeks-old when he died. Therefore, his brain grew for two additional weeks. Second, and more important, Mat was simply a larger child. At ten-weeks-old, his length was 62 cm. Exhibit 4 at 5. This size matches, exactly, the average size of a five-month-old male infant. Exhibit 27 at 248. The average weight of a five-month-old brain is 746 grams, virtually the same weight as Mat's brain. See tr. 223.

In post trial briefing, Ms. Nordwall contends that Mat's brain was heavy. Pet'r Post Trial Br. at 19-21. Ms. Nordwall criticizes an approach taken by Dr. Rourke-Adams involving standard deviations and uses an article from an online source, which she filed as exhibit 27, as a

⁵ Exhibit numbers were assigned to Dr. Shane's reports and other pieces of evidence after they were filed. Order, filed May 8, 2007.

basis for her criticism.⁶ Ms. Nordwall's attack misses the mark. Dr. Rourke-Adams recognized that her use of the standard deviation contained a mathematical error. Tr. 242. Thus, the finding that Mat's brain was appropriate for his size does not rely upon the standard deviations. Ms. Nordwall fails to consider that Mat's brain was larger than the brain of most two-month-old children because Mat was, simply, a large child.

Brain weight is a straightforward piece of evidence that requires no special knowledge to understand. Because Mat's brain weighed an appropriate amount for a child of his age and size, this fact does not support Dr. Shane's theory that Mat suffered an encephalopathy.

2. Edema Demonstrated by Autopsy Slides

In addition to basing his opinion that Mat suffered from an edema upon an observation that Mat's brain was excessively large, Dr. Shane also relies upon slides of Mat's brain created during the autopsy. Tr. 103, 150. A set of eight prints from these slides was filed as exhibit 25. Ms. Nordwall argues that glial cells proliferated, and these caused a vasogenic edema. Pet'r Post Trial Br. at 13-19, 22-27.

Unlike the weight of Mat's brain, this topic is difficult to understand because the experts not only differ in their opinions about how the brain responds to injury, but also in their interpretation of the same slides. Despite viewing the same slides, Dr. Shane and Dr. Rourke-Adams come to almost completely different interpretations of what is depicted on them. Resolving this dispute is difficult without having experience and training in using a microscope and examining brain cells. See tr. 308. Dr. Rourke-Adams attempted to assist this process by providing textbooks and articles that depict the different cells she describes. Tr. 295, discussing exhibit F, attachment 4 (Lucy Balian Rourke, Pathology of Perinatal Brain Injury (1982)) at 8.

According to Dr. Shane's interpretation of these slides, Mat's brain contained an excessive number of glial cells. Tr. 103, 114. From her observation of the same set of slides, Dr. Rourke-Adams determined that the number of glial cells in Mat's brain was greater than usual, but not excessively so. Tr. 208, 212, 300.

Glial cells are the cells of the brain that respond to injury. Tr. 103-4, 236, 246. "Astrocyte" is the name for a specific type of glial cell that performs this function. Tr. 276 (testimony of Dr. Shane), 293 (testimony of Dr. Rourke-Adams); exhibit F, attachment 2 (Greenfield's Neuropathology (David I. Graham and Peter L. Lantos, eds., 6th ed. (1997))) at 117.

According to Dr. Shane, after the brain is injured, the astrocytes manufacture chemical substances called cytokines. In producing cytokines, the astrocytes swell. Swollen astrocytes can be seen on slides, although the cytokines are not visible. Tr. 269-71. Dr. Shane believes that

⁶ Wikipedia may not be a reliable source of information. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006).

the slides of Mat's brain, notably exhibit 25, picture 0004, show swollen astrocytes. According to Dr. Shane, these swollen astrocytes are evidence that Mat suffered from cytotoxic edema. Tr. 272, 290.

The flaw in Dr. Shane's reasoning is his assertion that the slides show swollen astrocytes in Mat's brain. Supported by a well-regarded treatise, Dr. Rourke-Adams explained that when astrocytes enlarge, the first change is seen in the cells' nuclei. Swollen astrocytes are sometimes called Alzheimer Type II astrocytes. (They are named for the first scientist to recognize them – the same scientist for whom Alzheimer's disease is named.) Importantly, according to Dr. Rourke-Adams, slides from Mat's brain do not show any Alzheimer Type II astrocytes. Tr. 294-95.

A preponderance of the evidence supports a finding that the slides from Mat's brain did not depict any Alzheimer Type II astrocytes. Dr. Rourke-Adams was more persuasive, in part, because of her expertise. Although Dr. Rourke-Adams and Dr. Shane were recognized as experts in neuropathology, tr. 97-99, 155-55; Dr. Rourke-Adams has a more persuasive set of credentials. For example, Dr. Rourke-Adams is board-certified in neuropathology. Tr. 155. Dr. Shane does not have this certification. Tr. 98. She has also assisted in preparing the examinations for neuropathologists attempting to gain board certification, and served on editorial boards of different journals, a position for which her professional colleagues nominated her. Tr. 159, 219-20. She has won awards from national organizations and lectured internationally. Tr. 158, 220. These accomplishments indicate that Dr. Rourke-Adams's peers, who are presumably well informed about their own field, recognize her skills.

A second reason for finding Dr. Rourke-Adams more persuasive was her demeanor. See Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988) (authorizing finders of fact to consider demeanor of an expert when resolving conflicts in opinion). Explaining the basis for this finding is somewhat difficult because determinations about which witness is more credible or more persuasive "are by nature impressionistic." Tweten v. Sec'y of Health & Human Servs., 26 Cl. Ct. 405, 410 (1991).

Dr. Rourke-Adams presented her opinions confidently. Her testimony was well organized, showing her underlying reasoning. She also offered a way to compare the cells shown on the slides to cells shown in a treatise. Tr. 295.⁷ This presentation suggests that Dr. Rourke-Adams is sufficiently confident in her opinion and was willing to be tested on this point.

Dr. Rourke-Adams opined that the cells in Mat's brains were not swollen astrocytes. Tr. 305, 308, 312. For the reasons explained above, Dr. Rourke-Adams's testimony is persuasive.

⁷ While this offer was helpful in theory, it worked less well in practice. The exemplar submitted was a blurry black and white photocopy that could not be compared to the color reproductions. Compare exhibit F, attachment 4 at 8 with exhibit 25.

Therefore, the evidence does not support Dr. Shane's assertion that the slides show cytotoxic edema.

3. Fontanelle

Fontanelles are soft spots on a baby's skull where the skull bones have not completely fused. See Dorland's at 720. They can be either normal, tense and bulging, or sunken. Tr. 185.

According to the report from the emergency room doctor, Daniel O'Laughlin, Mat had "a sunken anterior fontanelle." Exhibit 9 at 2. The autopsy report states that the "anterior fontanelle is flat." Exhibit 11 at 2.

Ms. Nordwall argues that these reports "are inconsistent and therefore there is no conclusive evidence" about the state of Mat's fontanelle. Pet'r Post Trial Br. at 21. Ms. Nordwall is wrong in arguing that "sunken" is inconsistent with "flat."

In the context of describing a once round surface, such as a ball, "sunken" can mean nearly the same thing as "flat." When a ball loses its shape, the convex curve sinks inward and that resulting surface can be flat. When the curve sinks further inward, the surface becomes concave. Both "flat" and "sunken" are not the same as the convex curve normally seen with a spherical ball or a child's fontanelle.

Even assuming that "sunken" is inconsistent with "flat," Ms. Nordwall errs in arguing about the conclusiveness of the evidence. Dr. O'Laughlin's description of Mat's fontanelle is persuasive evidence that it was sunken when Mat died. In two places in his well-organized, detailed, four-page report – the section on physical examination and the section describing the course of treatment, Dr. O'Laughlin describes the fontanelle as sunken. In the latter section, Dr. O'Laughlin stated that he "performed a secondary survey and noted the anterior fontanelle being very sunken, concerning for possible dehydration." Exhibit 9 at 2. Because Dr. O'Laughlin was examining Mat for a specific purpose – to look for a cause of Mat's respiratory distress that was reversible – his observations are reliable. See Cucuras, 993 F.2d at 1528.

The fact that Mat's fontanelle was sunken contradicts Dr. Shane's theory that Mat's brain was swollen. A sunken fontanelle suggests dehydration or a lack of fluid in the brain. On this point, both Dr. O'Laughlin, the doctor who treated Mat in the emergency room, and Dr. Rourke-Adams agree. Exhibit 9 at 2; tr. 185. If Mat's brain were swollen with fluid, then the fontanelle would not be sunken.

In rebuttal, Dr. Shane explains why a fontanelle would not remain "bulging" after death. Tr. 229. Dr. Shane's point may be accurate. (However, Dr. Rourke-Adams contends with persuasiveness that bulging fontanelles remain swollen until the autopsy. Tr. 244-45.) But, Dr. Shane does not explain how an emergency room doctor would have described a "sunken" fontanelle in a patient on whom cardiopulmonary resuscitation was being attempted. Perhaps,

reasonable doctors could differ as to whether a fontanelle was either “bulging” or normal. It is doubtful that a doctor would mistake a bulging fontanelle for a sunken fontanelle.

By excluding or failing to consider Dr. O’Laughlin’s observation that Mat’s fontanelle was sunken, Dr. Shane’s opinion lacks reliability. Fact finders may reject opinion evidence when the opinion is based upon facts not supported in the record. 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.”); Burns by Burns v. Sec’y of Health and Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993); Loesch v. United States, 645 F.2d 905, 915 (Ct. Cl. 1981); Van Epps v. Sec’y of Health and Human Servs., 26 Cl. Ct. 650, 654-55 (1992).

4. Petechiae

“Petechiae are pinhead-sized hemorrhages seen in the skin, the sclera, and conjunctivae, and on mucosal surfaces in the mouth as well as the organs of the chest.” Exhibit G (A. Walker et al. Asphyxia in Encyclopedia of Forensic and Legal Medicine, Jason Payne-James et al., ed. 2005) at 151. Mat’s autopsy did not show any hemorrhages. Exhibit 11; tr. 234.

The parties dispute the significance of the lack of petechiae. Dr. Shane believes that the lack of hemorrhages means that Mat did not die of positional asphyxia because petechial hemorrhages (hemorrhages around the heart) appear when a person dies of that condition. Tr. 118, 135-36.

Dr. Rourke-Adams persuasively contradicts Dr. Shane’s argument. During the hearing, she expressed her opinion that hemorrhages are not always associated with positional asphyxia. Tr. 241. Because the experts took conflicting position, the parties were permitted to submit literature after the hearing supporting their respective positions. Order, filed May 10, 2007.

Exhibit G, submitted by respondent, resolves this dispute. The entry for asphyxial death states “cyanosis, edema, petechiae, and fluidity of blood [are not] reliable or indeed diagnostic as an indicator of asphyxia.” Exhibit G at 151. Thus, Mat’s lack of petechiae does not rule out Dr. Rourke-Adams’s determination that Mat died of positional asphyxia.

Dr. Shane did not produce any literature addressing petechiae, even though his point regarding petechial hemorrhage was very important to his opinion. Tr. 135-36, 238. In light of the strong statement in exhibit G that petechiae is not diagnostic of asphyxia, Dr. Shane’s opinion to the contrary is found to be not credible.

C. Causation In Fact

To prove causation in fact, a petitioner must establish at least 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 v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). 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).

In this case, Ms. Nordwall has met her burden with regard to the first (medical theory) and third (appropriate temporal relationship) factors. However, a preponderance of the evidence does not establish the second factor (that the vaccine was the reason for the injury).

For the first and third factors, the evidence largely matches the Vaccine Table. Dr. Shane opined that Mat suffered an encephalopathy caused by the DTaP vaccine and this encephalopathy caused his death. Exhibit 16. The Vaccine Injury Table recognizes that a vaccine containing pertussis can cause an encephalopathy. 42 C.F.R. § 100.3 ¶ II. Respondent conceded that an encephalopathy can cause death. Tr. 11-12.

Furthermore, in theory, the temporal relationship is appropriate. Mat died within 16 hours of receiving his vaccination. The Vaccine Injury Table associates an encephalopathy with a vaccine containing pertussis within the first 72 hours. 42 C.F.R. § 100.3 ¶ II; see also tr. 103, 130 (testimony of Dr. Shane about temporal relationship). Thus, the third factor of Althen is fulfilled.

However, Ms. Nordwall's claim fails to satisfy the second factor. She has failed to show that "the vaccine was the reason for the injury." Althen, 418 F.3d at 1278.

Ms. Nordwall relies upon Dr. Shane's opinion to establish that the DTaP vaccine caused an encephalopathy, which lead to Mat's untimely death. However, Dr. Shane's opinion that Mat suffered an encephalopathy is not persuasive for the reasons explained in section B, above. Thus, Ms. Nordwall has not met her burden of proving that the DTaP vaccine was the cause in fact of Mat's death. In addition, the evidence establishes that positional asphyxia was the cause of Mat's death.

D. Factor Unrelated

Whether a petitioner bears the burden of ruling out alternative causes or whether the respondent bears the burden of establishing an alternative cause is a point on which precedent is unclear. Compare Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (stating “[a] plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence.”) with Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1360 (Fed. Cir. 2006), cert. denied, ___ U.S. ___, 127 S.Ct. 2909 (2007) (Dyk, J., dissenting) (stating “[t]he majority today holds that petitioners . . . must establish, as essential elements of a prima facie showing of causation in off-Table cases, . . . an absence of ‘alternative causes’ of the injury.”).

Deciding which party bears the burden of proof is not necessary. Identifying the party bearing the burden of proof is decisive only when the evidence is truly in equipoise. Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988); Cook v. United States, 46 Fed. Cl. 110, 113 n.5 (2000); see also Director, OWCP v. Greenwich Collieries, 512 U.S. 267, 272-76 (1994) (discussing difference between burden of persuasion and burden of producing evidence).

Here, the evidence is not in equipoise. A preponderance of the evidence establishes that the cause of Mat’s unfortunate death was positional asphyxia.

A persuasive piece of evidence that Mat died of positional asphyxia is the report of the medical examiner. Exhibit 11 at 1, 6. Because the pathologist and the medical examiner rendered their opinions outside of the context of litigation, their opinions must be considered. Capizzano, 440 F.3d at 1326.

Ms. Nordwall argues that Mat could not have died of positional asphyxia because Mat had the ability to lift and to turn his head. If Mat had a problem breathing and was not impaired by an encephalopathy, he could have adjusted his nose and face to get air. Pet’r Post Trial Br. at 41, citing tr. 35-36 (testimony of Dr. Tori).

The facts, sadly, do not support this argument. At the age of ten weeks old, Mat could lift his head using muscles in his torso and muscles in both arms, like doing a push up. Mat also probably showed that he could lift his head when he was placed on a surface that was both horizontal and relatively firm, such as a carpeted floor.

Mat’s environment in the early morning of January 18, 2003, was much different for an infant only ten-weeks-old. Mat was swaddled, and therefore he could not use both arms to lift his chest sufficiently away from the bed to turn his head. Mat was also lying on his back, meaning to lift his head he had to use his abdominal muscles, like doing a sit-up. No evidence showed that ten-week-old infants have an ability to lift their heads when they are on their back. Finally, placing Mat in an angled position could have allowed him to slip lower in the blankets

surrounding him, causing the blankets to cover his nose and mouth. Tr. 124 (testimony of Dr. Shane recognizing that improper positioning can cause asphyxia), 166 (testimony of Dr. Rourke-Adams).

For these reasons, a preponderance of the evidence establishes that the cause of Mat's death was positional asphyxia, a factor not related to his earlier receipt of the DTaP vaccine. Consequently, Ms. Nordwall is not entitled to compensation.

IV. Conclusion

Mat's death was a tragedy. I extend my sympathy to Ms. Nordwall and Dr. Tori for the loss of a son whom they loved.

Nevertheless, entitlement to compensation pursuant to the Vaccine Act has not been shown. The Clerk's Office is ordered to enter judgment in favor of respondent.

IT IS SO ORDERED.

Christian J. Moran
Special Master