

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 20, 2018

* * * * *	*	
EVA CRUZ and OMAR LOPEZ	*	
JIMENEZ, Special Administrators of	*	UNPUBLISHED
the Estate of L.J.L.,	*	
	*	No. 14-1119V
Petitioners,	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH	*	Ruling on Facts; Diphtheria-Tetanus-
AND HUMAN SERVICES,	*	acellular-Pertussis ("DTaP"), Inactivated
	*	Poliovirus ("IPV"), Haemophilus Influenzae
Respondent.	*	B ("HiB"), Prevnar 13, and Rotavirus
* * * * *	*	Vaccinations; Death.

Karen H. Ross, Law Offices of Karen Ross, Henderson, NV, for petitioners.

Camille M. Collett, United States Department of Justice, Washington, D.C., for respondent.

RULING ON FACTS¹

On November 18, 2014, Eva Cruz and Omar Lopez Jimenez ("petitioners"; "the parents"; or individually, "the mother" and "the father"), as special administrators of the estate of L.J.L. ("the baby") timely filed a petition in the National Vaccine Injury Compensation Program (the "Vaccine Act" or the "Vaccine Program").² A fact hearing took place on May 1, 2018, in Las Vegas, Nevada. After carefully considering the full record, I hereby issue these final findings of fact.³

¹ Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this ruling contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The court's website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. Before the ruling is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the decision." Id. **If neither party files a motion for redaction within 14 days, the ruling will be posted on the court's website without any changes.** Id.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

³ Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record including all of the medical records, statements, expert reports, and medical literature submitted by the parties. This decision discusses the elements of the record I found most relevant to the outcome.

I. Procedural History

The petition provides that on November 19, 2012, the baby received five two-month old vaccinations: Diphtheria-Tetanus- acellular Pertussis ("DTaP"); Inactivated Poliovirus ("IPV"); Haemophilus Influenzae B ("HiB"); Prevnar 13; and Rotavirus. On the morning of November 21, 2012, the baby was found unresponsive in his bassinet and was later pronounced deceased. The petition alleges that in the period between the baby's vaccinations and his death, he demonstrated clinical signs and symptoms of a "significantly decreased level of consciousness," meeting the definition of an "acute encephalopathy" on the Vaccine Injury Table. The petition alleges that in the alternative, the vaccinations caused-in-fact an Off-Table Injury, namely an acute toxic metabolic encephalopathy and death. Petition (ECF No. 1). The petition was accompanied by affidavits from petitioners, Ms. Cruz ("the mother") and Mr. Lopez ("the father"), as well as Ms. Cruz's mother, Ms. Digna Cruz ("the grandmother"). Petitioners' Exhibit ("Pet. Ex.") 3.

Respondent recommended against compensation. See Respondent's Rule 4(c) Report ("Resp. Rept.") filed February 18, 2015 (ECF No. 10). Specifically, respondent contended that the contemporaneous records from the medical providers, the police, and the coroner conflicted with the witnesses' later allegations about the baby's behavior.

Over the next three years, each party filed multiple expert reports. An entitlement hearing was set for May 1-4, 2018. It was initially contemplated that this hearing would take both fact and expert testimony. On March 2, 2018, petitioners filed a prehearing brief. Pet. Brief (ECF No. 61). On April 11, 2018, respondent filed a responsive prehearing brief. Resp. Brief (ECF No. 71). After several status conferences with counsel addressing multiple aspects of the claim, I determined that the impending hearing would be limited to fact testimony. Afterwards, I would issue binding findings of fact to align the parties and their experts' understanding of the case. See Orders (ECF Nos. 69, 74).

A fact hearing was held on May 1, 2018, in Las Vegas, Nevada. The mother, father, and grandfather testified. On May 4, 2018, I issued an order summarizing my tentative factual findings. Order (ECF No. 87). This order provided that if either party would like post-hearing briefing, they could file a status report on the same within 7 days of the transcript. Id. at 7, n. 2. The transcript was filed on May 10, 2018. Transcript ("Tr.") (ECF No. 89). Neither party has requested post-hearing briefing. Thus, this matter is now ripe for adjudication.

II. Legal Standards Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." Cucuras, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). Cucuras, 993 F.2d at 1528; see also Reusser v. Sec'y of Health & Human Servs., 28 Fed. Cl. 516 (1993) (providing that written documentation recorded by a disinterested person at or soon after an event is

generally more reliable than the recollection of a party to a lawsuit many years later).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. Lowrie v. Sec’y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In Lowrie, the special master wrote that “written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” Lowrie, at *19.

The Court of Federal Claims has recognized that “medical records may be incomplete or inaccurate.” Camery v. Sec’y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. La Londe v. Sec’y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), aff’d, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” Camery, 42 Fed. Cl. at 391 (citing Blutstein v. Sec’y of Health & Human Servs., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” La Londe, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); see also Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. The Factual Record

A. Medical Records Prior to Vaccinations

The mother’s prenatal records reflect that she had regular medical appointments and her labs were normal. She denied drinking alcohol, using tobacco, and using non-prescribed or recreational drugs. She was 18 years old upon giving birth to L.J. L. in September 2012. Pet. Ex. 5 at 60-77, 82.⁴ She had an uncomplicated delivery by Caesarean section. Id. at 84. The baby’s

⁴ Respondent’s Rule 4(c) report and prehearing brief both provide: “For exhibits filed in this case, respondent cites to the page numbers in the bottom right corner of the page herein.” For uniformity, this ruling on facts will utilize the same page numbers.

Apgar scores was 9 at 1 minute and at 5 minutes. The newborn admission assessment provides that his birth weight was 6 pounds, 10 ounces; his length was 18.5 inches; and his head circumference was 31 centimeters. The physical assessment on this record is blank. Id. at 113. The baby received his first Hepatitis B (“Hep B”) vaccination at the hospital. Pet. Ex. 6 at 135. Mother and baby were discharged from the hospital on September 20, 2012. Pet. Ex. 5 at 126.

The parents established pediatric care with Dr. Michael Rosenman, M.D. His handwritten records are difficult to decipher in parts, but they do reflect well visits took place on September 24, 2012, and October 8, 2012. Pet. Ex. 6 at 131-32.

On November 5, 2012, Dr. Rosenman saw the baby again. Dr. Rosenman used a different form, labeled “sick visit.” Unlike his form for well visits, his form for this sick visit asks about social history. For “daycare”, there is a notation reaching both “Y” and “N.” The word “smoking” is circled, next to the letter “Y” (there is no corresponding letter “N”). For “pets,” there is a notation reaching the letter “Y,” but not the letter “N.” The complaint was colic. Dr. Rosenman circled “negative” to fever, URI (upper respiratory infection), cough, vomiting, diarrhea, constipation, pain, and rash. The physical examination was negative. The baby’s temperature was 98 degrees Fahrenheit. The plan provides: “[illegible] 11/18/2012 2 weeks.” Pet. Ex. 6 at 130. The second Hep B vaccination was administered. Id. at 135.⁵

On November 19, 2012, Dr. Rosenman saw the baby for a two-month well visit. A physical exam – including skin, head, eyes, ears, nose, throat (“HEENT”), chest, lungs, and neurology – was all negative. The baby’s temperature was 98.9 degrees Fahrenheit. Certain notations on the record are illegible. Pet. Ex. 6 at 129.⁶ The baby received his first DTaP, IPV, Hib, Prevnar 13, and Rotavirus vaccinations. Id. at 135.

B. Fire Department, EMS, and Hospital Records

The next contemporaneous records are from November 21, 2012. The Clark County Fire Department dispatcher received a 911 call at 8:58 a.m. Fire fighters arrived at the house at 9:05 a.m. Upon entering the house, they found the baby “lying supine on floor with CPR being performed by bystanders.” Pet. Ex. 19 at 2, 6.

The paramedics arrived shortly thereafter. They recorded: “According to family, pt was given his shots 2 days ago and had been getting progressively more sick with fever since then. Pt was fed and placed back in bed. Family then went to bed as well. Pt was found at 9 am by family member to be not breathing and unresponsive. Father began CPR and 911 was called. FD arrived to find pt in full arrest and quickly ran patient out to us as we arrived.” Pet. Ex. 11 at 1-2. The baby was placed in the ambulance. He was apneic, pulseless, and unresponsive. There

⁵ The mother later explained that the baby had been fussy and refusing his formula. At Dr. Rosenman’s suggestion, the mother gave the baby gas drops for a few days, which seemed to help. Pet. Ex. 1 at 17-18; Tr. 62-63.

⁶ After the fact hearing, I provided that “**Petitioners are strongly encouraged to ask Dr. Rosenman to transcribe his handwritten notes**” for the November 19, 2012, appointment. See Order entered May 4, 2018 (ECF No. 87) at 1 (emphasis in the original). To date, petitioners have not filed the transcribed records or otherwise addressed this issue with the Court.

were no obvious signs of trauma, but “strong signs of possible lividity noted to pt’s face, left back and left shoulder and arm.” He was cold to the touch. The rectal temperature was 92.1 degrees Fahrenheit. On the way to the hospital, the paramedics performed compressions and an intubation. They administered oxygen, intravenous fluids, and epinephrine. Id. at 2.

The emergency room report was signed by Dr. Theresa Vergara, M.D., but the historian was “EMS personnel.” That report provides that the baby “has had fever (since Monday). No cough, diarrhea, or vomiting. All systems otherwise negative.” Pet. Ex. 1 at 21. It also provides: “PMD visit Monday immunizations given. Had fever that night and continued Tuesday. Tylenol given by mom.” Id. The chief complaint is: “Mom fed baby at 6 or 6:30am. Around 8:50 am mom found the baby not breathing. Dad did CPR. Called 911.” Id.

A physical exam revealed no spontaneous pulse or respiration. The skin showed cyanosis and positive lividity. Further resuscitation efforts were unsuccessful. The baby was pronounced dead at 9:32 a.m. on November 21. The clinical impression was cardiorespiratory arrest, hypothermia, and a history of febrile illness. Id. at 22.

The baby’s mother was present in the resuscitation room, then taken to the quiet room. Id. Dr. Vergara informed the mother that the baby had passed away, most likely before the paramedics had arrived. A social worker then met with the mother and recorded: “[The baby had his 2 month immunizations on Monday. He had a fever Monday and yesterday. [Mother] states it went away with meds. Mother states she fed pt this am at 630. She states her mother went into the room at 900 to find pt not breathing. FOB attempted CPS [sic?] while EMS arrived. Several family members responded to RD for support. Det’s Martinez and Sauchek responded and interviewed pt’s mother and grandmother. FOB remained at the house. Prints done and bereavement materials given. Pt taken to Palm [mortuary].” Id. at 38.

C. Coroner and Police Records

At 12:26 p.m., reporting Officer Sean M. Scott of the Clark County Police Department entered an administrative report. Pet. Ex. 18 at 1. He recorded that the police arrived at the scene 15 minutes after EMS did. EMS had already transported the baby, mother, and grandmother to the hospital. The father told the police that the baby “had received a Hepatitis B shot 3 days ago and had been running a fever but other than that appeared to be fine.” At approximately 6:00 a.m. that morning, the mother had put the baby in the bassinet at the foot of the bed. The mother and father went to sleep. They woke to the grandmother screaming. The baby’s uncle (who also lived with the family) was performing CPR. Id. at 2. Officer Scott observed that the bassinet was located along the room’s west wall next to the bedroom door and at the foot of the bed. It contained a “multicolored, soft blanket,” part of which appeared to be “wadded or bunched up in a clump.” The padding was “very soft as well.” Id.

On November 21 at approximately 10:30 a.m., coroner investigator Nancy Dahl, arrived at the hospital after being informed of an apparent undetermined infant death. She met first with Detectives Martinez and Sauchek, who relayed that on November 21 at approximately 6:00 a.m., the mother had fed the baby approximately 4 ounces of formula. The mother “burrito” wrapped him and placed him on his left side. At approximately 9:00 a.m., the grandmother entered the

room. The grandmother thought “he didn’t look right, picked him up, realized he was unresponsive, put him back down, and began screaming.” Pet. Ex. 1 at 17. “The baby’s father, Omar Lopez then picked him up . . . while Ms. Cruz [the mother or the grandmother?] was attempting CPR, Mr. Lopez called 911 at 906 hours.” Id.

Investigator Dahl then met with the mother, who reported that the last pediatric visit was on November 19 at approximately 10:45 a.m. for scheduled shots. Afterwards, the baby “was congested and had a 101-degree fever throughout the day.” Id. at 18. After the mother gave him acetaminophen,⁷ the fever went down, but it came back at approximately 9:00 p.m. Following another dose of acetaminophen, it went down again. He had a normal temperature by November 20 at 3:00 a.m. However, by 10:00 a.m., it returned to 101 degrees. “She gave him another dose of [acetaminophen] and she stated the fever did not come back.” Id. The baby had a good appetite, eating approximately 3-4 ounces of formula every 3 hours and tolerating it well. He had regular bowel movements, the last being somewhat looser on November 20 at 6:30 a.m. Id. At the hospital, Investigator Dahl also observed the body and recorded: “lividity was positional, blanching and consistent with the position of the body.” Id. at 19.

Investigator Dahl then traveled to the house, where she “confirmed the above circumstances” with several police personnel. She examined the bedroom. She “observed one small stuffed toy and one small receiving blanket” inside the bassinet. Id. “Ms. Cruz stated the bassinet mattress was hard so she placed a standard sized pillow in it for comfort. The pillow was the same size as the bassinet and was approximately 2 inches thick.” Id. at 18.

Detectives Martinez and Kearns conducted a reenactment and “found that the decedent was placed on his left side with his back to the bassinet and found by his grandmother in the same position.” Id. at 20. “Per Ms. Cruz, other than the previously mentioned fever, there was nothing unusual within the last 24 hours.” Id.

D. Autopsy Report

An autopsy was performed for the Clark County, Nevada Coroner’s Office by Dr. Lisa Gavin, M.D. She wrote that the baby had a febrile illness in the days before his death. Pet. Ex. 1 at 2. Of possible relevance, the histopathology showed a mixed inflammatory response of lymphocytes, plasma cells, and occasional neutrophils in the tracheal, bronchial, and upper gastric mucosa. Id. at 3. Dr. Gavin commented that this mixed inflammatory response “could be related to recent antigen exposure; however, there was no associated edema and the inflammatory response was not vigorous enough as to obstruct the airways.” Id. at 4. Dr. Gavin also noted: “the nose and lips are unremarkable.” Id. at 6.

Dr. Gavin also wrote: “According to investigations, the decedent was wrapped in a blanket and placed on his left side in the bassinet. He was later found face down and

⁷ See also Pet. Ex. 17 at 77-81 (police photographs of “Little Fevers by Little Remedies Infant Fever/ Pain Reliever (acetaminophen)”).

unresponsive.” Id.⁸ She said that this purported face-down position was “the most compelling evidence as to the cause of death.” Id. at 4. She concluded that the cause of death was “positional asphyxia” and the manner of death was accidental. Id.

D. Facts According to Family Members

While L.J.L. was *in utero*, his mother Ms. Eva Cruz and his father Mr. Oscar Lopez Jimenez were living with Mr. Jimenez’s parents. Once the baby was born, he, the mother, and the father moved in with the maternal grandmother, Ms. Digna Cruz. These three named individuals produced affidavits in August 2014 and also testified at the fact hearing on May 1, 2018. The facts as told by each named individual are summarized below, in the order which they testified at the fact hearing.

1. Facts according to L.J.L.’s Grandmother, Ms. Digna Cruz⁹

The grandmother testified that to her knowledge, the mother did not smoke, drink, or use recreational drugs either during her pregnancy or after giving birth. Tr. 11-12. No one else in the home smoked. Tr. 12. The temperature in her home was usually set at 75 degrees Fahrenheit. Tr. 46.

The grandmother recalled that before the vaccinations, the baby was generally healthy. He previously had colic, as well as nasal congestion. Tr. 15-16, 45. However, he never had fever. Tr. 15-16. He was healthy before going to Dr. Rosenman and receiving the vaccinations on November 19. Pet. Ex. 3 at 45.

On November 19, the grandmother went to work and got home at about 4:30 pm. That afternoon and evening, the baby was crying; he was congested and the mother suctioned his nose; and he had a fever, which she knew because his forehead was hot. Tr. 19, 36, 44-45.

On November 20, the grandmother again went to work and returned at about 4:30 p.m. In her affidavit, she recalls attempting to feed the baby, which he did not accept. He was also congested, feverish, crying, and less responsive than usual. Pet. Ex. 3 at 45-46. At the hearing, she testified that the baby was generally “the same” as on the previous day. Tr. 25.

On November 21, the grandmother was not scheduled to work. Tr. 17. She recalled awakening at approximately 8:50 or 9:00 a.m. Pet. Ex. 3 at 45; Tr. 26. She went to the bedroom where the mother, the father, and the baby were sleeping. She opened the door and could see the baby clearly. The baby was in the center of the bassinet, lying on his left side, facing towards the door. He was purple. His eyes were closed. His eyes, nose, and mouth were not covered. Pet. Ex. 3 at 46; Tr. 26-28. His shoulders and the top of his arm were also exposed. Tr. 47.

⁸ However, respondent’s Rule 4(c) report provides that he was “unable to find any indication in the filed emergency room or coroner investigation records that specifically state that [the baby] was found face down.” Resp. Rept. at 6, n. 8. Similarly, my own full review of the records did not find any indication that the baby was found face down.

⁹ The grandmother’s primary language is Spanish. She testified with the assistance of a court-certified Spanish language interpreter. Tr. 9.

The baby was wrapped in the blanket which is shown in the police investigation photographs. She described the blanket as light and thin. Tr. 41. She recalled that the blanket came up to his chest. Tr. 25-28, 37-39. She recalled that there was a pacifier by the baby's side. Tr. 36-37. She said that the toy and the hat shown in the bassinet in the police investigation photographs were not there when she found him. Tr. 41-42. The grandmother also examined the bassinet and mattress at the hearing. She said that this was where the baby slept his entire life and that these items never covered his face. Tr. 42-43.¹⁰

The grandmother testified that when she saw the baby that morning – purple and unresponsive in his bassinet – she did not pick him up. She panicked and screamed, which awoke the mother and father. The father awoke and called 911. The first person to pick up the baby was the baby's grandfather, who began CPR. Pet. Ex. 46 at 3; Tr. 28-30.

The grandmother recalled that she and the mother rode in the ambulance to the hospital. She remembered talking to someone at the hospital. She agreed with petitioners' counsel's suggestion that the interviewer may have been from the coroner's office. She spoke with that person in Spanish, for approximately ten minutes. Tr. 31.

On cross-examination, the grandmother testified that she did not remember being interviewed by police Detective Martinez and Dr. Sauchek. She did not remember saying that she picked up and then put down the baby. Tr. 33-34.

2. Facts according to L.J.L.'s Mother, Ms. Eva Cruz

The mother averred that neither she nor anyone where she lived smoked, drank alcohol, or used recreational drugs. There were no pets. Pet. Ex. 3 at 45; Tr. 41, 52-53.

This was her first baby. At the hospital, she was taught how to carry, feed, and put him to sleep. She was taught to "burrito-wrap" him in a blanket, but not too tightly. She never varied from this approach. The hospital gave her one blanket. She swapped this out for a blanket that was equally thin, but "heavier" and "warmer." Tr. 56-58. She also recalled being told that the baby could sleep "on his back or on his side, however he felt well." Tr. 59. She said that she would generally place him to sleep on his back, but if he woke up, she might put him on his side to be more comfortable. *Id.* After leaving the hospital, they moved into the grandmother's house. The mother did not work outside the home. She was his primary caregiver. Tr. 62.

She recalled that at the November 19 visit where the baby received his vaccinations, he was in excellent health. Pet. Ex. 3 at 47; Tr. 64-66. She recalled a nurse saying that the baby might develop a fever, but that was a normal reaction to vaccinations. The baby could take Tylenol, but would not need to go to the emergency room. Pet. Ex. 3 at 48; Tr. 63-64.

They returned home at about 1:00 p.m. She bathed and fed the baby. Tr. 66. He napped for approximately two hours and was awake by the time the grandmother got home from work,

¹⁰ The parties' counsel, together, measured the mattress. They agreed that it was 16 $\frac{3}{4}$ inches wide, 31 inches long, and 1 $\frac{3}{4}$ inches thick. Tr. 48-49.

at approximately 4:30 p.m. By that time, he was acting fussy and felt hot. Tr. 113-14. The mother testified that at approximately 9:00 p.m., she took his rectal temperature and it was approximately 102 degrees Fahrenheit. Tr. 66-68; but see Pet. Ex. 3 at 48 (“100 degrees” at 9:00 p.m.). The mother administered the acetaminophen and his fever went down shortly thereafter. Pet. Ex. 3 at 48; Tr. 66-67. However, the baby was fussy and crying (much more than before, when he had colic). He only calmed down when he was held. Tr. 68-69. His nose was at first runny, then congested. That evening, she suctioned his nose twice per side. Tr. 70-71.

The mother testified that the baby also became less responsive. Before the vaccinations, he was able to establish eye contact. Tr. 60-61. After the vaccinations, he “wasn’t focusing” on or looking directly at people, instead, he was looking somewhere else, even when he was being fed. Tr. 72-73.

On November 20, the mother and the baby awoke at about 8:00 a.m. The baby had a fever of 102 degrees. She gave him the acetaminophen and his fever went down to 100 degrees. Pet. Ex. 3 at 48; Tr. 75-76. The mother recalled that he continued to have a fever throughout that day. She recalled taking his temperature that day, but not specifically when. She agreed with the undersigned’s suggestion that she took the temperature in the afternoon. Tr. 115-16.

The baby was still congested. The mother suctioned his nose in the morning. Pet. Ex. 3 at 48; Tr. 75. The mucus had gone from “liquidy and clear” to “thicker and... yellowish.” Tr. 76. Like on November 19, he was fussy unless he was held. Tr. 76-77. The mother also recalled that the baby did not finish his usual four ounces of formula. Additionally, his stools were a little watery and “yellowish” or “mustardy” in color. Tr. 77.¹¹ When the father came home at about 10:00 p.m., the mother went on an errand for about an hour. When she came back, the father and the baby were asleep. She went to sleep as well.

On November 21 at approximately 3:00 a.m.: “He [the baby] woke up crying. He felt hot.¹² I gave him a little bit of Tylenol. He had congestion and he was whiny. I fed him his bottle. He didn’t drink any of it. He only drank one ounce. Then I gave him his pacifier and he went back to sleep.” Tr. 79. She “burrito-wrapped” him in the blanket and put him back to sleep in his bassinet. This took between 25 minutes and one hour. Tr. 79-82; see also Pet. Ex. 3 at 49.

At approximately 6:00 a.m., the baby woke up crying again. She suctioned his nose, changed his diaper, fed him approximately one ounce of formula, burrito-wrapped him, gave him a pacifier, and placed him on his left side in the bassinet. Tr. 83; see also Pet. Ex. 3 at 49.

Afterwards, the baby was quiet and did not cry, so the mother went to sleep. Her next recollection was the grandmother screaming about the baby. The mother and father got up. The

¹¹ The mother also testified that on November 20, 2012, the baby had two bowel movements compared to his daily average of four. That night between midnight and 6:00 a.m., he had one more. They all had the same composition. The mother agreed that “none of them particularly looked like diarrhea.” Tr. 99-100.

¹² The mother testified that she “didn’t remember” if she had taken the baby’s temperature over the course of the night. Tr. 116-17. But later, she said “I remember throughout the night I would take his temperature.” Tr. 123. However, she did not state whether this was by assessing if he “felt hot” or with a thermometer.

father called 911. The grandfather and the uncle came into the room in response to the grandmother screaming. The mother “didn’t get a chance to see [the baby] when [the grandmother] screamed.” They took the baby into the living room and began CPR. Tr. 90; see also Pet. Ex. 3 at 49.

The mother went in the ambulance to the hospital. She recalls that the baby was rushed into the emergency room and the medical professionals “trying to bring him back.” Tr. 92. She recalled a female doctor saying that the baby had died and it was because his body “wasn’t able to fight off” vaccines. Tr. 92-93, 118-122. The mother did not recall telling the doctor that the baby had recently been vaccinated. However, the paramedics’ record reflects that the family said the baby had received vaccinations two days prior and had become progressively sicker with fever since then. Tr. 122; Pet. Ex. 11 at 3.

The mother only recalled giving one report, possibly to someone from the coroner’s office. Tr. 91. She “would have thought they would have [taken] more time to ask more questions. But they didn’t, they just wanted to know the main things; what had happened at that moment. And that’s all they wanted to know. They didn’t ask for anything else.” Tr. 92. She did not recall being asked details such as whether the baby had vaccinations, had a fever, was fussy, or had abnormal stools. The interview took about ten minutes. It was in English, separate from the grandmother. Tr. 92-94. This was “right away” after the baby was pronounced dead. Tr. 108.

On cross-examination, the mother testified that she also recalled being interviewed by two detectives at the hospital. She agreed that she understood the gravity of their questions about the circumstances which led to her baby’s death and that she had every reason to be truthful with the police. Tr. 100-01. She disagreed with the police and coroner investigator’s record that on November 20 at 10:00 a.m., the baby had a fever of 101 degrees, after which she “gave him another dose of Little Fevers and she stated the fever did not come back.” Pet. Ex. 1 at 18. The mother recalled that the baby maintained a fever “until the day of his death”, including “midnight on the 21st.” Tr. 103; see also 110. She “probably had forgot” to tell the police these details. Id. She generally did not remember what she told the police. Tr. 103-111. She felt the people who interviewed her after the baby’s death took less time than her counsel did later. Tr. 122-23.

The mother testified that after the baby was declared dead and she was interviewed, she and the grandmother remained at the hospital for approximately two hours. Tr. 108. They viewed the baby one last time and then went home. Tr. 94. The police were there taking pictures.

She disputed several records about the baby’s sleeping environment. First, Investigator Dahl’s report provided: “Ms. Cruz stated the bassinet mattress was hard so she placed a standard-sized pillow in it for comfort.” Pet. Ex. 1 at 19. The mother countered that she did not put a pillow on top of the mattress in the bassinet. Rather, she placed a pillowcase around the mattress. Tr. 109-10.

The mother also said that she customarily tucked the pillowcase's sides in, under the mattress. Tr. 84-89. But the police photos seemed to show the mattress "had been lifted up already." Tr. 91-92.

The mother said that she did not remember the bassinet containing the toy and the hat shown in the photos. Tr. 91-92. She said that the police were already there, and then "asked me after I'd come into the room to show them how I wrapped the baby into a burrito." Tr. 95.

3. Facts according to L.J.L.'s Father, Mr. Oscar Lopez Jimenez

Like the mother, the father recalled that on November 19, the baby was healthy; they went to the two-month well visit; and they were told that fever often occurs following vaccination, but if that happened, the baby could take over-the-counter medicine but didn't need to go to the emergency room. After the doctor's visit, the father went to his job at the airport. He was on his regular shift, from 1:30 – 9:30 p.m. He returned home at about 10:00 p.m. He recalled the mother saying that the baby was fussy. Tr. 129-33. The father recalled that on November 20, he spent some time with the baby in the morning, then went to work, returned home at about 10:00 p.m., and then spent additional time with the baby before they went to sleep. Pet. Ex. 3 at 52; Tr. 135-36.

The father testified that normally, the baby was able to look into the parents' eyes. Tr. 129. And normally, the father would tickle the baby, grab him, and carry him around. The baby would laugh, "like a normal child." The baby would "react to anything." But after the vaccinations, the baby "wasn't himself anymore." When the adults fed him or talked to him, he didn't make eye contact. Rather, he stared at the ceiling "like a zombie." Tr. 134-37, 142. The father testified that he believed something was wrong. He planned to take the baby to the doctor the following day. Tr. 134-37.

The father did not get up and respond to the baby overnight. He awoke that morning, upon the grandmother screaming. In his affidavit, the father does not address the baby's position upon being found in the bassinet or who first picked the baby up. The father stated that he called 911 while the grandfather began CPR. Pet. Ex. 3 at 52.

At the hearing, the father testified that the grandmother may have picked the baby up. Additionally, the father thought he saw the baby "face down or on his side." However, the father stated several times that he couldn't really remember and that everything happened very quickly. Tr. 139-44. His testimony was somewhat confused. It was unclear whether he was providing his memories of what he witnessed that morning, or whether he was providing his beliefs as to what occurred. For example, he testified, consistently with the records and the other witnesses, that he was awakened by the grandmother screaming. But then he said he believed the grandmother may have picked the baby up and then put him down again. If the grandmother in fact did so, it was likely before the father woke up and was able to observe. Moreover, the grandmother testified unequivocally that she did not pick the baby up, rather, she screamed and then her husband came into the room, picked up the baby, and carried him into the living room to begin CPR. Tr. 30.

The father testified that he did not recall the hat and the stuffed animal being in the bassinet, as they were shown in the police investigation photos. He recalled those items being on the nightstand. He suggested that the police either placed those items in the bassinet, or directed him, the father, to do so. On this point as well, the father stated that he couldn't remember and it was "horrible" to think about. Tr. 143-44.

The father disagreed with Officer Scott's record of the father saying the baby "had received a Hepatitis B shot 3 days ago and had been running a fever but other than that appeared to be fine." See Pet. Ex. 18 at 2. The father said the baby had not been fine, but the officers "rushed" him and did not ask specific questions. Tr. 137-38. Finally, he did not remember who told him that the baby had passed away. It may have been one of the police officers. Tr. 139.

IV. Findings of Fact

I have carefully reviewed all of the records from the medical providers, the fire and police departments, and the coroner's office; as well as the fact witnesses' affidavits and their testimony. Based on this review, I make the following findings of fact, by a preponderance of the evidence.

- 1) This was the mother's first child. She received regular prenatal care. She did not drink, use recreational drugs, or smoke while she was pregnant or after giving birth. The baby was born at term via Caesarean section. Pet. Ex. 5 at 60-77, 82.
- 2) The record as a whole does not establish that anyone smoked in the home where the mother lived while she was pregnant, or the home where she and the baby lived after he was born. I did consider Dr. Rosenman's handwritten circle around the word "smoking" in the social history from the November 5, 2012, sick visit. This notation is unclear, as the word "smoking" is next to the letter "Y", but no letter "N." Pet. Ex. 6 at 130. Additionally, all three fact witnesses provided that there was no smoking in the grandmother's home. I find their testimony to be wholly persuasive. Tr. 11-12, 52-53, 128. Accordingly, I conclude that there was no smoking in the home.
- 3) The baby was generally healthy, with the exception of some colic. At the hospital, the mother received a suction device which was capable of cleaning the baby's nose. Tr. 6-7. The record does not establish that the suction was used at any specific time prior to the vaccinations.
- 4) The baby received the first Hep B vaccination at the hospital shortly after his birth, and the second Hep B vaccination at Dr. Rosenman's office on November 6, 2012. There is no record of adverse events following these vaccinations.
- 5) On November 19, 2012 at approximately 11:00 a.m., the mother and father took the baby to his two-month well visit with Dr. Rosenman. Pet. Ex. 1 at 18; Tr. 66; 129-30. The baby received the first DTaP, IPV, Hib, Prevnar 13, and Rotavirus vaccinations. He did not receive any other vaccinations. Pet. Ex. 6 at 135.

- 6) There is no indication that the baby had congestion, fever, or other symptoms at this appointment. Although portions of Dr. Rosenman's handwritten record are difficult to read, he clearly marked "no" throughout the entire list of symptoms. Pet. Ex. 6 at 130. Later records do not say that the baby was sick before receiving the vaccinations. They only provide that the baby received his vaccinations and became sick that same day. See Pet. Ex. 1 at 21; Pet. Ex. 11 at 1-2, 38. The witnesses all agreed that the baby was healthy before receiving the vaccinations. Pet. Ex. 3 at 45, 47, 51; Tr. 64-66; 131-33.
- 7) I accept the parents' account that they were told at Dr. Rosenman's office that fever was a common after-effect of vaccinations. If the baby developed a fever, they could give him over-the-counter medication; and fever was not a reason to go to the emergency room. Tr. 64-64; 131-33. While this is not reflected in the records, it is common advice from medical professionals following vaccination, based on my review of cases in the Vaccine Program.
- 8) That afternoon or early evening, the baby developed a fever and he began taking acetaminophen. The fever came down with each dose of acetaminophen, but then returned. See, e.g., Pet. Ex. 1 at 18, 21.
- 9) I find that the fever persisted until at least overnight on November 20 - 21. I carefully considered all of the evidence on this issue, including Investigator Dahl's record providing that the baby had a fever on November 20 at approximately 10:00 a.m., after which he took acetaminophen and "the fever did not come back." Pet. Ex. 1 at 18. Investigator Dahl's record is entitled to some weight, as it was made shortly after the baby's death by a disinterested party. However, she was not a medical provider gathering information for the purposes of treatment. She was interviewing a mother who had just witnessed unsuccessful attempts at resuscitating her child and then learned that her child had passed away. Pet. Ex. 1 at 22.

Several other contemporaneous records suggest that the baby's fever persisted for a longer period of time. Pet. Ex. 11 at 1 (paramedics' record: the baby "progressively more sick with fever" since Monday); Pet. Ex. 1 at 21 (emergency room record: he "had fever (since Monday)"; he "had fever [Monday night] and continued Tuesday"). Additionally, the mother testified that Investigator Dahl's record was incorrect. The mother recalled that she took the baby's temperature, found that he still had a fever, and gave him additional acetaminophen later in the day on Tuesday, November 20. Tr. 115-16. She also recalled that on Wednesday, November 21 at 3:00 a.m., when the baby awoke crying, he "felt hot" and she gave him additional acetaminophen. Tr. 79. The mother also testified that the coroner investigator and police interviews were short, right after the baby had passed away. Tr. 91-94; 100. She could not remember the details of what she told them, but "probably forgot" to give the correct details. Tr. 103-11. I found the mother to be a credible witness. Accordingly, I accept the mother's account that the baby still had a fever on November 21 at 3:00 a.m.

- 10) After the vaccinations, the baby developed some degree of nasal congestion. Several records do not mention either the presence or absence of nasal congestion. Pet. Ex. 11 at 1-2; Pet. Ex. 1 at 21; id. at 38; Pet. Ex. 18 at 1. However, Investigator Dahl does record the mother stating that the baby was “congested.” Pet. Ex. 1 at 18. I will also accept the additional details about the congestion, provided by the mother. Namely, she suctioned the baby’s nose on both sides on the evening of November 19, Tr. 70-71, as well as the morning of November 20, Tr. 75. On November 20, the mucus went from “liquidy and clear” to “thicker and... yellowish.” Tr. 76.
- 11) The mother suctioned the baby’s nose on November 19 in the evening; November 20 at 8:00 a.m.; and November 21 at 6:00 a.m. Tr. 70-71, 75, 83. This is consistent with the notation of congestion, and the mother’s testimony on this point was credible.
- 12) The baby also had minor bowel issues. The emergency room record provides that the baby did not have diarrhea. Pet. Ex. 1 at 21. Investigator Dahl recorded the mother’s statement that the baby had regular bowel movements, the last being somewhat looser on November 20, 2012 at 6:30 a.m. Pet. Ex. 1 at 18. The mother testified that his bowel movements were watery and “yellowish” or “mustardy” in color. Tr. 77. However, contrary to Dr. Dahl’s record, the mother testified that there were several stools of this kind beginning on November 20. Id. The mother also recalled changing his diaper on November 21 at approximately 6:00 a.m. Id. at 83. Therefore, I hereby find that from November 20 to his death, the baby had at least one loose stool which was yellowish or mustardy in color and which did not represent diarrhea.
- 13) The history of the baby’s feeding after the vaccination is somewhat unclear. Records from the paramedics, the emergency room, and the police do not specifically mention feeding. Pet. Ex. 11 at 1-2; Pet. Ex. 1 at 21; Pet. Ex. 18 at 2. The social worker recorded that the mother had fed the baby on November 21 at 6:30 a.m. However, this record does not mention any issues with feeding, such as the baby consuming less formula at that specific time or over the approximately two days since the vaccination. See Pet. Ex. 1 at 38. The police and Investigator Dahl recorded the mother saying that the baby had a good appetite, eating approximately 3-4 ounces of formula every 3 hours and tolerating it well. Pet. Ex. 1 at 18. , Investigator Dahl noted in her summary that the baby took approximately four ounces of formula on November 21 at approximately 6:00 a.m. Id. at 17. However, Investigator Dahl also noted that she observed two bottles on the dresser in the bedroom. Each contained approximately two ounces of formula. Id. at 18. The witnesses contended that after receiving the vaccinations, the baby took less than his normal four ounces at each feeding. The mother specifically testified that the baby drank only one ounce on November 21 at 3:00 a.m., and again at 6:00 a.m. Tr. 79-83. The mother’s testimony is in fact consistent with the unfinished bottles observed by Investigator Dahl. I hereby conclude that the baby consumed less than normal at the last two feedings.

- 14)** With regard to the baby's behavior during the time in question, the records and testimony are not clear. The records do not mention any specific issues other than fever. Pet. Ex. 11 at 1-2; Pet. Ex. 1 at 21; Pet. Ex. 1 at 17-18; Pet. Ex. 18 at 1-2. The paramedics' record that the baby had been getting "progressively more sick with fever" could be interpreted broadly to refer to various sickness behaviors. Pet. Ex. 11 at 1-2. But it could also refer to the fever persisting, getting progressively higher, or uncontrolled by medication, any of which might make the parents increasingly concerned. But the police report, which provides that the baby "had been running a fever but other than that appeared to be fine," seems to suggest there were no other sickness behaviors. Pet. Ex. 18 at 2. In contrast, the mother testified that the baby was unusually fussy and cried a lot. The mother had to pick him up, carry him around, and rock him in order for him to stop crying. Tr. 68-69. The mother and the father also recalled that the baby lost his previous ability to make eye contact and interact with them. Tr. 60-61, 73, 129, 134-37, 142. Upon review, I find it plausible that after the vaccinations, the baby was fussy and cried somewhat more than he usually did. This could be consistent with fever, as his mother described. However, I find it more difficult to accept the testimony that the baby was significantly less responsive. First, this testimony was not particularly clear or compelling. It is perhaps difficult to detail a two-month old infant's baseline relationship with his environment, and how that seemed to change. Moreover, the testimony was somewhat inconsistent. Decreased eye contact and interactions with family members may suggest a diminution of consciousness. However, the baby's fussiness and crying, which abated when he was held, seems to suggest continued awareness. Respondent's ("Resp.") Ex. H at 5. In sum, I do not find that the later descriptions that the baby exhibited a significantly decreased responsiveness to his environment are sufficiently clear, consistent, and compelling to outweigh the contemporaneous records, which provide no such facts. Moreover, I do not find that a two-month old child's lack of eye contact while feeding can be reliably described several years after the fact.
- 15)** While not addressed in the records, per the parents' testimony, the baby was put to sleep in the bassinet next to the parents' bed on November 21 at approximately midnight. He woke up at approximately 3:00 a.m. The mother thought he "felt hot," then gave him a little bit of the fever-reducing medication, fed him, gave him his pacifier, burrito-wrapped him in a blanket, and placed him back to sleep in the bassinet. Tr. 79-82, 135-36.
- 16)** Sometime between 6:00 - 6:30 a.m., the baby woke up again, at which point the mother fed him. Pet. Ex. 1 at 21, 38, 19; Pet. Ex. 18 at 1-2; Tr. 83. The mother added that she also suctioned his nose and changed his diaper at this time. Tr. 83. The mother then burrito-wrapped him and placed him on his left side in the bassinet. Pet. Ex. 1 at 17, 21, 38, 19; Pet. Ex. 18 at 1-2; Tr. 83.

- 17) Upon review of the scene investigation photographs and the testimony, I find that the blanket came up to about the baby's chest and did not cover his breathing passages.
- 18) Shortly before 9:00 a.m., the baby was found unresponsive in his bassinet by his grandmother. The emergency room record provides that "mom found the baby not breathing." Pet. Ex. 1 at 21. However, several other records and the testimony establish that the grandmother found the baby and then woke the parents. Pet. Ex. 1 at 17, 20, 38; Pet. Ex. 18 at 1; Tr. 28-30, 90, 139-43.
- 19) The grandmother found the baby lying on his left side. See Pet. Ex. 1 at 20 (the police's finding that the baby "was placed on his left side... and found by his grandmother in the same position"); Pet. Ex. 1 at 18-19 (Investigator Dahl's observation of lividity on the left side); Tr. 26-28 (grandmother's testimony that he was on his left side). I did not find any support for Dr. Gavin's later notation that "according to investigations, [the baby] was... found face down." Pet. Ex. 1 at 2; see also Resp. Rept. at 6, n. 8.
- 20) The grandmother added that the baby was purple with his eyes closed. She could see his eyes, nose, and mouth. Tr. 26-28. She could also see his shoulders and the top of his right arm. Tr. 47. The baby – from his mid-chest level to his feet - was wrapped in a thin, light blanket. Tr. 25-28, 37-39. The temperature in the home was usually set to 75 degrees Fahrenheit. I also accept the grandmother's testimony to these facts.
- 21) The record as a whole does not reflect that there were any items in the bassinet which impeded the baby's breathing. The police reenactment photos and the testimony are consistent that there was a pacifier in the bassinet. The police reenactment photos show a stuffed toy and a hat in the bassinet, which would have been close by, but probably not close enough to block the baby's face. Pet. Ex. 17. Investigator Dahl also noted the presence of a stuffed toy. Pet. Ex. 1 at 18. However, it is unclear who participated in the reenactment. Moreover, the testimony cast doubt on these facts. The grandmother, who originally found the baby, testified that she could clearly see his face. Tr. 26-28. She did not recall seeing the toy or the hat. The father, who slept in the room with the bassinet, also testified that it had not contained these items. Tr. 143-44. I have some doubt that these items were in the bassinet, but even if they were, they were unlikely to obstruct the baby's breathing.
- 22) The bassinet was made up of a mattress, placed inside a soft surrounding barrier with an attached skirt, on top of a firm base and supports. The mattress was 31 inches long, 16 ¾ inches wide, and 1 ¾ inch thick as measured in the courtroom.

According to Investigator Dahl, the mother "stated the bassinet mattress was hard so she placed a standard sized pillow in it for comfort[, which] was the same size as the bassinet and was approximately 2 inches thick." Pet. Ex. 1 at 18. However, a pillow is not mentioned in any other records or clearly shown in the police reenactment photos. The photos do show that the center of the bassinet has a multi-colored pattern, which contrasts with the white sides and skirt. However, the fabric on the

center seems smooth. The center seems safely underneath the side walls. Pet. Ex. 17. Additionally, the mother testified that Investigator Dahl's record was incorrect. The mother stated that she did not place a pillow on top of the mattress. Rather, she placed a pillowcase around the mattress and tucked any excess fabric under the mattress, inside the bassinet. Tr. 84-89.

It would appear that where Investigator Dahl used the word pillow, she was actually referring to the pillowcase which was the same size of the bassinet mattress and was covered it on all sides. I conclude that there was no additional pillow in the bassinet, rather, the mattress was inside of a pillowcase.

Additionally, the grandmother testified that she found the baby lying in the center of the bassinet. I found that testimony to be credible.

Accordingly, there is no indication that the mattress or other components of the bassinet acted as an external obstruction to the baby's breathing.¹³

- 23) The majority of the autopsy report – including the examination, histopathology, left-sided lividity, measurements, descriptions, and weights – are consistent with the other evidence. These portions of the autopsy report are accepted as fact.
- 24) However, the autopsy report's statements that the baby was found face-down and he died of positional asphyxia are inconsistent with the finding of left-sided lividity. These statements are also inconsistent with the other contemporaneous records and the testimony. Therefore, I do not accept that the baby was found face-down and that he died of positional asphyxia.

V. Conclusion

I have carefully reviewed the record and considered all of the evidence submitted in support of petitioners' claim. This reasoned opinion presents my final findings of fact regarding the period between the baby's vaccinations and his death. Accordingly, the following is **ORDERED**:

- 1) Each party shall discuss these final findings of fact (as well as my other orders issued after the May 1, 2018, fact hearing) with their experts. Each expert must rely on the facts as I have found them in this ruling.

¹³ I believe that this ruling addresses the facts most significant to causation in this case. For example, I found it crucial to address the position in which the baby was found (on his left side) and by whom (the grandmother). However, I do not find it necessary or feasible to resolve certain facts. For example, it remains unclear who first picked up the baby. The grandmother insisted that she did not pick him up. But Investigator Dahl recorded, per the police officers, that the grandmother did pick the baby up. There is a decent likelihood that the police officers obtained this account from the father. However, the father testified that he was sleeping when the grandmother first entered the bedroom, saw the baby, and screamed. I did consider this matter, but find there is insufficient evidence to conclude who picked up the baby first.

- 2) **Within 30 days, no later than Friday, July 20, 2018,** petitioners shall file a status report indicating whether they intend to proceed with this case, and if so, whether it will be with their current experts or if they intend to retain different or additional experts. If petitioners choose to proceed, they also file an Amended Petition.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master