In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 27, 2017

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LINDSEY PELTON, *parent of* N.L.P., *deceased*, *	
*	No. 14-674V
Petitioner, *	
v. *	Chief Special Master Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES, *	Diptheria-Tetanus-Acellular Pertussis ("DTAP"); Hepatitis B ("Hep B"); Inactivated Poliovirus ("IPV");
Respondent. *	Haemophilus Influenzae Type B ("Hib"); Pneumococcal Conjugate; Rotavirus; Sudden Infant Death Syndrome; Asphyxia.
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Patricia A. Finn, Patricia Finn, P.C., Piermont, NY, for petitioner.
Ryan D. Pyles, United States Department of Justice, Washington, D.C., for respondent.

DECISION[1]

On July 29, 2014, Lindsey Pelton filed a petition on behalf of her deceased son, N.L.P., pursuant to the National Vaccine Injury Compensation Program.[2] Ms. Pelton alleged that a diphtheria-tetanus-acellular pertussis (DTaP), Hepatitis B (Hep B), inactivated poliovirus (IPV), haemophilus influenzae type b (Hib), pneumococcal conjugate, and/or a rotavirus vaccination administered to N.L.P. on August 23, 2012, are causally related to his death on August 24, 2012, at four months of age. Petition at Preamble, ¶ 3. Although the cause and manner of death listed on N.L.P.'s death certificate are asphyxia and co-sleeping (Exhibit 7), petitioner contends that what N.L.P. experienced was vaccine-caused Sudden Infant Death Syndrome, ("SIDS") or "a vaccine

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

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

caused death which has no specific hallmarks." Exhibit 16, p. 10.

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has not met her legal burden. Petitioner has failed to provide preponderant evidence that the vaccinations that N.L.P. received on August 23, 2014, caused his death. Accordingly, petitioner is not entitled to compensation and her petition is dismissed.

I. BACKGROUND

A. Procedural History

The petition was filed on July 29, 2014. Petitioner obtained counsel on March, 3, 2015, and the first medical records, including an autopsy report and death certificate, were filed on April 2, 2015. See Exhibits 6, 7. A status conference was held on April 14, 2015, during which the undersigned discussed the records that had been filed to date, including the results and conclusions set forth in the autopsy report and the cause of death listed in the death certificate. The undersigned stated that "[b]ecause the autopsy report states that the child's cause of death was asphyxia due to an accident (prone co-sleeping in adult bed)," there was a question as to whether there was a reasonable basis to pursue the case. Order dated Apr. 15, 2015.

On May 15, 2015, petitioner filed a status report stating that she wished to proceed with litigation of the case and was consulting with potential experts. Pet. Status Report dated May 15, 2015. Respondent filed a status report on June 11, 2015, requesting that petitioner file, *inter alia*, "any and all police reports pertinent to and/or investigative of the death of [N.L.P.], and any and all records of child protective services' investigations related to [N.L.P.] both before and after his death, if any." Resp. Status Report, filed June 11, 2015. Respondent's Rule 4(c) report was filed on August 26, 2015, and reiterated respondent's request for those records. Resp. Report at 2-3. Petitioner filed Rockdale Police records and records from Atlanta Maternal Fetal Medicine on September 25, 2015. Petitioner has since filed autopsy photos, a 911 recording, police records, and additional medical records. See Exhibits 12-15. No records from child protective services were filed, nor has petitioner indicated that they are unavailable.

On October 22, 2015, an order to show cause issued because petitioner had failed to provide any evidence, let alone preponderant evidence, in support of her claim that N.L.P.'s death was causally connected to his vaccinations. On autopsy, it was reported that N.L.P. had been "sleeping in bed with his mother when he was found unresponsive, face down." Exhibit 6, p. 2. The cause of death was ruled to be asphyxia due to co-sleeping in an adult bed. Id., pp. 6-7. N.L.P.'s death certificate also lists the cause of death as asphyxia as a consequence of prone co-sleeping in an adult bed. Exhibit 7. The other medical and emergency personnel records that petitioner submitted were consistent with the autopsy report findings regarding the cause of N.L.P.'s death, and petitioner had not submitted an expert opinion to support her claim. Petitioner had only shown a temporal relationship between N.L.P.'s death and his vaccination, which would not be sufficient to support causation even if other causes of death had been eliminated. Therefore, petitioner was ordered to file proof of evidence supporting her claim no later than November 23, 2015. Order dated October 22, 2015.

On November 20, 2015, petitioner requested and was granted an extension of the above deadline so that she could file the expert report of Dr. Laurel Waters. Subsequently, on December 7, 2015, petitioner filed Dr. Waters's Expert Report and curriculum vitae. Respondent was ordered to file a responsive expert report and on June 1, 2016, filed the curriculum vitae and expert report of Dr. Sara Vargas. On July 14, 2016, a Rule 5 conference was held, in which the undersigned provided her tentative findings based on the expert reports and medical records filed in the case, and knowledge gained from adjudicating similar recent cases in the Program, that it was unlikely that petitioner could prevail. Order dated July 19, 2016. Subsequently, petitioner filed an additional expert report by Dr. Waters, and numerous medical journal articles. See filings dated August 17, 2016. Petitioner also filed a status report indicating that she intended to file a motion for a ruling on the record. On October 11, 2016, petitioner filed her motion for a ruling on the record. Respondent filed her response to the motion on October 28, 2016.

This matter is now ripe for adjudication on petitioner's motion for a ruling on the record.

B. Summary of Relevant Facts

N.L.P. was born prematurely at 33 weeks on April 22, 2012. He weighed four pounds and .09 ounces, and his APGARS were very good at nine and nine. Exhibit 9, pp. 22-24. Because he was premature, he was admitted to the Neonatal Intensive Care Unit ("NICU"). Id., p. 23. He required phototherapy for elevated bilirubin, and the records note that he was breastfed by his mother. Id., p. 24. N.L.P. experienced several episodes of bradycardia (low heart rate) and was seen by a cardiologist. Id., p. 25. The bradycardia was thought to be associated with maternal cardiac medications, including digoxin and metoprolol. Id. N.L.P. was discharged on April 28, 2012, on the seventh day of his life, in stable condition. Id., p. 27.

N.L.P. was seen for his one-week well-child check up on May 1, 2012, by Dr. Cheryl A. Manning. At that time, he weighed four pounds and three and a half ounces and was assessed as normal for his age. Exhibit 3, p. 2. Weight checks were repeated on May 10 and 16, and N.L.P. showed good weight gain. Id., pp. 5-6. At his one month well-child checkup, N.L.P. was prescribed medication for esophageal reflux and preterm formula was prescribed. He weighed five pounds and four and a half ounces. Id., pp. 7-8. On June 7, 2012, N.P.L returned for a weight check, and he weighed five pounds and 14 ounces and was noted to be breastfeeding well with good weight gain, but continuing to supplement with formula. Id., p. 9.

At his two-month well-child check up on June 29, 2012, N.L.P.'s reflux was better and he was doing well. Exhibit 3, p. 10. At this time, he was no longer being breast fed but was on formula. Id. He weighed seven pounds and 12.5 ounces. He received immunizations, including Hep B, Pentacel, Rotovirus, and Prevnar 13. Id., p. 11. N.L.P. returned on August 23, 2012, for his four-month well-child check. There were questions regarding "teething and gnawing," and he was noted to be "drooling with fever 99-100 on and off for the past [two] weeks," although he was noted to be afebrile in the office. Id., p. 12. Otherwise, N.L.P. was "eating fine and playing well, sleeping ok." Id. No vaccine reactions to the prior immunizations were noted. Id. N.P.L weighed 12 pounds and 0.5 ounces. A referral was made to Dr. Christina Weeks, an ophthalmologist, but a reason was not documented. Id., p. 13. N.L.P. received Pentacel, Prevnar 13 and Rotovirus vaccines. Id. It was recommended that N.L.P. begin solid food, beginning with cereals, and advancing to vegetables and fruits. Exhibit 3, p. 12. After the pediatrician visit that day, Ms. Pelton administered Tylenol to N.L.P., and he slept. Exhibit 14, p. 7.

The evening of August 23, 2012, Ms. Pelton went to bed at about 11:00 PM. She put N.L.P. in bed with her, placing him on his back, but "he roll[ed] over to his stomach." Exhibit 14, p. 7. N.L.P. woke up during the night, and Ms. Pelton changed his diaper, gave him one and a half ounces of formula, and they went back to sleep. The next morning, Ms. Pelton awoke about 11:00 AM. She put her hand on N.L.P.'s back and he did not move. She removed the blanket, picked him up, and saw he was not breathing. Id. 911 was called. Police arrived and administered CPR, but resuscitative efforts were unsuccessful. Id., p. 8. Inspection of the bed revealed that the head and the foot of the bed were both elevated, creating "a dip in the middle of the bed." Ex. 14, p. 9. Saliva and blood were found in the area where N.P.L was sleeping. Id.

Dr. Jonathan Eisenstat performed an autopsy at the Dekalb County Forensic Science Center. Ex. 6, p. 2. In his external examination, Dr. Eisenstat noted "lividity on the face with blanching around the nose and mouth." Id., p. 3. Internal examination was remarkable for "scattered petechiae"[3] on the epicardium, pleural surfaces, and throughout the thymus. Id., p. 4. Histologic analysis revealed no specific pathological findings other than a "few microscopic foci of hemorrhage" in heart tissue, medullary congestion of the adrenal gland, and congestion in the lung tissue with "[i]ntravascular chronic inflammation." Id., pp. 5-6. Dr. Eisenstat's opinion was as follows:

> **Opinion:**
> This [four] month ex-32-6/7 week gestational age old baby boy, [N.L.P.] died of asphyxia. Scene investigation revealed the decedent being face down in an adult sized bed co-sleeping with an adult. Autopsy revealed an area of pallor surrounding the nose and mouth, consistent with being in a prone position. A child of this age is unable to extricate himself from a situation of low oxygenation while prone. There is no inflicted trauma to the body and postmortem toxicology and histology were unremarkable, thus the manner of death is accident due to the asphyxia. The incident report from Rockdale Sheriff's office and medical records were reviewed. Scene photographs were reviewed and reveal an adult sized bed with thick bedding and anterior lividity with marked pallor around the nose and mouth of [N.L.P.] while in the ambulance.

Exhibit 6, p. 7.

The cause of N.L.P.'s death was asphyxia, and the manner of his death was accidental ("prone co-sleeping in adult bed"). Exhibit 6, p. 6; Exhibit 7, p. 1.

II. STANDARDS FOR ADJUDICATION

The Vaccine Act was established to compensate vaccine-related injuries and deaths. §300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons.

[3] A petechia (petechiae, plural, or petechial hemorrhage) is "a pinpoint, non-raised, perfectly round purplish red spot caused by intradermal or submucous hemorrhage." Dorland's Illustrated Medical Dictionary at 1422 (32d ed. 2012).

The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioners' burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioners must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccine's injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

To receive compensation under the Program, petitioner must prove either: (1) that N.L.P. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table— corresponding to a vaccine that he received, or (2) that N.L.P. suffered an injury that was actually caused by a vaccination. See §§ 300aa-13(a)(1)(A) and 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that N.L.P. suffered a Table injury, and the evidence does not support a Table injury, she must prove that the vaccines N.L.P. received caused his death. To do so, they must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his death ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his death ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and his death ("Althen Prong Three"). § 300aa–13(a)(1); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The causation theory must relate to the injury alleged. Thus, petitioner must provide a reputable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioners cannot establish entitlement to compensation based solely on their assertions. Rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 300aa-13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material contained in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 300aa-13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); Althen, 418 F.3d at 1280 ("close calls" are resolved in petitioner's favor).

Another important aspect of the causation-in-fact case law under the Vaccine Act concerns the factors that a special master should consider in evaluating the reliability of expert testimony

and other scientific evidence relating to causation issues. In Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), the United States Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In Terran v.Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize Daubert's factors as a framework for evaluating the reliability of causation-in-fact theories actually presented in Program cases.

> 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). In addition, where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed.Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the ipse dixit of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 743 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 146 (1997)).

III. EXPERT OPINIONS AND CAUSATION ANALYSIS

The issue to be resolved is whether the vaccines that N.L.P. received on August 24, 2012, caused or contributed to his death. Petitioner contends, via expert reports by pediatric pathologist Dr. Laurel Waters, that N.L.P.'s death was the result of either vaccine-caused SIDS or "a vaccine caused death which has no specific hallmarks." Exhibit 16, p. 10. However, respondent contends that N.L.P.'s cause of death was unequivocally found to be asphyxia and that, especially in light of that finding, there is insufficient evidence to suggest vaccine causation. Resp. Report at 4. Respondent supports her view with an expert report by Dr. Sara Vargas, who is also a pediatric pathologist.[4] As noted above, petitioner has not alleged, and cannot establish, that N.L.P.'s death was the result of any vaccine Table injury. Accordingly, petitioner's claim turns on the outcome of the undersigned's Althen analysis below.

[4] In her report, Dr. Vargas declined to characterize the findings relating to asphyxia as "unequivocal" as respondent suggested in the Rule 4 report; however, Dr. Vargas nonetheless opined that "they strongly support an asphyxia-related 'sleeping accident' as the cause of death in this case, and asphyxia is the most likely cause of death here." Exhibit A, p. 6.

A. Expert Opinions

(1) Petitioner's Expert Dr. Laurel Waters

Dr. Laurel Waters is a pediatric pathologist and assistant clinical professor at the University of California at Davis School of Medicine, Department of Pathology and Laboratory Medicine, where she teaches pediatric and placental pathology. Exhibit 17, p. 1. She received her M.D. in 1978 from the University of California at Davis and is board certified in pediatric pathology, anatomic and clinical pathology, and nuclear medicine. Id. She also has extensive clinical laboratory experience. Id., pp. 2-3.

Dr. Waters opines that N.L.P. was "not shown to be asphyxiated unequivocally by the autopsy report or the death certificate." Pet. Motion at ¶ 4; Exhibit 16, Ex. 23. She defines asphyxia as "an inadequate amount of oxygen to sustain normal metabolic processes." Exhibit 16, p. 6. According to Dr. Waters, characteristic findings on autopsy traditionally thought to be diagnostic for asphyxia, include "petechial hemorrhages, congestion, cyanosis, dilation of the right heart and fluid blood." Exhibit 16, p. 6, quoting Exhibit 18 (Byard, Roger W., Sudden Death in the Young (3rd Ed. 2011))(hereinafter "Byard").[5] Dr. Waters notes that N.L.P. did not have "facial or conjunctival petechiae," and thus she questions asphyxia as a cause of death. Id. Also, she notes that photographs show a large area of pallor or blanching seen on the back, which, she seems to suggest, call into question whether N.L.P. was prone. Thus, Dr. Waters questions Dr. Eisenstat's conclusions upon autopsy and examination as to cause of death.

According to Dr. Waters, the diagnostic criteria for asphyxia are now obsolete, and more recently, "these findings have been seen in [SIDS]."[6] Exhibit 16, p. 6. She believes that the fact that N.L.P. was found "prone and co-sleeping in an adult bed should be considered risk factors [for SIDS] and not causes of death." Id. An additional risk factor for SIDS includes N.L.P.'s prematurity, as he was born at 33 weeks gestation. Id. Instead of asphyxia, Dr. Waters believes that N.L.P.'s cause of death could represent SIDS. Id. In the alternative, considering the time course, Dr. Waters opines that N.L.P.'s death was caused by his vaccines, and that he had a "vaccine caused death which has no specific hallmarks." She concludes that "the vaccines are likely to have caused the death which was only a day after a full set of infant vaccinations." Id., p. 10.

Dr. Waters defines SIDS as "the sudden death of an infant under one year of age which remains unexplained after a thorough case investigation, including performance of a complete

[5] Petitioner filed only excerpts.

[6] In support of her discussion regarding SIDS and co-sleeping, Dr. Waters cites the following: Exhibit 20 (Li, Ling et al., Observations on increased accidental deaths in infancy while cosleeping in the State of Maryland, Am. J. Forensic Med. Pathol., 2009; 40:318-321)(hereinafter "Li, et al."); Exhibit 21 (Knight, Laura D., et al., Cosleeping and Sudden Unexpected Infant Deaths in Kentucky: a 10-year retrospective case review, Am. J. Forensic Med. Pathol., 2005; 26:28-32)(hereinafter "Knight, et al."); and Exhibit 22 (Blair, Peter S., et al., Bed-sharing in the absence of hazardous circumstances: is there a risk of sudden death syndrome? An analysis from two case-controlled studies in the UK, PLoS ONE 9(9): e107799 (hereinafter "Blair, et al.").

autopsy, examination of the death scene, and review of the clinical history." Exhibit 16, p. 8. She explains that prone sleeping is associated with SIDS, and she identifies a number of mechanisms of death that have been attributed to SIDS, including "smothering, diaphragmatic splinting/fatigue, rebreathing of carbon dioxide, reflex lowering of vasomotor tone with tachycardia, [and] blunting of arousal responses including decreased cardiac response to auditory stimulation." Ex. 16, p. 9. While Dr. Waters concedes that research has not yet identified a mechanism of death in SIDS, she suggests that there is "agreement on a basic model known as the 'triple risk' or 'fatal triangle.'" Exhibit 16, p. 10.

According to this model, SIDS occurs when three factors are simultaneously present: an underlying vulnerability in the infant, a critical developmental period, and an exogenous stressor. The diagram below illustrates the Triple Risk Model:

Exhibit 18, p. 5 (Figure 14.1).

Dr. Waters proposes that vaccines can be an exogenous stressor in a subset of SIDS cases. Exhibit 16, p. 10. She concedes, however, that "[a]t this point in time vaccine-related infant deaths would have no specific hallmarks so they would look exactly like SIDS." Id. In contrast, Dr. Waters acknowledges that prone sleeping is among the known or identified stressors contributing to SIDS. Id.

In a supplemental report, Dr. Waters reviews several additional papers (discussed further below) examining temporal relationships between vaccinations and infant deaths.[7] See Exhibit 23. In light of these articles, she reiterated that additional research is needed to determine whether there is an association between SIDS and immunizations. According to Dr. Waters, each of the

[7] Specifically, these papers are: Exhibit 24 (Pedro L. Moro et al., Deaths Reported to the Vaccine Adverse Event Report System, United States, 1997-2013, Vaccines. Clinical Infectious Disease 2015:61 (September 15), 980-987) (hereinafter "Moro, et al."); Exhibit 25 (Jacqueline Muller-Nordhorn, et al., Association between sudden infant death syndrome and diphtheria-tetanus-pertussis immunization: an ecological study, BMJ Pediatrics 2015, 15:1) (hereinafter "Muller-Nordhorn, et al."); and Exhibit 26 (Miller, Neil Z., and Gary S. Goldman, Infant mortality rates regressed against number of vaccine doses routinely given: Is there a biochemical or synergistic toxicity?, Human and Experimental Toxicology 30(9) 1420-28 (2011))(hereinafter "Miller and Goldman").

cited papers is either supportive of a causal link between vaccine and SIDS or points to the need for additional research on that question. Exhibit 23, pp. 4-7.

(2) Respondent's Expert Dr. Sara Vargas

Dr. Sara Oakes Vargas is a pathologist at three Boston area hospitals: Children's Hospital, Brigham and Women's Hospital, and Beth-Israel Deaconess Medical Center. Exhibit B, p. 2. She is also an associate professor at Harvard University. Id. She received her M.D. in 1994 from the University of Vermont College of Medicine. She is a diplomate of the National Board of Medical Examiners and the American Board of Pathology (Anatomic and Clinical Pathology and Pediatric Pathology). Id.

Dr. Vargas agreed that SIDS could reasonably be included in a differential diagnosis for N.L.P. but opined that the autopsy findings are "fully in keeping with asphyxia," with the facial lividity and blanching around the nose and mouth being the main finding in support of the diagnosis. Exhibit A, p. 5. Dr. Vargas agreed that this finding indicates that N.L.P. was in a prone position and further suggested that the finding indicates that the mouth and nose were pressed against something. Id., p. 7. She explained that "[t]his is because blood pools in the dependent part of the body, but in areas where pressure is applied, the blood is prevented from pooling. This is fully compatible with asphyxiation." Id.

Dr. Vargas also noted that "[a] postmortem determination of the cause of death is made by combining scene investigation and clinical history with autopsy findings." Exhibit A, p. 7. In that regard, Dr. Vargas stressed that scene evidence also contributes to a finding of accidental asphyxia, noting factors including a trough-shaped bed and thick multilayered soft bedding. Id., p. 6.

Dr. Vargas opined on behalf of respondent that "[v]accinations are not known to cause or contribute to asphyxia." Exhibit A, p. 6. She concluded that N.L.P. "died while co-sleeping with his mother with soft bedding, while lying prone in the trough-shaped contour of a mattress, in the setting of a maternal CNS-depressant medication. The cause of death, more likely than not, was asphyxia, which is supported by gross and microscopic autopsy findings in conjunction with a convincing scene investigation. There is no evidence that immunizations caused, or contributed in any way, to [N.L.P.'s] death." Id., p. 8.

B. Althen Analysis

(1) Althen Prong One: Petitioner's Medical Theory

Under Althen Prong One, petitioners must set forth a medical theory explaining how the vaccines could have caused N.L.P.'s death. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009); Pafford, 451 F.3d at 1355-56. A petitioner's theory of causation must be informed by a "sound and reliable medical or scientific explanation." Knudsen, 35 F.3d at 548; see also Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 300aa- 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). With this standard in mind, the undersigned concludes that upon review of Dr. Waters's reports, the literature she has cited, and Dr. Vargas's

competing opinion, petitioner has not met her burden of demonstrating a medical theory causally linking N.L.P.'s death and his vaccinations.

Dr. Waters's principle theory of causation centers on characterizing N.L.P.'s death as a SIDS event. Dr. Waters acknowledges that there is no clear understanding of the mechanism of death in SIDS and that many mechanisms have been hypothesized. Exhibit 16, pp. 9-10. She posits, however, that vaccines may be one among many potential exogenous stressors contributing to SIDS in the context of a generally accepted triple risk model for SIDS causation, contending that "[i]t is very likely that a subset of SIDS cases are caused by vaccines as they can be an exogenous stressor." Id., p. 10. She concedes that "at this point in time vaccine-related infant deaths would have no specific hallmarks so they would look exactly like SIDS." Id. Thus, at base, her theory is premised on a demonstrable association between SIDS and vaccination; however, evidence of that association is lacking.[8]

Although petitioner is not required to provide medical literature supporting her theory (Althen, 418 F.3d at 1279), the basis for an expert's opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it.") (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980)). A special master does not need to

[8] The undersigned notes that her decision in this case is consistent with those in other similar SIDS cases heard by special masters in the Vaccine Program and upheld on review, in which petitioners have been denied entitlement because of the lack of sufficient proof of causation. See, e.g., Doe/11 v. Sec'y of Health & Human Servs., 601 F.3d 1349 (Fed. Cir. 2010) (upholding Special Master Campbell-Smith's decision that a death labeled "SIDS" was not caused by a hepatitis B vaccine); Waterman v. Sec'y of Health & Human Servs., No. 13-960V, 2015 WL 4481244 (Fed. Cl. Spec. Mstr. at June 30, 2015) (Special Master Hamilton-Fieldman denied entitlement in a SIDS case finding that petitioners did not prove that their child suffered an encephalopathy prior to his death); (mot. for review denied 123 Fed. Cl. 564 (Fed. Cl. 2015) (Chief Judge Campbell-Smith)) Sanchez v. Sec'y of Health & Human Servs., No. 11-651V, 2013 WL 4476750 (Fed. Cl. Spec. Mstr. at July 26, 2013) (Special Master Millman found that petitioner failed to prove that vaccinations caused SIDS death); Bigbee v. Sec'y of Health & Human Servs., No. 06-663V, 2012 WL 1237759 (Fed. Cl. Spec. Mstr. Mar. 22, 2012) (Special Master Golkiewicz held that petitioners failed to produce preponderant evidence that the vaccines caused the child's death); Nordwall v. Sec'y of Health & Human Servs., No. 05-0123V, 2008 WL 857661 (Fed. Cl. Spec. Mstr. Feb. 19, 2008) (Special Master Moran held that a SIDS death was not due to a vaccine but rather "positional asphyxia") (mot. for review denied, 83 Fed. Cl. 477 (Fed. Cl. 2008)); Heller v. Sec'y of Health & Human Servs., No. 96-797V, 1998 WL 408612 (Fed. Cl. Spec. Mstr. June 22, 1998) (Special Master Millman found that studies did not show a causal link and that petitioner failed to demonstrate a causal relationship between DPT vaccine and SIDS); and Cozart v. Sec'y of Health & Human Servs., 126 Fed. Cl. 488 (Fed. Cl. 2016) (denying a motion for review where entitlement was denied because petitioners failed to establish that their son's SIDS death was caused by his vaccinations).

credit "expert opinion testimony that is connected to the existing data or methodology 'only by the ipse dixit of the expert.'" Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 61 (2011) (quoting Cedillo ex rel. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010).

When two well-qualified experts opine in contradictory fashion to one another on vaccine causation, support (or lack thereof) in the scientific literature is one factor identified in Daubert to consider when deciding if the expert testimony is reliable. Daubert, 509 U.S. at 596. Moreover, although petitioner is not required to present epidemiological evidence in support of her theory, it is well established that where such evidence is presented, the special master may evaluate it. See, e.g., Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009)(stating that "[a]lthough Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury."); see also Flores v. Sec'y of Health & Human Servs., 115 Fed. Cl. 157 (2014), aff'd 586 Fed. Appx. 588 (Mem.) (Fed. Cir. 2014) (holding that it was not improper for the special master to consider articles submitted by the parties to "determine whether they supported or detracted from [petitioner's] theory of causation . . .").

Here, Dr. Waters's own citations not only fail to support her theory, they undercut her assertion that a subset of SIDS cases can be casually linked to vaccination. Specifically, this assertion is explicitly rejected in many of the articles she submitted. For example, Moro et al., concluded upon their study of VAERS reports from 1997-2013 that there are no "concerning patterns that would suggest causal relationships between vaccinations and deaths." Exhibit 24, p. 7. In fact, in explaining their results, the authors highlighted a prior study that found an age-adjusted death rate within 60 days of vaccination that was lower than the U.S. death rate. Id. The authors additionally noted that an Institute of Medicine ("IOM") review in 2003 rejected a causal association between multiple simultaneous vaccines and SIDS. Id., p. 5. The authors further explained that their own study showed a downward trend in SIDS reports submitted to VAERS. Id. They determined that "[t]here is considerable evidence that vaccination is not causally associated with SIDS." Id.

Another study cited by petitioner, Muller-Nordhorn, et al., sought to conduct an ecological analysis of SIDS mortality rates in the United States from 1968 to 2009 to determine if there was an association with diphtheria-tetanus-pertussis immunization. That study concluded that there is an inverse association. That is, increased DTP immunization was associated with decreased SIDS mortality. Exhibit 25, p. 1 (abstract).

Dr. Waters also cited Byard as authority on the pathological findings of SIDS versus asphyxia. Exhibit 16, p. 6 (citing Exhibit 18, p. 7). As noted by respondent's expert, however, Byard reported that there is no evidence that vaccination can cause SIDS. Specifically, Byard wrote that "it has been demonstrated convincingly in many studies from a number of countries that immunization is not causally related to SIDS." Exhibit 18, p. 9.

In her supplemental report, Dr. Waters argued that the various studies cited by Byard were not appropriately designed and that despite stating that there is no evidence of a link between vaccination and SIDS, Byard nonetheless included vaccinations on a table of postulated causal

mechanisms.[9] Exhibit 23, p 3. She raised similar questions about Moro, et al., and Muller-Nordhorn, et al., arguing in effect that aspects of those studies left the question of vaccine-causation open to further exploration or debate. Id., p. 4-5. Dr. Waters stressed, for example, that the above-mentioned IOM report cited by Moro, et al., concluded that there was inadequate evidence to accept or reject a causal link between vaccination and SIDS. Exhibit 23, p. 4. Nonetheless Dr. Waters's assertion that these studies are flawed or inconclusive is not tantamount to evidence of a link. Even if the undersigned fully credited her criticisms, there would still be no evidence in this record affirmatively supporting her theory.

In total, Dr. Waters cited, and petitioner filed, eight articles or books chapters. Of those eight sources, seven examined evidence relating to the cause(s) of SIDS events.[10] Of those seven, three directly contradict petitioner's theory as described above. Three additional articles: Li, et al. (Exhibit 20), Knight, et al. (Exhibit 21), and Blair, et al. (Exhibit 22), evaluated the risks of co-sleeping and related environmental factors without addressing vaccines as a potential cause of SIDS. Only one of the sources cited by petitioner, Miller and Goldman (Exhibit 26), draws a conclusion potentially supportive of petitioner's theory. That article posits a correlation among developed nations between greater numbers of routine childhood vaccinations and higher infant mortality rates. Exhibit 26. Upon review, however, the undersigned does not find this article persuasive, especially standing alone in contrast to the other above-discussed sources.

First, Miller & Goldman acknowledge a number of confounding factors contributing to infant mortality for which they did not adjust. Additionally, the authors merely speculate, but do not substantiate, that many infant deaths are misclassified as being unrelated to vaccination. In any event, even if fully credited, correlation between vaccine doses and overall infant mortality does not explain how vaccines could cause such injuries and does not suffice to establish a causal theory.[11] See, e.g., Waterman, 2015 WL 4481244, at *6 (finding in a SIDS case that citation to an

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[9] Since these underlying studies discussed by Byard are not part of the record of this case, the undersigned does not reach the question of whether those studies were appropriately designed or not. Dr. Waters is incorrect to suggest, however, that Byard's inclusion of immunizations on his table of postulated causes of SIDS is inconsistent with the conclusion that prior studies have not found any link between vaccination and SIDS. The table Dr. Waters referenced is only a summary of postulated, or previously explored, causes. It does not purport to identify likely causes.

[10] One of petitioner's cited sources (Exhibit 19, Hanzlick) is limited to the proper way to complete a death certificate and does not address the evidence supporting various potential causes of SIDS.

[11] Dr. Waters also points out that the Miller and Goldman article cited further studies by Torch et al., and Walker et al., suggesting increased mortality from SIDS in the days and weeks following diphtheria-pertussis-tetanus vaccinations. Ex. 23, p. 7; Ex. 26, pp. 5-6. However, these studies are not a part of the record of this case. Significantly, Miller and Goldman also cite, but do not discuss, three additional studies that found no evidence of correlation between vaccination and SIDS. Ex. 26, p. 5. Moreover, Moro et al., caution that "[b]ecause a large number of vaccines are given to young children (often simultaneously) at scheduled well-child visits, especially during the first year of life, deaths occurring in close temporal association following vaccination are likely to occur by chance alone." Ex. 24, pp. 6-7.

article correlating vaccine doses and infant mortality is insufficient to satisfy Althen Prong One.)

Thus, Dr. Waters's opinion that vaccines can cause a SIDS event is unpersuasive. Upon review of the entire record, it appears that there is a significant analytical gap between Dr. Waters's theory and the generally-accepted science, leaving Dr. Waters's ipse dixit as the sole basis for this theory. All of the literature she has cited is incongruent with her theory, either because it does not reach the relevant questions or because it contains conclusions directly contrary to her theory. To be clear, the undersigned is not requiring petitioner to produce supporting medical literature. Nor does petitioner have a burden to come forward with a description of the biological mechanism by which vaccine-causation could be found. See, e.g., Knudsen, 35 F.3d at 548-49. On this record, however, Dr. Waters has not provided any other reliable basis upon which to credit her opinion.

Identifying vaccinations simply as one exogenous stressor among many potential exogenous stressors without further explanation falls short of demonstrating proof of a causal theory connecting vaccination to N.L.P.'s death as required under Althen Prong One. If petitioner wished to establish a medical theory other than by reliance on the epidemiological evidence discussed above, it would be incumbent upon petitioner to come forward with some explanation of how vaccination could be considered an exogenous stressor similar to the other generally-accepted or hypothesized stressors or otherwise consistent with the triple risk hypothesis. Absent that, there remains a significant gap in petitioner's theory. That is, the triple risk hypothesis alone does not actually link vaccines to SIDS.

Nor does Dr. Waters's alternative suggestion that N.L.P.'s death otherwise represents "a vaccine caused death which has no specific hallmarks," constitute a medical theory consistent with Althen Prong One. Absent her discussion of SIDS, Dr. Waters does not even posit an alternate cause of death, though she disputes asphyxia as the cause of death, let alone seek to explain how that death was vaccine-caused. Nor does she suggest to what vaccine or vaccines such a death could be attributable. Indeed, her suggestion that such a death would lack any specific hallmark effectively disclaims any demonstrable medical theory consistent with Althen Prong One linking N.L.P.'s death to vaccination. Instead, Dr. Waters relies exclusively on the time-course alone to establish such a link, suggesting that "the timing of [N.L.P.'s] death, a day after a full set of vaccinations, is suspicious for vaccines having a causative role." Exhibit 23, p. 3. This is not sufficient. First, a suspicion of causation does not meet the preponderance standard. See, e.g., W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352 (Fed. Cir. 2013) (stating that "petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury.") Moreover, a temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury").

For all of the reasons above, the undersigned finds that petitioner has not established by preponderant evidence a medical theory causally linking N.L.P.'s death to his vaccinations.

(2) Althen Prong Two: Logical Sequence of Cause and Effect

Althen Prong Two requires preponderant evidence of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. This

prong is sometimes referred to as the "did it cause" test; i.e., the question is whether the vaccine (or vaccines) caused the alleged injury. Broekelschen, 618 F.3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case . . . ."); Pafford, 451 F.3d at 3.

In this case, Dr. Eisenstat concluded upon examination and autopsy that N.L.P.'s cause of death was asphyxia and that the manner of death was accidental. Exhibit 7, p. 7. N.L.P.'s death certificate likewise states that the immediate cause of his death was asphyxia, listing prone co-sleeping in an adult bed as an underlying cause, and further indicating that the injury occurred because the "child rolled over in bed." Exhibit 6.

Dr. Vargas opined on behalf of respondent that "vaccinations are not known to cause or contribute to asphyxia." Exhibit A, p. 6. Nor does petitioner seek to demonstrate a cause and effect linking N.L.P.'s asphyxia to vaccination. Instead, petitioner disputes that asphyxia was the cause of death, arguing instead that N.L.P. experienced SIDS or some other unspecified "vaccine death which has no specific hallmarks." Exhibit 16, p. 10. Specifically, Dr. Waters contends that Dr. Eisenstat's conclusion that N.L.P. experienced accidental asphyxia is flawed, because he incorrectly conflated risk factors for asphyxia with definitive causes of death and misinterpreted certain autopsy findings consistent with SIDS as indicative of asphyxia. Exhibit 16, pp. 6-7. The undersigned does not find either argument persuasive.

Dr. Waters suggests with regard to N.L.P.'s death certificate that "the risk factors for sudden death should be in the section describing how the injury occurred or in the box for other significant conditions with a notation of 'risk factor.'" Exhibit 16, p. 7. She contends that "'prone co-sleeping in adult bed' is a statement of risk factors not causes of death," that position and sleeping arrangement should not be considered definitively causative, and that "most infants who sleep prone and/or co-sleep do not die." Id.

In support of this argument, Dr. Waters cites Cause of Death and the Death Certificate, Important Information for Physicians, Coroners, Medical Examiners, and the Public, edited by Randy Hanzlick, M.D. See Exhibit 19. This is a work prepared by the Forensic Pathology, Autopsy, and Neuropathology Committees of the College of American Pathologists and the National Association of Medical Examiners. Id., p. 2. Contrary to Dr. Waters's assertion, however, this document does not call into question the manner in which N.L.P.'s death certificate was completed. Even in the context of an unexplained death such as SIDS, the College of American Pathologists indicates that a condition such as bed-sharing "could be a stressor or possible external cause of death." Id., p. 5. In that regard, a specific example is provided wherein causes of death include "positional asphyxia," and "wedging between adult bed mattress and wall." Id., p. 9.

Significantly, Dr. Waters does not simply argue that the death certificate was improperly completed, but also further disputes that co-sleeping could have contributed to the death in actuality. She states:

> [T]he [SIDS] literature is clear that all the mentioned factors are simply risk factors as numerous infant nights are spent with the risk factors without death occurring. [N.L.P.]'s usual sleeping environment contained these risk factors every night. The

only difference the night he died was that he had gotten vaccines the day before.

Exhibit 23, p. 3.

Dr. Waters suggests that because most co-sleeping infants do not die, co-sleeping can be considered only a risk factor and not a cause of death. That co-sleeping does not lead to death in many or even most instances does not preclude it from being identified as a cause of death when, as here, evidence supports that conclusion. It is not true that "the only difference the night [N.L.P.] died was that he had gotten vaccines the day before." Evidence suggests that N.L.P. rolled over into a prone position the night of his death with further evidence suggesting that he was covered by bedding. In that regard, Dr. Waters overlooks the specific facts which contributed to the determination that N.L.P. died of asphyxia due to co-sleeping. As Dr. Vargas noted, "[a] postmortem determination of the cause of death is made by combining scene investigation and clinical history with autopsy findings." Exhibit A, p. 7.

Specifically, first responders elicited a history in which petitioner reported that when N.L.P. was discovered to be non-responsive, he had been lying on his stomach[12] and covered by a blanket and that there was saliva in the bed. Exhibit 14, pp. 7-8. Investigators confirmed that there was saliva and blood on the bed sheet.[13] Id., p. 9. Investigators also observed that the adult bed in which N.L.P. was co-sleeping was elevated at both the head and foot of the bed, creating a trough or "dip."[14] Exhibit 14, pp. 8-9. The coroner reportedly demonstrated to the investigators on scene his view that the bedding arrangement likely contributed to the death. Exhibit 14, p. 9. Upon review of the scene photographs during autopsy, Dr. Eisenstat noted the bedding to be "thick." Exhibit 6, p. 7.

In addition to the scene evidence, Dr. Eisenstat indicated that a number of physical findings also supported asphyxiation as the cause of death. He concluded in his autopsy report that N.L.P. had "an area of pallor surrounding the nose and mouth, consistent with being in a prone position." Exhibit 6, p. 7. Dr. Eisenstat also externally observed "lividity on the face with blanching around the nose and mouth." Id., p. 3. Internally he noted "petechiae, thymus, epicardium, and lungs." Id., p. 7.

Dr. Vargas likewise opined that the autopsy findings are "fully in keeping with asphyxia," with the facial lividity and blanching around the nose and mouth being the main finding in support of the diagnosis. Exhibit A, p. 5. Dr. Vargas agreed that this finding indicates that N.L.P. was in a

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[12] Petitioner reported that she had initially put N.L.P. to bed on his back, but that she generally knew him to roll over onto his stomach at night. Exhibit 14, p. 7. She also described checking on him during the night by putting her hand on his back. Id. She described him as "face down" when she found him unresponsive. Id., p. 11.

[13] Blood staining in upper airway secretions is suggestive of asphyxia. Ex. 16, p. 7.

[14] Respondent filed a case report by Combrinck and Byard suggesting that such dips present an asphyxiation danger in themselves. Exhibit C (Combrinck, Marais and Roger Byard, Infant Asphyxia, Soft Mattresses, and the "Trough" Effect, Am J. Forensic Med. Pathol. Vol. 32, No. 3, Sept. 2011).

prone position and further suggested that the finding indicates that the mouth and nose were pressed against something. Exhibit A, p. 7. She explained that "[t]his is because blood pools in the dependent part of the body, but in areas where pressure is applied, the blood is prevented from pooling. This is fully consistent with asphyxiation." Id.

Although Dr. Waters concedes that the blanching on the nose and mouth may indicate a prone position, she contends that Dr. Eisenstat failed to address in his report a larger area of pallor or blanching seen on the child's back, which she observed upon review of the autopsy photographs. Dr. Waters suggests that the blanching on the back suggests a supine position. Exhibit 23, p. 2. Dr. Waters also contends that the pattern of internal petechiae of the thymus, epicardium and lungs, is more consistent with SIDS than asphyxia and that N.L.P. lacked facial and conjunctival petechiae that would be expected with asphyxia. Exhibit 16, p. 6.

Dr. Waters again fails to find significant support for her opinion in the materials she cited. As noted above, Dr. Waters relied on Byard as authority on the pathological findings of SIDS versus asphyxia. Exhibit 16, p. 6 (citing Byard, Exhibit 18). Byard specifically cautions that "there may be minimal findings at autopsy to support [a] diagnosis of asphyxia, leading to misclassification of some [of] these deaths in infants as SIDS." Exhibit 18, p. 3. Moreover, regarding the facial and conjunctival petechiae that Dr. Waters considers very important to an asphyxia diagnosis, Byard explains that such a finding is only expected in cases where vascular compression has prevented capillaries from draining. Thus, it is found in cases of hanging or crushing asphyxia and is not expected in cases of pure hypoxia from smothering or suffocation. Exhibit 18, p. 4.

Regarding Dr. Waters's description of blanching on N.L.P.'s back and lividity on the posterior of his legs (Exhibit 23, p. 2), Byard explains that post-mortem lividity may continue to shift for a number of hours after death and that "most SIDS infants have posterior lividity, as they were either on their backs, or were placed in that position soon after being found." Exhibit. 18, p. 7. In light of this explanation, and especially given that petitioner herself reported that N.L.P. was found on his stomach and not supine (Exhibit 14, pp. 7, 11), it is unlikely that the blanching Dr. Waters observed has the significance she claims. For her part, Dr. Vargas disputed that the pallor on N.L.P.'s back is inconsistent with asphyxiation, noting a number of possible explanations, including post-mortem repositioning of the body by first responders. Exhibit A, p. 7.

Additionally, although Byard notes that 68 to 95% of SIDS victims have petechial hemorrhages in the thymus, epicardium and lungs, he also noted that thymic petechiae "are certainly not specific to SIDS deaths." Exhibit 18, p. 7. Nothing in the record suggests that such findings are inconsistent with asphyxia. Indeed, Dr. Waters conceded in her supplemental report that this pattern of petechial hemorrhages is typical in asphyxia deaths. Exhibit 23, p. 1. Dr. Vargas likewise opined that the internal petechiae found in N.L.P. are also consistent with asphyxiation. Exhibit A, p. 5. Also significant in that regard, Dr. Waters agrees that asphyxia actually is the cause of death in a subset of SIDS cases, suggesting that a finding consistent with SIDS should not necessarily be exclusionary for asphyxia. Exhibit 23, p. 3. Dr. Waters notes that SIDS is a diagnosis of exclusion, stating that "other causes of sudden death in infants need to be ruled out before giving the diagnosis of SIDS." Id., p. 2.

In light of all of the above, and in consideration of the record as a whole, including Dr. Waters's opinion and supporting literature, Dr. Vargas's competing opinion, and the opinions and

records of Dr. Eisenstat and the coroners, the undersigned does not find any basis to question the cause of death listed on N.L.P.'s death certificate. Medical records generally constitute trustworthy evidence. Cucuras v. Sec. Health & Human Servs., 993 F.2d 1525 (Fed. Cir. 1993). Moreover, although rebuttable, the "medical records and medical opinion testimony" of treating physicians can be "quite probative," because "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1278); accord Andreu, 569 F.3d at 1376. Although neither Dr. Eisenstat nor the coroner are treating physicians, it remains the case that they were better positioned than Dr. Waters to evaluate the cause and effect based on in-person inspection of the scene and physical examination of the body. Dr. Waters's critique of Dr. Eisenstat's autopsy report and of the coroner's conclusion as stated in the death certificate is not persuasive, leaving accidental asphyxiation, and not SIDS, as the most likely cause of N.L.P.'s death.

The undersigned further notes in the interest of completeness that petitioner's alternate theory of an unspecified "vaccine death which has no specific hallmarks," fails under Althen Prong Two for the same reason it failed under Althen Prong One. As noted above, absent her discussion of SIDS, Dr. Waters's alternate suggestion of an unspecified "vaccine death" does not posit any specific cause of death alternate to the above-discussed asphyxia or SIDS. Nor does she suggest that the asphyxia was caused by N.L.P.'s vaccines. Her suggestion that such a death would lack any specific hallmark effectively disclaims any demonstration of cause and effect linking N.L.P.'s death to vaccination. Dr. Waters relies exclusively on the time-course alone to establish such a link, suggesting that "the timing of [N.L.P.'s] death, a day after a full set of vaccinations, is suspicious for vaccines having a causative role." Exhibit 23, p. 3. But mere suspicion of a temporal relationship is not sufficient to establish causation. See, e.g., W.C., supra; Veryzer, supra.

For these reasons, the undersigned finds that petitioner failed to provide preponderant evidence of a logical sequence of cause and effect showing that N.L.P.'s vaccinations caused his death.

(3) Althen Prong Three: Proximate Temporal Relationship

Under Althen Prong Three, petitioner must provide "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." De Bazan, 539 F.3d at 1352. The acceptable temporal association will vary according to the particular medical theory advanced in the case. See Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury").

In the present case, given that N.L.P. died just one day following his vaccinations, there is no question that N.L.P.'s death occurred close-in-time to his vaccinations. However, the undersigned's determinations regarding Althen Prongs One and Two are dispositive in this case. Moreover, petitioner has not provided evidence regarding an appropriate timeframe for the occurrence of the type of vaccine-caused death petitioner asserts. Indeed, SIDS deaths are, by their nature, unexplained, with no clear etiology.

Even if petitioner had proved a vaccine-related cause of death, a temporal relationship alone cannot establish causation, nor is it sufficient on its own to meet Althen Prong Three. Veryzer, 100 Fed. Cl. at 356. Thus, petitioner's failure to meet Althen Prongs One and Two means that they cannot be compensated. See, e.g., Koehn v. Sec'y of Health & Human Servs., 2013 WL 321487 (Fed. Cl. 2013) (citing Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to Prong Two when respondent conceded that petitioner met Prong Three); aff'd 773 F.3d 1239 (Fed. Cir. 2014).

IV. CONCLUSION

For all of the reasons discussed above, the undersigned finds that petitioners have not established entitlement to compensation and their petition must be dismissed. In the absence of a timely filed motion for review filed pursuant to Vaccine Rule 23, the Clerk of Court SHALL ENTER JUDGMENT consistent with this decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master