IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 06-559V
Filed: September 14, 2007

GABRIEL GENE RODRIGUEZ, and JENNIFER ANN RODRIGUEZ,	*	
	*	Show Cause; DtaP; Table Injury; Encephalopathy; Death
Petitioners,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

John E. McHugh, Esq., New York, NY, for Petitioners
Robin L. Brodrick, Esq., U.S. Department of Justice, Washington, DC, for Respondent

ORDER TO SHOW CAUSE

VOWELL, Special Master:

On July 31, 2006, petitioners Gabriel ["Mr. Rodriguez"] and Jennifer Rodriguez ["Mrs. Rodriguez"] timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.[1] [the "Vaccine Act" or "Program"], based on the death of their daughter, Giavanna[2] Maria Rodriguez ["Giavanna"]. The petition alleged that Giavanna received "DT DTaP Daptaal,"[3] Hib,

[1] Hereinafter, for ease of citation, all "§" references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

[2] Throughout the transcript, Giavanna's name is misspelled as "Giovana." There are numerous other spelling and transcription errors in this transcript

[3] "DT" refers to a pediatric strength diphtheria and tetanus vaccination. Neil M. Davis, MEDICAL ABBREVIATIONS ["MED. ABBREV."] at 122 (2005). If Giavanna had received a DT vaccination, this would be an entirely different case, as only the pertussis containing vaccines have an associated Table injury of

hepatitis B, IPV, and PVC [4] vaccinations on September 14, 2004, and was found that afternoon "blue and not breathing." Petition ["Pet."], ¶¶ 4, 5. Giavanna was admitted to Albany Medical Center, where she subsequently died on the morning of September 15, 2004. *Id.*, ¶¶ 5, 6. Petitioners deferred a demand for damages, but indicated that they would seek an award of their actual costs, as well as the statutory award based on a vaccine-related death. *Id.*, ¶ 12.

The petition was accompanied by Giavanna's medical, birth, vaccination, hospitalization, and autopsy records; death certificate; and records from the Vaccine Adverse Event Reporting System ["VAERS"] reflecting a search for DTaP and "sids"[5] cases.[6] The petition alleged that Giavanna's death was a "table injury with regard to the DTaP vaccination" and a non-table case with regard to the other vaccines, unless further investigation disclosed her death was due to anaphylaxis. Pet., ¶ 7. The petition also referenced a number of medical journal articles.[7] *Id.*, ¶ 10.

I. Procedural Matters

I held an initial status conference, pursuant to Vaccine Rule 4(a), on August 29, 2006. At that conference, I ordered petitioners to file an expert medical report by September 29, 2006, because one did not accompany the petition. The report of Dr. John Shane, a pathologist, was filed on September 8, 2006. The Emergency Medical Service records were received on October 16, 2006. Respondent's Vaccine Rule 4(c)

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encephalopathy. *See* Vaccine Injury Table ["Table"], 42 C.F.R. § 100.3(a)(II). "DTaP" refers to a diphtheria, tetanus, and acellular pertussis vaccination. MED. ABBREV. at 122. Although the petition identifies a "Daptaal" vaccine, the accompanying vaccination record (Petitioners' Exhibit ["Pet. Ex."] 3, p. 1 refers to a "Daptacel" vaccine. The PHYSICIAN'S DESK REFERENCE ["PDR"] at 2950 (61st ed. 2007) indicates that Daptacel is the brand name for Sanofi-Pasteur's version of the DTaP vaccine.

[4] "Hib" refers to a Hemophilus influenzae type B vaccine. "IPV" refers to a polio vaccine. "PCV" refers to a pneumococcal conjugate vaccine. All of the vaccinations Giavanna received are listed on the Vaccine Injury Table, 42 C.F.R. § 100.3.

[5] Referring to "Sudden Infant Death Syndrome." *See* MED. ABBREV. at 329. The Institute of Medicine Report ["IOM Report"] entitled "Vaccines and Sudden Unexpected Death in Infancy" explains the difference between "SIDS" and "SUDI": "SUDI includes deaths that can be attributed to identifiable causes and deaths for which the causes remain uncertain. SIDS is the diagnosis most commonly given to the deaths of uncertain cause." IOM Report, Abstract at 1. *See also* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1833 (30th ed. 2003) (defining "SIDS").

[6] Filing such excerpts from the VAERS data base, without expert reports interpreting them, establishes nothing more than that some infants die from unknown causes after administration of vaccines. As most infants receive routine childhood vaccinations and SIDS is a cause of death only ascribed to infants, these reports do nothing toward meeting petitioners' burden of proof.

[7] Although petitioners' counsel indicated that he would file them (Transcript ["Tr."] at 8), to date, he has failed to do so.

report and an expert medical report from Dr. Lucy B. Rorke-Adams, a pediatric neuropathologist, were both filed on November 30, 2006. Supplemental reports by each expert and the literature upon which they relied were filed subsequently.

At the Vaccine Rule 5 status conference held on January 5, 2007, I suggested that the parties consider using the slides of tissue taken at autopsy as exhibits in this case, as both experts reports made reference to them and appeared to disagree about what was present on the slides. Order, dated February 7, 2007. Prints of the relevant slides were filed by both parties.

I conducted an entitlement hearing in Philadelphia, PA, on May 18, 2007. Petitioner Gabriel Rodriguez; Giavanna's grandmother, Mary Rodriguez; and Dr. Shane testified for petitioners. Doctor Rorke-Adams testified for respondent. Prior to the hearing, the parties filed, pursuant to my Order, a Joint Status Report Concerning Issues in Dispute ["Jt. Status Rpt."]. Post-hearing briefs and responses thereto having been filed, this case is now ripe for decision.

Based on the factual findings and my legal analysis, as set forth below, respondent is ordered to show cause by September 30, 2007, why I should not issue a decision finding for petitioners based on the existence of a Vaccine Table encephalopathy. Petitioners are ordered to show cause by September 30, 2007, why I should order damages involving petitioners' actual costs, in addition to the statutory award of $250,000 authorized in cases of vaccine-related death.

Additionally, neither the petition nor any of the exhibits filed in this case establishes that petitioners brought their petition on behalf of Giavanna's estate. Only the vaccine-injured person has a cause of action under the Act. Mr. and Mrs. Rodriguez may well be Giavanna's legal representatives, but they must establish their status as such, either by reference to a state statute that gives them that capacity or by demonstrating their appointment by a court of competent jurisdiction. *See* §§ 300aa–11(a)(9) and 11(b)(1)(A). They may then amend their petition to indicate their representative capacity.

II. Factual Findings

A. Stipulated Matters

The parties stipulated to the following facts in the Joint Status Report:

(1) Giavanna received DTaP, IPV, Hib, Hep B,[8] and PCV vaccines;

[8] "Hep B" refers to the hepatitis B vaccine.

(2) Giavanna received the vaccines during a well-baby visit at 11:30 AM on September 14, 2004;

(3) She was found unresponsive and in pulmonary arrest at about 4:00 PM on September 14, 2004; and

(4) She was pronounced dead at 6:20 AM on September 15, 2004.

B. Facts Based on Hearing Testimony and Exhibits

Giavanna was born on May 4, 2004. Pet. Ex. 2,[9] p. 1. She was a large baby, weighing 9 pounds, 13.5 ounces. *Id.*, p. 3. Her father testified that Giavanna's two older brothers were big babies, too. Tr. at 12. Her mother experienced some preterm contractions throughout the pregnancy, but Giavanna was delivered at term. Pet. Ex. 4, pp. 5, 8. Her Apgar[10] scores of 8 and 9 indicate that she was a healthy newborn, although she had shoulder dystocia during the birth. *Id.*, p. 9. She was discharged to home on May 6, 2004. *Id.*, p. 30.

She had well baby check-ups on May 11, June 8, and July 15, 2004. Pet. Ex. 3, pp. 2, 4. Minor concerns were noted at each of these visits: a small subconjunctival hemorrhage in her right eye and mild abdominal icterus at the May visit; problems with gas and fussiness at the June visit; and a history of occasional gasps of a few seconds with a color change at the July visit. In reference to the "gasps", Mary Rodriguez testified that Giavanna was a rapid eater and would gasp to catch her breath after gulping her milk. Tr. at 35-36. At each visit, the doctor's impression was that Giavanna was a well infant. Pet. Ex. 3, p. 2. She received several vaccinations at the July visit without any record of ill effects. *Id*.

Giavanna's four-month well baby visit was on September 14, 2004. The medical records indicated she was doing well and noted several developmental milestones.

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[9] The exhibits that accompanied the petition, including this one, were originally filed using letters rather than numbers. Some of petitioners' exhibits were not given any exhibit designations. The Guidelines for Practice Under The National Vaccine Injury Compensation Program, found at www.uscfc.uscourts.gov, indicate that petitioners' exhibits should be filed using numbers; respondent's exhibits should use letters. As additional exhibits were filed, both parties mistakenly reused an exhibit number or letter to refer to a new exhibit. Before trial, I prepared a list of all the exhibits filed to date and assigned a unique number or letter to each. The exhibit list was provided to each party prior to the hearing, with instructions to use the new exhibit designations in testimony. I later filed this Exhibit List into the record. *See* attachment to Order, dated July 11, 2007.

[10] The Apgar score is a numerical assessment of a newborn's condition, usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND'S at 1670.

Pet. Ex. 3, p. 4. During his clear, concise, and highly credible testimony, Mr. Rodriguez testified about other milestones not listed on her medical records. He indicated that she could roll over, lift her head and look around, and that she tracked voices and sounds. Tr. at 13-14. I have no reason to doubt that Giavanna had demonstrated the milestones Mr. Rodriguez described.

Mr. Rodriguez was caring for Giavanna and her older brothers, Timothy and Michael, on September 14, 2004, while his wife was at work. Timothy went to school that morning, returning home at about 2:00 PM. Tr. at 12-13, 19, 23. At 11:00 AM, Mr. Rodriguez took Michael and Giavanna to their pediatrician's office for Michael's three-year and Giavanna's four-month check-ups. Michael was not due for any vaccinations (Tr. at 37); Giavanna received several that day, although Mr. Rodriguez was not sure which ones. Tr. at 13-14. He was not in the room when she received the vaccinations. Tr. at 31.

Mr. Rodriguez's mother, Mary Rodriguez, worked at the pediatrician's office and actually administered two of the shots Giavanna received. Tr. at 15, 34. To avoid upsetting Michael, the doctor's employees administered Giavanna's vaccinations at the end of the 11:30 AM appointment. *Id.* at 36-37.

After the vaccinations, Mr. Rodriguez stayed to talk with his mother for about half an hour and arrived at home a little after noon. Tr. at 15. Mary Rodriguez testified that they left closer to 12:30 PM. Tr. at 37. Based on the testimony by Mary Rodriguez indicating that the office's practice was to schedule the last morning appointment at 11:30 AM (Tr. at 36), and the testimony from both fact witnesses that they talked for some time after Giavanna's vaccinations, I conclude that the appointment was for 11:30 AM, and that Giavanna most likely received her vaccinations at around noon.

After arriving home, Giavanna played on the floor while Mr. Rodriguez prepared lunch for Michael. After lunch, Mr. Rodriguez tried to get Giavanna to take a bottle and to take her nap at her usual time of from 1:00 to 3:00 PM. She would not take her bottle, which was abnormal for her. He put her back on the floor to play and then tried again to get her to take a bottle, but she was fussy and irritable. Mr. Rodriguez compared her behavior to that of his other children when they were teething or had an ear infection. Tr. at 15-16. She was not screaming or crying hysterically. Tr. at 31. She responded briefly, both to his voice and her toys, for a few minutes and then became fussy again. Tr. at 32. She was still irritable when Mr. Rodriguez finally put her into her crib at around 3:30 PM. Tr. at 16.

He placed her on her back in her crib. She had a blanket, wedge, and a pacifier. She was cranky, did not want to take her pacifier, and was crying when he left the room. He returned two or three minutes later to give her the pacifier again and to try to comfort her. He left the room at around 3:30 or 3:35 PM. Tr. at 17.

Mr. Rodriguez went outside with Michael and returned about 15 or 20 minutes later to check on Giavanna. When he entered the room, Giavanna was lying on her stomach with her eyes closed. Tr. at 18. One eye, her nose, and part of her mouth were visible to him. Tr. at 22. He immediately knew there was something wrong, and lifted her out of the crib. She was limp and her eyes were rolled back. He placed her on the floor and began CPR. He gave her the first set of rescue breaths and then ran to call 911. He continued CPR, consisting of both chest compressions and rescue breathing. *Id*. at 18-19, 32-33.

While Mr. Rodriguez continued rescue breathing, Timothy talked with the 911 dispatcher until the first police officer arrived at their home about five minutes after the emergency call. That officer took Giavanna to the kitchen. The medics then arrived and began trying to resuscitate her. While the medics worked on Giavanna, Mr. Rodriguez called both the pediatrician's office and his mother, who had left work and was driving to her lake house.[11] Tr. at 19-20, 39.

An emergency room physician, Dr. Doynow, arrived within 10 minutes. Within 15 minutes after the medics had arrived, Giavanna was taken to the ambulance and then to the hospital. The hospital was approximately a 10-15 minute drive from the Rodriguez home. Tr. at 20-21.

The emergency response records indicate that the 911 call was received at 4:06 PM and that the medics arrived on the scene at 4:08 PM. Giavanna was transported via ambulance at 4:30 PM, arriving at the hospital emergency room at 4:43 PM. Pet. Ex. 8, p. 1. Giavanna had no pulse, respiration, or blood pressure when the emergency response team arrived. She was unresponsive, pale and cyanotic, with dilated pupils. *Id*. After intubation and bag mask oxygen, faint respirations were noted and her color improved. After two doses of epinephrine, a heart monitor showed a heart rate of 70, although a pulse rate could not be determined. *Id.*, p. 2. After a third dose of epinephrine, her heart rate rose to 130 beats per minute, still without a palpable pulse. *Id*., p. 3. Throughout, Giavanna remained unresponsive. *Id.*, p. 1.

Her temperature on arrival at the emergency room at Albany Medical Center Hospital was subnormal, at 95.1 degrees Fahrenheit.[12] She had a heart rate of 146 and

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[11] Mr. Rodriguez's testimony was that he called his mother while medical personnel were working to resuscitate Giavanna. Tr. at 19. He made no reference to any earlier telephone call. Mary Rodriguez's testimony was that he called her first while Giavanna was being fussy and irritable after the shot, and that he called her again at around 4:00 PM to tell her that Giavanna was "gone." Tr. at 39. It is unnecessary to resolve whether he made one or two calls to his mother. In any event, I found both witnesses to be credible, and I am confident that this discrepancy resulted from an honest mistake.

[12] An airway temperature was recorded as 39 degrees Celsius at 5:05 PM, or approximately 20 minutes after her arrival at the hospital. Pet. Ex. 5, p. 11; Pet. Ex. 8, p. 1. This reading is the equivalent of

very low blood pressure of 57/20. Her pupils were non-reactive. She had no movement in her arms and no response to pain. Pet. Ex. 5, p. 5-6. She had no skin rashes. *Id*., p. 15, 21.

The discharge summary, at Pet. Ex. 5, pp. 2-3, provides a concise explanation of what happened after medical personnel began caring for her at the hospital. She did not have a palpable pulse upon arrival, but resuscitative efforts succeeded in restoring one. She was admitted to the pediatric intensive care unit ["PICU"] with severe acidosis. She was comatose and exhibited some signs of seizure activity. The discharge summary states that she had a fever of 101.6 degrees Fahrenheit upon admission to the PICU; the time of this temperature reading is not reflected in the records. Her pupils were in mid-position and fixed. She had some gasping respirations and a flaccid paralysis with no response to painful stimulation. She appeared to be in a deep coma. *Id.*, p. 2. I specifically find there is no evidence showing that Giavanna was febrile at any point prior to her admission to the PICU. *Compare* Pet. Ex. 5, p. 15 (temperature recorded as 95.1 degrees Fahrenheit in emergency room record), *with* p. 20 ("temp elevated, Tylenol given") in the PICU notes and p. 21 (temperature recorded as 101.6) in PICU attending note with the time recorded as 6:00 PM to 11:15 PM.

Her parents were advised that Giavanna's prognosis for any meaningful recovery was dismal. Pet. Ex. 5, p. 22. Approximately twelve hours after Giavanna's admission, her heart rate plunged to 50 beats per minute and she was ashen and cyanotic. Her breathing tube was removed and she died in her mother's arms at 6:20 AM on September 15, 2004. *Id*., p. 2.

Although the discharge summary indicated that the cause of death was cardiopulmonary arrest due to probable aspiration and asphyxia[13] (Pet. Ex. 5, p. 2), the death certificate had cardiopulmonary arrest crossed out, and an entry reading "cause undetermined after autopsy and investigation" was included. *Id*., p. 1; Pet Ex. 3, p. 12.

An autopsy was performed by Dr. Jeffery Hubbard, but he was unable to determine either the cause or manner of Giavanna's death. There was no evidence of respiratory compromise, although Dr. Hubbard noted that pathologists were unable to

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a temperature of 102.2 degrees Fahrenheit. There is a note on this record with a time of 5:50 PM stating, "temp 37 (adult mode will not function on heater)." This reference to a heater tends to indicate that the temperature recorded at 5:05 PM may have been something other than Giavanna's body temperature. The earliest indication that Giavanna was febrile covered the period 6:00 PM to 11:15 PM. Pet. Ex. 5, p. 21.

[13] During Mr. Rodriguez's conversation with the police officers, he indicated that he was concerned that she might had suffocated on a blanket in her crib, but the blanket was tested and ruled out. Tr. at 28-29. Also, his description of the position of Giavanna's face at the time he found her would be inconsistent with suffocation, because her nose and part of her mouth were visible. I have no way of knowing how much of the original cause of death determination may have been based on his statement.

distinguish SIDS cases from respiratory obstruction. Pet. Ex. 3, p. 13. He concluded that the microscopic bronchopneumonia he observed on autopsy was the result of brain death. *Id*.

I have not summarized the expert medical testimony, as it primarily concerns the actual causation claim. In view of my tentative finding that this case meets the criteria for a Table encephalopathy, it is unnecessary to address the evidence pertaining to the actual causation claim. However, I note that the two experts frequently disagreed about what the tissue slides taken at Giavanna's autopsy actually showed. In general, I found Dr. Rorke-Adams to be a more qualified, reliable, and credible witness than Dr. Shane, particularly with respect to the autopsy slides and what they represented. To the extent that the experts addressed the Table injury issue, I have included relevant portions of their testimony in the following section.

In making the factual findings above, and my tentative conclusion on causation, I have considered the record as a whole.[14]

III. Analysis.

A. In General

Respondent's failure to concede that this is a Table case is inexplicable. There appears to be no genuine issue that, within 72 hours of her DTaP vaccination, Giavanna had an encephalopathy meeting the definition of that condition found in the Vaccine Injury Table. Once a petitioner establishes that the vaccine recipient suffered the injury listed on the Table within the time frame specified, it is immaterial what caused the condition, unless the respondent intends to offer evidence that the injury was caused by a "factor unrelated" to the vaccine. In that case, the burden of proof rests with the respondent to show that the "factor unrelated" caused the condition. Additionally, the postulated alternative cause may not be an idiopathic, unknown, or unexplained cause.

In encephalopathy cases, respondent may attempt to show that the encephalopathy was caused by a number of specific alternate causes listed on the Table. If preponderant evidence of any of these alternative causes is introduced, the idiopathic, unknown, or unexplained alternative cause rule is modified to allow respondent to demonstrate that the encephalopathy resulted from one of these

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[14] *See* § 300aa–13(a): "Compensation shall be awarded...if the special master or court finds on the record as a whole..." *See also*, § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation). As the Table requires, I have considered the entire medical record in reaching my determination that Giavanna's encephalopathy is a condition set forth on the Table. 42 C.F.R. § 100.3(b)(2)(iv).

specified alternate causes, without the necessity of demonstrating what "caused the cause."

However, in this case, respondent is not relying on any of the Table's listed alternate causes of an encephalopathy. By labeling Giavanna's death as an anoxic encephalopathy or SIDS, respondent appears to be sidestepping the idiopathic nature of either cause. I expand upon each of these issues in section C, below.

By offering my factual findings and analysis at this time in an order, rather than in a decision, I am offering respondent the opportunity to re-examine the essentially uncontradicted facts of this case, and to settle or concede it. By the same token, I am offering petitioners the opportunity to accept either a settlement or the statutory death award, rather than litigate the issue of whether costs plus the death benefit may be awarded under the Act. I note that the decision by Judge Wheeler in *Zatuchni v. Sec'y, HHS*, 73 Fed. Cl. 451 (2006), on appeal to the Federal Circuit, presented facts different from those in the instant case. The vaccine recipient in *Zatuchni* was alive at the time she filed the petition and died during the processing of her case from vaccine-related causes. Thus, any Federal Circuit opinion in *Zatuchni* is unlikely to be dispositive of the limitations on a damage award in this case.

B. Applicable Law

The Vaccine Act has two separate methods by which a petitioner may establish entitlement to compensation for an injury. A petitioner may show by the preponderance of the evidence either that: (1) the vaccine recipient sustained a Table injury or (2) the vaccine recipient's injury was actually caused by a vaccine. §§ 300aa–11(c)(1). A Table injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

The Qualifications and Aids to Interpretation ["QAI"] portion of the Table[15] adds, in essence, definitions for the terms used in the Table. One of the conditions specified for compensation after receipt of a pertussis-containing vaccine is an encephalopathy within 0-72 hours from administration of the vaccine. Although the definition of an encephalopathy has changed since the Act was originally passed, Giavanna's condition fits well within the current definition. The QAI provides in pertinent part:

> (2) Encephalopathy. For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic

[15] The Vaccine Injury Table must be interpreted by reference to the QAI's definition of key terms. *Althen v. Sec'y, HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005).

encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

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

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

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (*see* paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

The QAI further provides:

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

42 C.F.R § 100.3(b)(2)(iii).

C. Discussion

Giavanna was admitted to Albany Medical Center Hospital within 72 hours of her

DTaP vaccination with what squarely met the definition of a "significantly decreased level of consciousness." She did not respond to painful stimuli and her pupils were fixed (non-reactive). In short, she was in a deep coma.

In addition to the medical records, petitioner offered expert testimony that Giavanna met the Table definition. After reviewing the Table definition, Dr. Shane testified that she "did have an altered level of consciousness." Tr. at 78. Even respondent's expert, Dr. Rorke-Adams testified: "If the word 'encephalopathy' is used alone, it is basically a clinical description of the facts that the individual's higher mental functions are not behaving properly. It is related to the fact that they are lethargic, or they are unconscious, or there is something wrong with their ability to think. This is an encephalopathy." Tr. at 141-42. This description matched Giavanna's condition upon arrival at the hospital.

Granted, Giavanna's condition persisted for slightly less than 14 hours after admission to the hospital and for about 15 hours after her father found her limp and unresponsive in her crib, and the QAI requires that the chronic encephalopathy persist for more than six months. The persistence requirement of the QAI must be interpreted in light of § 300aa–13(a)(1)'s mandate that the petitioner demonstrate the matters required under § 300aa–11(c)(1). Section § 300aa–11(c)(1)(C)(i) requires a petitioner to allege and prove that the vaccine recipient, "died from the administration of such vaccine, and the first symptom or manifestation of the onset or the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table...."

Whether death alone within 72 hours of vaccination, without evidence of a preceding "seriously decreased level of consciousness," constitutes an encephalopathy is not the issue in this case.[16] Here, Giavanna suffered an encephalopathy and died without regaining consciousness. Petitioners are not using Giavanna's death to establish the existence of an encephalopathy–the encephalopathy was obvious.

The Federal Circuit's analysis in *Hellebrand, supra,* n. 17, is instructive in

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[16] Petitioners argue that the Federal Circuit decision in *Jay v. Sec'y, HHS*, 998 F. 2d 979 (Fed. Cir. 1993), means that death itself constitutes evidence of an encephalopathy. Certain language in *Jay* appears to support their position: "[T]here is no more profound and permanent change in level of consciousness than death." 998 F.2d at 984, n. 6. The court also commented: "We can find nothing in the Vaccine Act which precludes death from being used as evidence of a table injury, here encephalopathy." *Jay*, 998 F.2d at 983. While *Jay* could be read as saying that any death attributable to SIDS, within 72 hours after receiving a pertussis-containing vaccine, constitutes a Table encephalopathy, another 1993 decision of the Federal Circuit contradicts that interpretation. In *Hellebrand v. Sec'y, HHS*, 999 F.2d 1565 (Fed. Cir. 1993), the circuit court reversed a decision by the Court of Federal Claims that held a SIDS death, within the Table time frame after a DPT vaccination, constituted a Table injury. 999 F.2d at 1571. *Hellebrand* is discussed in more detail, *infra*.

interpreting the Table requirements, even though the case dealt with a condition that no longer appears on the Table. Lucy Hellebrand received a DPT vaccination in the afternoon, was seen alive in her crib at midnight, and was found dead the next morning. The medical examiner classified her death as SIDS. In their Vaccine Act petition, Lucy's parents contended that she had experienced the then-existing Table injury of shock-collapse (also known as a hypotonic-hyporesponsive collapse) sometime within 72 hours of a DPT vaccination. *Hellebrand*, 999 F.2d at 1566. The special master refused to consider her death as evidence that she had experienced cardiovascular or respiratory arrest, conditions the QAI considered as evidence of shock-collapse. Finding an absence of symptoms of shock-collapse or any other Table injury, and that petitioners had not established that the vaccine caused Lucy's death, the special master held that the petitioners were not entitled to compensation. Reversing the special master's decision, the Claims Court held that a SIDS death within 72 hours of a DPT vaccination established the Table injury of shock-collapse. *Id*., at 1568; *see also Hodges v. Sec'y, HHS*, 9 F. 3d 958 (Fed. Cir. 1993) (death is not a Table injury of HHE).

The Federal Circuit disagreed, saying, in essence, that if Congress had intended that any death within 72 hours of administration of a DPT vaccine constituted a Table death, Congress would have said so. *Id.,* at 1570-71.

In this case, even if petitioners were contending that Giavanna's initial lapse into unconsciousness was the Table injury, I do not need to reach that issue. Giavanna was resuscitated. She was alive, even though she was in a deep coma. It is that coma that constitutes an encephalopathic state. These uncontroverted facts are sufficient to shift the burden to respondent. Petitioners need not prove anything further regarding the cause of Giavanna's coma. They now benefit from the statutory presumption that her death was vaccine-caused.

However, the presumption is a rebuttable one, and in the case of an encephalopathy, respondent has two routes available for that rebuttal. First, respondent may demonstrate that the encephalopathy was caused by "an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma...." 42 C.F.R § 100.3(b)(2)(iii). Second, respondent may, pursuant to § 300aa–13(a)(1)(B), show by "a preponderance of the evidence that the...death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition."

There no evidence that Giavanna had any infection, toxin, metabolic disturbance, lesion, genetic disorder, or suffered from any trauma. Nothing of this nature was disclosed on autopsy. Respondent's expert, a preeminent pediatric neuropathologist, could only say that, prior to the encephalopathy, Giavanna suffered a cardio-respiratory arrest from an unknown cause. Respondent is thus unable to prove any of the QAI factors listed caused Giavanna's arrest.

Turning then to the "factor unrelated" analysis in subsection 13(a)(1)(B), I again find an absence of proof. Respondent has failed to establish any other cause for Giavanna's death. Viewing respondent's evidence in its most favorable light, Giavanna died from SIDS–or as the pathologist who performed the autopsy stated, the mode and manner of her death are "undetermined." The Vaccine Act excludes "any idiopathic, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" from the "factors unrelated" to the vaccine upon which respondent's proof may rest.

Respondent argues that Dr. Rorke-Adams' testimony demonstrates the existence of a "factor unrelated." I fully agree that Dr. Rorke-Adams' testimony can be summarized as indicating Giavanna suffered "an anoxic encephalopathy which was caused by a cardio-respiratory arrest of unknown etiology." Res. Reply Brief at 3. That was, indeed, Dr. Rorke-Adams' testimony. The problem with respondent's argument is the phrase "of unknown etiology." Ultimately, every death can be reduced to the phrase "cardio-respiratory arrest." However, respondent must establish what caused that cardio-respiratory arrest in order to rebut the presumption that Giavanna's death is compensable as a Table injury.

Doctor Rorke-Adams' testimony was clear, lucid, and compelling on the issue of vaccine causation of Giavanna's death. Were I to reach the issue of actual causation, my conclusions regarding petitioners' entitlement to compensation might well be different. Her opinion undercut that of Dr. Shane on how a vaccine could cause Giavanna's condition and ultimately her death. However, more importantly, it demonstrated that the pathologic findings upon which he based his opinion were either not present or he misinterpreted them.

However, when faced with a Table injury, I do not have to reach any conclusion on causation. Causation is presumed. As the Federal Circuit has stated: "The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation. The Table replaces traditional tort standards of causation in fact with a causation in law based on temporal association." *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992). No changes to the Act or the Table in the 15 years since *Grant* have altered that assessment. See also, H.R. Rept. No. 99-908, 99th Cong., 2d Sess. p. 18 (1986 U.S. Code Cong. and Admin. News 6359) (noting that Congress was well aware that the Vaccine Table might "provide compensation to some children whose illness is not, in fact, vaccine-related."). Doctor Rorke-Adams' testimony largely focused on the question of actual causation. To the extent her testimony addressed the "factors unrelated" issue, she was unable to opine that anything other than something unknown caused Giavanna to stop breathing, suffer a cardiac arrest, or otherwise induced a coma. As she testified on cross-examination:

> Q: Doctor, can you tell us today from what you know about this case what caused this young lady to die?

A: No, I don't know why she had a cardio-respiratory arrest.

Tr. at 221.

I do not know why Giavanna's heartbeat and breathing tragically stopped, sometime between 3:00 PM and 4:00 PM, on the afternoon of September 14, 2004. After resuscitative efforts, she was alive, albeit in a deep coma. A coma within 72 hours of DTaP vaccination constitutes a Table encephalopathy. Thus, I do not need to know what caused those terrible and devastating events, because the Vaccine Table has provided a cause in law. Absent preponderant evidence that a factor unrelated to the vaccine was causal, I must find for petitioners.

I note that I am not the only special master to decide that a diagnosis of "anoxic encephalopathy" is insufficient to remove the Table presumption of vaccine causation in what have sometimes been called "aborted SIDS" cases. Like Giavanna, the infants in these cases are found unconscious, often without either pulse or respiration, are resuscitated, but never regain consciousness. In his opinion in *Hess v. Sec'y, HHS*, No. 90-760, 1991 WL 123577 (Cl. Ct. Spec. Mstr. June 17, 1991), Special Master Hastings found that a death following an anoxic encephalopathy was a Table injury. As he explained: "Obviously, a death that is caused by an anoxic encephalopathy is a sequala *both* to the event that triggered the oxygen deprivation *and* to the encephalopathy itself." (emphasis original). *Hess* at *3.

IV. Conclusion

Respondent is hereby ordered to show cause **by Friday, October 5, 2007**, why I should not find that petitioners have met their burden to demonstrate a Table injury.

Petitioners contended that Giavanna's death was a Table death. I agree. Accordingly, I read § 300aa–15(a)(2) to limit their award to the $250,000 authorized for a vaccine-related death. Petitioners are hereby ordered to show cause **by Friday, October 5, 2007**, why I should not order compensation in the amount of $250,000. They are likewise ordered to demonstrate their capacity to represent Giavanna's estate, either by statute or by their appointment by a court of competent jurisdiction, **by Friday, October 5, 2007.**

IT IS SO ORDERED.

Denise K. Vowell
Special Master