

**OFFICE OF SPECIAL MASTERS**

Filed: August 31, 2005

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TODD NILSON, parent and legal guardian \*  
of JOSEPH EDWARD NILSON, deceased, \*

Petitioner, \*

v. \*

No. 98-797V

SECRETARY OF HEALTH \*  
AND HUMAN SERVICES, \*

Respondent. \*

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Richard H. Moeller, Sioux City, Iowa, for Petitioner.

Linda S. Renzi, United States Department of Justice, Washington, D.C., for Respondent.

**DECISION**<sup>1</sup>

**SWEENEY**, Special Master

On October 16, 1998, Todd Nilson, as parent and legal guardian of Joseph Edward Nilson (“Joey”), deceased, filed a petition for compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. II 2003). The petition alleges that Joey suffered from anaphylaxis or anaphylactic shock and the sequelae of cardiac arrest and death as a result of the oral polio virus (“OPV”);<sup>2</sup> diphtheria, tetanus, and pertussis

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<sup>1</sup> The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secret or commercial or financial information that is privileged or confidential or (2) medical information that would constitute “a clearly unwarranted invasion of privacy.”

<sup>2</sup> The OPV vaccine is “a live vaccine containing attenuated poliovirus . . . and used for immunization against poliomyelitis; administered orally.” Dorland’s Illustrated Medical Dictionary 2000 (30th ed. 2003).

(“DTP”);<sup>3</sup> and measles, mumps, and rubella (“MMR”)<sup>4</sup> vaccinations he received on October 11, 1996.

This case implicates three vaccines: DPT, MMR, and OPV. The question presented is whether the October 11, 1996 administration of any one or combination of these vaccines caused Joey to suffer an encephalopathy as defined in the Vaccine Injury Table (“Table”), 42 C.F.R. § 100.3, or in the alternative, whether his encephalopathy or subsequent death eight days later was caused in fact by his vaccinations. The key factors in the special master’s decision were the credentials and credibility of the expert witnesses, who presented diametrically opposed views at hearing. The testimony of respondent’s expert witness, a highly-credentialed and experienced pediatric neurologist, was far more persuasive than that of petitioner’s expert witness. Indeed, the experts were grossly mismatched. After reviewing the medical records, petitioner’s affidavits, and medical literature, and weighing the testimony of the two expert witnesses, the special master finds that petitioner failed to carry his burden of proving by a preponderance of the evidence that Joey suffered a Table injury or that Joey’s collapse and death were caused in fact by any one or a combination of the vaccines he received on October 11, 1996. The testimony of respondent’s expert convinced the special master by a preponderance of evidence that Joey’s encephalopathy was caused by a factor unrelated to the vaccine.

### FACTUAL HISTORY

Joey was born on September 7, 1991, at Fairview Ridges Hospital (“Fairview Ridges”) in Burnsville, Minnesota, to Todd Nilson and Jayne Pasch.<sup>5</sup> Pet. at 1. Ms. Pasch’s pregnancy was uncomplicated and Joey was declared a “normal newborn male.” Pet. Ex. 2 at 4-5.

Five days after he was born, on September 12, 1991, Joey was taken back to Fairview Ridges with complaints of fussiness and fever. Id. at 5. Due to the bloody fluid obtained from a

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<sup>3</sup> The DTP vaccine is “a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 1998.

<sup>4</sup> The MMR vaccine is “a combination of live attenuated measles, mumps, and rubella viruses, administered subcutaneously for simultaneous immunization against measles, mumps, and rubella.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 1999.

<sup>5</sup> All references to the Petition shall be designated herein as “Pet. at \_\_\_.” All references to the pertinent Petitioner’s Exhibit shall be designated herein as “Pet. Ex. \_\_\_ at \_\_\_.” All references to the pertinent Respondent’s Exhibit shall be designated herein as “Resp’t Ex. \_\_\_ at \_\_\_.”

traumatic spinal tap, Joey was admitted to the hospital to rule out sepsis.<sup>6</sup> Id. Joey was discharged on September 16, 1991. Id. at 7.

Almost three years later, on July 4, 1994, Joey was taken to the emergency room at Fairview Ridges with coughing and wheezing.<sup>7</sup> Pet. Ex. 5 at 1-8. Joey had been taking antibiotics for almost two weeks, but had begun to cough and wheeze the previous day while camping. Id. Additionally, Joey had been taking medication for a rash on his ankles, hands, and feet, but recently developed a new rash on his back. Id. Joey was diagnosed with an acute asthmatic attack. Id. at 4, 17.

Due to difficulty breathing, Joey returned to the emergency room at Fairview Ridges on July 14, 1994. Id. at 9-16. Steve Tvedte, M.D., diagnosed a viral syndrome with reactive airway disease and atopic eczema. Id. During another trip to the emergency room at Fairview Ridges on October 9, 1994, Patricia M. Cook, M.D., diagnosed asthmatic bronchitis. Id. at 19-26.

In November 1994, Mr. Nilson was awarded legal physical custody of Joey. Pet. Ex. 11 at 1. Joey began to reside with Mr. Nilson and his wife, Cathy True, in Jefferson, South Dakota. Id. Soon thereafter, on November 7, 1994, Joey was seen at the emergency room at St. Luke's Regional Medical Center ("St. Luke's") in Sioux City, Iowa, with an asthma attack. Pet. Ex. 6 at 1-5.

On November 9, 1994, Mr. Nilson and Mr. Nilson's mother brought Joey in to see Janice K. Galli, D.O., at Morningside Family Practice, for a complete physical examination. Pet. Ex. 3 at 1. Mr. Nilson expressed concern about Joey's possible emotional and physical abuse and Joey's paternal grandmother added her concerns about possible immune system problems. Id. Upon examination, Dr. Galli reported that Joey was somewhat age inappropriate in his behavior, was easily distracted, and had speech patterns somewhat below what was expected. Id. Dr. Galli diagnosed poorly-controlled asthma and a probable left inguinal hernia or hydrocele.<sup>8</sup> Id. Dr. Galli recommended allergy testing and prescribed medication to treat the asthma. Id.

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<sup>6</sup> Sepsis is "the presence in the blood or other tissues of pathogenic microorganisms or their toxins." Dorland's Illustrated Medical Dictionary, supra note 2, at 1681.

<sup>7</sup> A "Patient Progress Record" indicates that Joey was taken to Fairview Ridges on June 4, 1994, and not July 4, 1994. Pet. Ex. 5 at 1. Due to the extreme similarity between the symptoms reported on the Patient Progress Record and the symptoms described in the remaining records dated July 4, 1994, the court will treat the handwritten "6/4/94" as an error.

<sup>8</sup> A hernia is "the protrusion of a loop or knuckle of an organ or tissue through an abnormal opening." Dorland's Illustrated Medical Dictionary, supra note 2, at 841. An inguinal hernia is a "hernia of an intestinal loop into the inguinal canal." Id. A hydrocele is a circumscribed collection of fluid, especially a collection of fluid in the tunica vaginalis testis or along the spermatic cord." Id. at 870.

Throughout the rest of 1994 and the beginning of 1995, Joey made multiple visits to Morningside Family Practice and the emergency rooms at St. Luke's and Fairview Ridges due to his asthma. See id. at 2-5; Pet. Ex. 5 at 27-33; Pet. Ex. 6 at 6-21. Additionally, Joey was seen on December 19, 1994, by John N. Redwine, D.O., at Morningside Family Practice, for his left hydrocele. Pet. Ex. 3 at 3.

On March 16, 1995, Joey was evaluated by allergist James D. Oggel, M.D., at Sioux City Allergy Associates. Pet. Ex. 4 at 1-2. Dr. Oggel recommended that Joey have minimal exposure to molds. Id. at 2. Joey had two follow-up examinations with Dr. Oggel: March 27, 1995, and August 16, 1995. Id. at 4.

On April 5, 1995, Joey's babysitter brought Joey to the emergency room at St. Luke's because she was unable to keep Joey awake and was having difficulty arousing him. Pet. Ex. 6 at 31. The emergency room physician, Paul A. Berger, M.D., found Joey to be stuporous and in a sleep-like state. Id. Dr. Berger diagnosed hypoglycemia.<sup>9</sup> Id. at 32. Joey awoke after an administration of glucose, but still appeared somewhat distant. Id. Dr. Galli then arrived in the emergency room to examine Joey. Id. at 33-34. While Joey was in the emergency room, he again became unresponsive and developed subtle seizure-like activity. Id. at 34. In order to receive care from a pediatric neurologist, Joey was transferred to McKennan Hospital in Sioux Falls, South Dakota. Id. Joey's discharge diagnosis from St. Luke's was: "coma of undetermined etiology associated with hypoglycemia, hypothermia,<sup>10</sup> and a metabolic acidemia.<sup>11</sup> Seizure activity questioned primary or secondary to other abnormalities." Id. (footnotes added).

At McKennan Hospital, Joey was examined by pediatrician Nancy L. Carroll, M.D., endocrinologist Jerome M. Blake, M.D., and pediatric neurologist Jorge D. Sanchez, M.D. Pet. Ex. 9 at 6-13. Dr. Carroll noted that Joey had two episodes of vomiting the prior weekend,<sup>12</sup> but did not find any neurological abnormalities in her examination and thus recommended an endocrinology consultation for further evaluation of the hypoglycemia. Id. at 7-9. Dr. Sanchez

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<sup>9</sup> Hypoglycemia is "an abnormally diminished concentration of glucose in the blood, which may lead to tremulousness, cold sweat, piloerection, hypothermia, and headache; when chronic and severe it may cause central nervous system manifestations that in rare cases can even be fatal." Dorland's Illustrated Medical Dictionary, supra note 2, at 894.

<sup>10</sup> Hypothermia is "a reduction of core body temperature to 35°C (95°F) or lower . . . ." Dorland's Illustrated Medical Dictionary, supra note 2, at 899.

<sup>11</sup> Acidemia is "a decreased pH (increased hydrogen ion concentration) in the blood." Dorland's Illustrated Medical Dictionary, supra note 2, at 16.

<sup>12</sup> The dates of the prior weekend were Saturday, April 1, 1995, and Sunday, April 2, 1995.

concluded with Dr. Carroll's assessment. Id. at 13. Dr. Blake noted that Joey had never before had a hypoglycemic event and that there was no explanation for the onset of Joey's current hypoglycemia. Id. at 11-12. Dr. Blake was able to rule out an adrenal insufficiency as a cause and posited that Joey could be experiencing ketonic hypoglycemia,<sup>13</sup> a common hypoglycemia, or an organic acidemia,<sup>14</sup> which was very rare. Id. at 12. Dr. Blake recommended monitoring of Joey's blood sugar levels after vomiting and a follow-up visit with Dr. John Shelso in Sioux City.<sup>15</sup> Id. Joey was discharged from McKennan Hospital on April 7, 1995. Id. at 2.

Between April 17, 1995, and January 22, 1996, the physicians at Morningside Family Practice treated Joey for a variety of usual childhood ailments, as well as his asthma. Pet. Ex. 3 at 6-8. Additionally, Joey visited the emergency room at St. Luke's on January 14, 1996, and was diagnosed by Dr. Berger with an acute exacerbation of asthma and an upper respiratory infection/bronchitis. Pet. Ex. 6 at 54.

On February 2, 1996, Joey had successful surgery at St. Luke's to repair bilateral inguinal hernias. Pet. Ex. 7.

Joey continued to be treated for typical childhood ailments and asthma-related conditions between March 19, 1996, and September 23, 1996, at Morningside Family Practice and at the emergency room at St. Luke's. Pet. Ex. 3 at 9-11; Pet. Ex. 6 at 56-70. During an examination on September 23, 1996, Dr. Galli placed Joey back on the medication Prelone.<sup>16</sup> Pet. Ex. 3 at 11.

On October 2, 1996, Mr. Nilson telephoned Morningside Family Practice. Pet. Ex. 3 at 11. He told the nurse who took the telephone call that he was bringing Joey in for a physical examination and vaccinations later that day and was concerned about Joey receiving vaccinations while taking Prelone. Id. The nurse consulted with someone at the St. Luke's pharmacy who said that if Joey was taking a high dose corticosteroid, vaccinations were not recommended because they would be less effective. Id. The nurse also consulted with two of the physicians at

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<sup>13</sup> Ketonic hypoglycemia is "episodic hypoglycemia, ketonuria, convulsions, and vomiting occurring in young children in the early morning after carbohydrate deprivation." Dorland's Illustrated Medical Dictionary, supra note 2, at 894.

<sup>14</sup> Organic acidemia is the "increased concentration of one or more organic acids in the blood." Dorland's Illustrated Medical Dictionary, supra note 2, at 16.

<sup>15</sup> There is no indication in the medical records that Joey was ever examined by Dr. Shelso.

<sup>16</sup> Prelone is the "trademark for a preparation of prednisolone," which is "a synthetic glucocorticoid derived from cortisol, administered orally in replacement therapy for adrenocortical insufficiency and as an antiinflammatory and immunosuppressant in a wide variety of conditions." Dorland's Illustrated Medical Dictionary, supra note 2, at 1500, 1502.

Morningside Family Practice: one physician recommended waiting two weeks for the vaccinations and the other physician stated that so long as the Prelone use was short-term, Joey could have his vaccinations. Id. The nurse shared all of this information with Mr. Nilson. Id.

Mr. Nilson brought Joey in for his physical examination on October 2, 1996, as scheduled. Id. at 13. The pediatrician noted that Joey's developmental milestones were up to date, declared Joey to be a well child for preschool, and advised that Joey wait one week after stopping the Prelone before getting his vaccinations. Id.

On October 11, 1996, Joey returned to Morningside Family Practice and received his DTP, OPV, and MMR vaccinations. Id. at 12. After receiving the vaccinations, Mr. Nilson and his wife took Joey to a movie and dinner at Burger King, where Joey had a sandwich and french fries. Pet. Ex. 11 at 1. Joey slept in the car during the ride home. Id.

The next morning, on October 12, 1996, Joey awoke complaining of pain and soreness in his leg where he received his vaccinations. Id. The morning was uneventful; Joey ate a breakfast of doughnuts, fruit snacks, and juice. Id. Joey's lunch consisted of broiled chicken and Lipton noodles. Id.; Pet. Ex. 12 at 1.

Joey's paternal grandmother, Irma Jean Nilson, and one of Joey's playmates came to Joey's house. Pet. Ex. 11 at 1; Pet. Ex. 12 at 1. Mr. Nilson and his wife left to play golf and Mrs. Nilson took the two children to the mall, where they had ice cream. Pet. Ex. 11 at 1; Pet. Ex. 12 at 1. After a brief stop at home, Mrs. Nilson took the children to the playground. Pet. Ex. 12 at 1. Mrs. Nilson described what happened:

Approximately 1-1 1/2 hours later, after playing on the merry-go-round, Joey began complaining of a stomach ache. Figuring that he might need to use the restroom, I decided to take the children back home. On our way walking back home, I noticed that Joey began turning blue in the hands and face. I attempted to pick Joey up, and he stated, "Don't pick me up, Grandma." Joey then suddenly collapsed to the ground on the perimeter of the park near his home.

Id. Mrs. Nilson further stated that Joey was not coughing or wheezing and did not ask for his nebulizer in the moments just prior to his collapse. Pet. Ex. 24 at 2. Based upon her observations of and experiences with Joey, Mrs. Nilson does not believe that Joey experienced an asthma attack. Id.

Next, according to Mrs. Nilson, a passerby summoned help. Pet. Ex. 12 at 1. The bulk of the medical records explain that cardiopulmonary resuscitation ("CPR")<sup>17</sup> was performed within

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<sup>17</sup> Cardiopulmonary resuscitation is "the artificial substitution of heart and lung action as indicated for cardiac arrest or apparent sudden death resulting from electric shock, drowning, respiratory arrest, and other causes. The two major components of CPR are artificial respiration

a few minutes of Joey's collapse. See Pet. Ex. 13 at 1 (reporting that CPR was being performed upon the first responders' arrival); id. at 3 (stating that CPR was begun approximately three minutes after Joey's collapse); Pet. Ex. 15 at 4 (reporting that a bystander did perform mouth-to-mouth resuscitation). But see Pet. Ex. 14 at 2, 4 (stating that no bystander CPR was performed).

The local emergency team reported that upon their arrival, "the patient was unresponsive, non-breathing, no pulse. We continued with CPR . . . . Patient had been spinning on a merry-go-round got off and complained of not feeling well. Patient then collapsed. We suctioned patient [intermittently] due to vomiting." Pet. Ex. 13 at 1. The paramedics then arrived and advanced resuscitation was performed. Id. at 2-3; Pet. Ex. 14 at 2. The paramedics transported Joey to Marian Health Center in Sioux City. Pet. Ex. 12 at 1; Pet. Ex. 13 at 3.

Upon his arrival at Marian Health Center, Joey initially responded to medications, but after a drop in his heart rate, chest compressions were continued for an additional two minutes. Pet. Ex. 14 at 2. Joey remained ventilated during his entire stay at the emergency room at Marian Health Center. Id. A computed tomography scan ("CT scan")<sup>18</sup> and a chest x-ray were both normal. Id. at 2, 7. Joey's glucose level was initially low but was raised with an infusion of intravenous glucose. Id. at 4. S. M. Caldwell, M.D., made the following assessment of Joey:

1. Status post full arrest.
2. Metabolic acidosis,<sup>19</sup> resolving.
3. Asthma with some acute exacerbation.
4. Unknown etiology of the acute cardiac arrest.

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and closed chest cardiac massage." Dorland's Illustrated Medical Dictionary, supra note 2, at 1617.

<sup>18</sup> A CT scan is a "recording of internal body images at a predetermined plane by means of the tomograph." Dorland's Illustrated Medical Dictionary, supra note 2, at 1919. A tomograph is "an apparatus for moving an x-ray source in one direction as the film is moved in the opposite direction, thus showing in detail a predetermined plane of tissue while blurring or eliminating detail in other planes." Id. In a CT scan, "the emergent x-ray beam is measured by a scintillation counter; the electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube." Id.

<sup>19</sup> Acidosis is "the accumulation of acid and hydrogen ions or depletion of the alkaline reserve (bicarbonate content) in the blood and body tissues, resulting in a decrease of pH." Dorland's Illustrated Medical Dictionary, supra note 2, at 17. In metabolic acidosis, "the acid-base status of the body shifts towards the acid side because of loss of base or retention of acids other than carbonic acid (fixed or nonvolatile acids) . . . ." Id.

Id. at 3 (footnote and emphasis added). With Joey’s condition stabilized, Dr. Caldwell effected Joey’s transfer to McKennan Hospital. Id. at 2-3.

Joey remained unresponsive throughout the transport to McKennan Hospital, where he was admitted to the Pediatric Intensive Care Unit under the care of Dr. Carroll. Pet. Ex. 15 at 4, 23. Dr. Carroll’s examination of Joey revealed a “flaccid unresponsive child who is intubated and on a ventilator and has three intravenous lines . . . . He is passing copious amounts of foul-smelling, yellow stool with watery loss, chunks and blood. . . . The child is having some agonal type gasping respiratory type effort.” Id. at 5. Dr. Carroll’s two impressions were: “Probable severe acute bronchospasm possibly complicated by hypoglycemia leading to full cardiac arrest”<sup>20</sup> and “Child shows clear signs of severe hypoxic brain injury. Prognosis is not good.”<sup>21</sup> Id. at 6. Joey began to have “jerking movements of the jaw and neck suggesting possible seizure activity.” Id.

The next day, on October 13, 1996, pediatric endocrinologist Laura A. Keppen, M.D., performed a metabolic evaluation of Joey. Id. at 7-8. Dr. Keppen reported: “The history of the episode that occurred October 12, 1996, does not sound like hypoglycemia, and does not sound consistent with an inborn error of metabolism that could cause hypoglycemia. It sounds like it could have been respiratory or cardiac. The possibility of an allergic component could also be considered if he would have had a bronchospasm.” Id. at 8 (emphasis added).

Also on October 13, 1996, Dr. Sanchez performed a neurological examination of Joey. Id. at 10. Joey did not respond to pain or other painful stimuli. Id. Dr. Sanchez reported that an electroencephalogram (“EEG”)<sup>22</sup> done that day showed significant slowing. Id. Dr. Sanchez indicated Joey was a “[c]omatose patient secondary to respiratory or cardiorespiratory arrest for unknown reason.” Id. A head CT scan on this day showed “moderate diffuse edema and small ventricles.” Id. at 18.

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<sup>20</sup> A bronchospasm is a “spasmodic contraction of the smooth muscle of the bronchi, as occurs in asthma.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 254. Bronchi are the large air passages of the lungs. Id.

<sup>21</sup> Hypoxic refers to the “reduction of oxygen supply to tissue below physiological levels despite adequate perfusion of the tissue by blood.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 254.

<sup>22</sup> An EEG is “a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 596.



On October 14, 1996, Joey was evaluated by cardiologist Ronald B. Shapiro, M.D. Id. at 12-14. An echocardiogram<sup>23</sup> performed that day revealed normal cardiac activity and an electrocardiogram (“ECG”)<sup>24</sup> performed two days prior appeared essentially normal. Id. at 13. Dr. Shapiro could not determine a cardiac cause for Joey’s collapse based upon his clinical examination or the results of the echocardiogram and ECG. Id. at 13-14.

Another CT scan was performed on October 16, 1996, and “showed progressively more severe edema consistent with global anoxic ischemic event.”<sup>25</sup> Id. at 18. A cerebral brain flow study<sup>26</sup> was also done on this day and cerebral blood flow was present. Id.

On October 17, 1996, nephrologist Robert G. Henrickson, M.D., evaluated Joey for hypernatremia.<sup>27</sup> Id. at 15-16. Dr. Henrickson reported: “Differential diagnosis includes saline resuscitation fluid which I believe was given in a very correct and appropriate manner. Also I believe that from a temporal point of view the hypernatremia did seem to become more dramatic with mannitol therapy. At this time calculations would suggest that the patient is two or three liters deficit for free water.” Id.

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<sup>23</sup> An echocardiogram is the record produced by a graphic recording of “the position and motion of the heart walls or the internal structures of the heart and neighboring tissue by the echo obtained from beams of ultrasonic waves directed through the chest wall.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 585.

<sup>24</sup> An ECG is “a graphic tracing of the variations in electrical potential caused by the excitation of the heart muscle and detected at the body surface.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 595.

<sup>25</sup> Anoxia is “a total lack of oxygen” and can be used interchangeably with the term “hypoxia.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 96. Ischemia is the “deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel.” Id. at 954.

<sup>26</sup> A cerebral brain flow study is technically referred to as cerebral scintigraphy, and is a procedure used to confirm the clinical diagnosis of brain death by determining if there is cerebral blood flow. American College of Radiology, ACR Practice Guideline for the Performance of Cerebral Scintigraphy for Brain Death, at [http://www.acr.org/s\\_acr/bin.asp?CID=1074&DID=12192&DOC=FILE.PDF](http://www.acr.org/s_acr/bin.asp?CID=1074&DID=12192&DOC=FILE.PDF) (last revised 2002). After the administration of a radiopharmaceutical, “two-dimensional images of the distribution of radioactivity in tissues” are produced by a scintillation camera. Id.; Dorland’s Illustrated Medical Dictionary, supra note 2, at 1667.

<sup>27</sup> Hypernatremia is “excessive sodium in the blood.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 884.

A brain flow study was repeated on October 18, 1996, and cerebral blood flow was absent. *Id.* at 18. The results of this study were confirmed with another study performed on October 19, 1996. *Id.* Due to the results of the brain flow studies, as well as Joey's absence of reflexes and lack of respiratory effort, a diagnosis of brain death was established. *Id.* With the approval of Joey's parents, Joey was removed from life support at 12:33 p.m. on October 19, 1996. *Id.* Joey subsequently died. Pet. Ex. 16 at 1. Dr. Carroll indicated that the probable cause of death was "severe acute bronchospasm leading to respiratory and cardiac arrest." Pet. Ex. 15 at 18. Joey's death certificate listed Joey's immediate cause of death as "unknown." Pet. Ex. 16 at 1.

Joey's parents granted permission for a limited autopsy of Joey's heart, lungs, liver, and skin. Pet. Ex. 17 at 1. Pathologist Alfred E. Hartmann, M.D., performed the autopsy on October 20, 1996. *Id.* at 2. Dr. Hartmann reported: "The witnessed sudden cardiorespiratory arrest, along with the pulmonary histological findings, are compatible with the consideration of a chronic asthmatic bronchitis as the underlying cause of the initial cardiorespiratory arrest. The cause of death is sudden cardiorespiratory arrest leading to cerebral central medullary dysfunction." *Id.* at 3. William D. Edwards, M.D., of the Mayo Clinic, agreed with the assessment that Joey's chronic asthmatic bronchitis was the underlying cause of the initial cardiopulmonary arrest. Pet. Ex. 18 at 1.

## DISCUSSION

### The Vaccine Act and Federal Circuit Precedent

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioner<sup>28</sup> proves, by a preponderance of the evidence, all of the elements set forth in § 300aa-11(c)(1)<sup>29</sup> of

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<sup>28</sup> Section 11(b)(1) requires that: (1) only the "person who sustained a vaccine-related injury . . . or the legal representative of any person who died as the result of the administration of a [Table vaccine] . . ." can bring an action for vaccine injury-related claims (so long as the requirements of subsection (c)(1) are satisfied) and (2) that no previous civil action was filed in the same matter.

<sup>29</sup> Petitioner, the legal representative of his minor child who was allegedly injured and died as the result of the administration of a Table vaccine(s), is the appropriate person to maintain this action. In addition, subsection (c)(1) requires, *inter alia*, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that the minor child either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner, as his son's legal representative, has not previously collected an award or settlement of a civil

the Vaccine Act and that the illness is not due to factors unrelated to the administration of the vaccine.<sup>30</sup> Petitioner can recover in one of two ways: either by proving a Table injury or by proving causation in fact. If petitioner proves a Table injury, there is an automatic presumption of causation. Petitioner can prove a Table injury if he shows that Joey received a vaccine listed on the Table and suffered an injury, or an acute complication or sequela of that injury, associated with that vaccine within the prescribed time period. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), -13(a)(1)(A). However, respondent can rebut the presumption by showing that a factor unrelated to the vaccine(s) caused the injury. Id. § 300aa-13(a)(1)(B).

As described above, on October 11, 1996, Joey received the MMR, DPT, and OPV vaccinations, all of which are listed on the Table.<sup>31</sup> The following day, October 12, 1996, Joey suffered an encephalopathy and subsequently, on October 19, 1996, Joey died. An encephalopathy occurring within three days of the administration of the DPT vaccination and within 15 days of receipt of the MMR vaccine can constitute a Table injury if other statutory requirements are satisfied.

The Table defines encephalopathy as an acute encephalopathy followed by a chronic encephalopathy persisting for more than six months past the date of vaccination. 42 C.F.R. § 100.3(b)(2). For children aged 18 months or older, an acute encephalopathy is an encephalopathy that lasts for at least 24 hours and is characterized by at least two of the following symptoms: (1) a significant change in mental status (specifically, a confusional state, delirium, or psychosis) not related to medication, (2) a significantly decreased level of consciousness, or (3) a seizure associated with loss of consciousness. Id. § 100.3(b)(2)(i)(B).

Further, a “significantly decreased level of consciousness” is defined by the presence of at least one of the following three clinical signs for 24 hours or longer: (1) decreased or absent response to the child’s environment, (2) decreased or absent eye contact, or (3) inconsistent or absent responses to external stimuli. Id. § 100.3(b)(2)(i)(D). However, “[t]he following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant

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action for damages arising from the alleged vaccine-related injury or death.

<sup>30</sup> Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a). The petition in this case was timely filed.

<sup>31</sup> The Table injuries for the MMR vaccine include anaphylaxis/anaphylactic shock (within 0-4 hours postvaccination), encephalopathy/encephalitis (5-15 days), chronic arthritis (7-42 days), thrombocytopenic purpura (7-30 days), and vaccine-strain measles viral infection in an immunodeficient patient (0-6 months). 42 C.F.R. § 100.3(a)(III)-(V). The Table injuries for the DPT vaccine include anaphylaxis/anaphylactic shock (0-4 hours), encephalopathy/encephalitis (5-15 days), and brachial neuritis (2-28 days). Id. § 100.3(a)(I)-(II). The Table injuries for the OPV vaccine include paralytic polio (0-30 days or 0-6 months, depending on the patient) and vaccine-strain polio virus infection (0-30 days or 0-6 months). Id. § 100.3(a)(VI).

change in either mental status or level of consciousness . . . : Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle.” Id. § 100.3(b)(2)(i)(E). Further, “[a]n encephalopathy shall not be considered to be a condition set forth in the Table if . . . 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 . . . .” Id. (emphasis added). Thus, if respondent can prove by a preponderance of the evidence that Joey’s encephalopathy was caused by a factor unrelated to the vaccine, such as a metabolic disturbance, then petitioner must proceed on an actual causation theory. Here, petitioner has argued in the alternative.

In order to prevail under a theory of causation in fact, petitioner must show by a preponderance of evidence that the vaccine in question caused the injury. Bunting v. Sec’y of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991). The Federal Circuit has explained what is required to meet that burden. Specifically, petitioner must establish that the vaccine can cause the injury in question, as well as show that the vaccine is in fact the cause of the injury alleged. Hines ex rel. Sevier v. Sec’y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991). To make the requisite showing, petitioner must offer “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Shyface v. Sec’y of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999) (quoting Grant v. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). Although petitioner need not demonstrate her theory of causation to medical or scientific certainty, Knudsen ex rel. Knudsen v. Secretary of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994), causation in fact requires a reputable medical or scientific explanation supporting this logical sequence of cause and effect. Jay v. Sec’y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993) (quoting Grant, 956 F.2d at 1148). As Congress directed, “[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation” for a petitioner seeking to prove causation in fact. H.R. Rep. No. 99-908, at 15 (1986).

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Petitioner must not only show that but for the vaccine he would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface, 165 F.3d at 1352. In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). As the Federal Circuit explained in Knudsen, medical probability means biologic credibility or plausibility: “Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.” 35 F.3d at 547.

In a recent decision, the Federal Circuit instructed:

Concisely stated, [petitioner’s] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of

cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [petitioner] satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

Althen v. Sec’y of HHS, No. 04-5146, 2005 WL 1793399, at \*2 (Fed. Cir. July 29, 2005). The Federal Circuit further explained that the “heavy lifting” required to establish causation by a preponderance of evidence in causation-in-fact cases should not be misconstrued to indicate that the burden is higher than that required by statute:

While it may be true that proof of causation by preponderant evidence is not as “easy” as proof of causation by operation of law, neither Hodges nor Lampe instructs that the preponderance standard itself is to be made more onerous in vaccine cases. Nor is it to be made more difficult merely because our cases have referred to it as “heavy lifting.”

Id. at \*4. This directive notwithstanding, the evidence at trial showed that petitioner cannot prevail because Joey’s encephalopathy was caused by a factor unrelated to the vaccines he received on October 11, 1996; namely, a metabolic disturbance brought about by his cardiorespiratory arrest, which is described in the medical records and explained by respondent’s expert pediatric neurologist. Chronic asthmatic bronchitis, not the vaccines, was the underlying cause of Joey’s initial cardiorespiratory arrest. The vaccines neither caused nor contributed to Joey’s cardiac arrest, encephalopathy, and death.

### **Hearing**

The court conducted a hearing in this matter on July 21, 2004, in Baton Rouge, Louisiana. Petitioner presented two fact witnesses, Joey’s father and stepmother, and one expert witness, Stephanie Cave, M.D. Respondent’s sole witness was Max Wiznitzer, M.D. Although the Nilsons’ fact testimony was compelling and clearly evidenced their devotion to Joey, it did not illuminate or contradict the medical records or either experts’ interpretation of the medical records. Consequently, the following discussion does not rely upon their testimony. However, expert testimony was critical to the disposition of the issues presented in this case and is discussed below.

## Testimony of Petitioner's Expert: Stephanie Cave, M.D.

Dr. Cave received her medical training at Louisiana State University ("LSU") Medical School in New Orleans, graduating in 1983.<sup>32</sup> Tr. at 27. Dr. Cave then served her residency at Earl K. Long Hospital in Baton Rouge. Id. Dr. Cave is board certified in family medicine, but not in pediatrics or neurology. Id. at 27, 72. Dr. Cave has been on the clinical faculty at LSU Medical School since 1986 and currently is in private practice. Id. at 28-29. For 12 years, Dr. Cave had a typical primary care family practice, but, in 1996, she left that practice to begin work with patients with special problems, such as children with autism. Id. at 29. She is not presently practicing in a hospital and described having "more of a clinic practice." Id.

At present, Dr. Cave has 2,500 autistic children in her practice. Id. She also sees adults with problems such as chronic fatigue and depression. Id. Additionally, she is engaged in nutritional therapy with cancer patients who are pre- and post-chemotherapy. Id. As part of her clinical practice, Dr. Cave performs biochemical workups on her patients' cellular chemistry levels. Id. at 31. According to Dr. Cave, because there are so many toxic industries in Baton Rouge, there is a large number of people who are unable to function because of their exposure to petrochemicals and heavy metals. Id. Dr. Cave treats these people using a nutritional program, drugs, and medications. Id. Dr. Cave states that she has been successful in lowering the amount of toxins in her patients' bodies, thereby assisting them to resume their prior lifestyles. Id.

Dr. Cave explained that she has a special interest in allergy medicine because many people in the Baton Rouge area are not only strongly allergic, but also have an overlay of asthma because of the heavy presence of petrochemicals. Id. at 33. In addition to a very strong ozone problem, she also finds there are numerous environmental toxic exposures. Id. In describing the relationship between allergy and asthma, Dr. Cave explained that "[m]ost of the asthma that we see has an allergic basis. We can usually treat the allergies of the patient and take care of the symptoms of asthma." Id. at 33-34. She also sees a lot of heavy metal toxicity in the asthmatics. Id. at 34. Dr. Cave further explained that "[a]sthma is autoimmune. And the presence of heavy metals will push toward an autoimmune picture. This is a picture in which the patient is reacting against their own tissues in many instances." Id.

Dr. Cave testified that vaccines are of special interest to her because approximately 80 percent of the children she treats are brought to her by parents who believe that their child suffered a vaccine injury. Id. at 35. According to Dr. Cave, she is "finding that the children are toxic. They have heavy metals. We're finding seven and eight and nine heavy metals per child. And we're finding particularly aluminum and ethylmercury<sup>33</sup> which are in the vaccines—have

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<sup>32</sup> All references to the Transcript of the July 21, 2004 proceedings shall be designated herein as "Tr. at \_\_\_."

<sup>33</sup> Ethylmercury is a type of mercury, a naturally-occurring metal. National Immunization Program, Mercury and Vaccines (Thimerosal), at <http://www.cdc.gov/nip/vacsafe/>

been in the vaccines.” Id. (footnote added). Dr. Cave believes that her clinical findings have particular relevance here because Joey received a vaccine containing ethylmercury. Id. at 37. She believes there is a connection between aluminum and ethylmercury and asthma. Id. at 38-39.

1. Dr. Cave Testified that the Toxic Vaccines Joey Received Resulted in a Table Injury.

Dr. Cave’s clinical experience and focus on heavy metals, asthma, allergies, and vaccines led her to conclude that the vaccines administered to Joey on October 11, 1996, caused his encephalopathy and death. Id. at 41-42. Dr. Cave explained that Joey was an immunocompromised, sickly child with a history of asthma who was on steroids much of the time. Id. at 41, 50. Despite that history, “He was given very toxic vaccines. He was given ethylmercury and aluminum and viruses. And the very next day, within 24 hours, without any signs of asthma as he’s had many times in the past, the child collapsed.”<sup>34</sup> Id. at 50.

Given her view that Joey’s health was poor, that his immune system was compromised, and that the vaccines Joey received on October 11, 1996 were “toxic,” it is not surprising that Dr. Cave rejects the autopsy conclusion that Joey’s acute bronchospasm caused his encephalopathy and death. Id. at 66. Dr. Cave bases her opinion on the fact that Joey went into metabolic acidosis rather than respiratory acidosis<sup>35</sup> and because there is no mention in the medical records that Joey exhibited such classic asthma symptoms as coughing or wheezing on the day of his collapse. Id. at 63-64. Dr. Cave testified that Joey’s ability to converse with his grandmother just before his collapse shows that his asthma was not the source of his problem on the playground: “A child who is dying of asthma doesn’t talk. They can’t get air. They can’t elicit a conversation.” Id. at 64. Dr. Cave reasoned, “Look at the picture of the child. The child looked well on that day. A child with an acute asthmatic attack doesn’t look well and all of a sudden collapse and lose consciousness.” Id. at 67.

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concerns/thimerosal/thimerosal-vacs-facts.htm (last updated May 18, 2004). Thimerosal, a preservative that helps prevent bacterial contamination, contains approximately 49 percent ethylmercury. Id. Thimerosal was removed from most childhood vaccines beginning in 1999. National Immunization Program, Thimerosal and Vaccines, at <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/faqs-thimerosal.htm> (last updated May 18, 2004). Only one of the vaccines at issue in this case—DPT—contained thimerosal. Id.

<sup>34</sup> Dr. Cave testified that she would not have recommended that Joey be vaccinated on October 11, 1996. Tr. at 187. And she believes that if he had not received the three vaccinations that day, Joey would still be alive. Id. at 49-50.

<sup>35</sup> Respiratory acidosis is “acidosis due to excess retention of carbon dioxide in the body . . . ; it is seen in chronic obstructive pulmonary disease and other conditions that interfere with normal ventilation.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 17.

After rejecting chronic asthmatic bronchitis as the underlying cause of Joey's decline and death, Dr. Cave testified to her belief that Joey's collapse met the Table definition of encephalopathy. Id. at 47, 67, 93. Dr. Cave stated that Joey's event lasted for at least 24 hours and was characterized by a change in mental status that was not medicine-related, and a significantly decreased level of consciousness. Id. at 44-45. Additionally, Dr. Cave testified that there was no indication that Joey's collapse was caused by a toxin or metabolic acidosis. Id. at 44-45, 90. Further, Dr. Cave indicated that the only reason Joey could not meet the six-month requirement for a chronic encephalopathy was because he died. Id. at 45.

Dr. Cave testified that certain medical literature supports her theory of causation: that Joey, an immunocompromised, sickly child with asthma, was given very toxic vaccines containing ethylmercury, aluminum, and viruses, and within 24 hours collapsed, suffered an encephalopathy, and subsequently died. Id. at 50. One article cited by Dr. Cave was written by neurologist Charles M. Poser, M.D., and published in Mealey's Litigation Report.<sup>36</sup> Id. at 51-55. Dr. Cave stated that Dr. Poser's article explained that adverse vaccine reactions, which involve

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<sup>36</sup> Dr. Poser's article was filed as pages 25-26 of Petitioner's Exhibit 23.

Mealey's Litigation Report: Thimerosal and Vaccines ("Mealey's") is a publication written for attorneys. It:

tracks lawsuits nationwide claiming autism and other neurological defects were caused by exposure to the mercury-containing preservative thimerosal in vaccines. Mealey's helps litigators and insurance professionals stay abreast of thimerosal and other vaccine-related litigation in state and federal courts, as well as the National Childhood Vaccine Injury Program. Coverage includes recently filed lawsuits, the latest unearthed discovery, defenses, novel theories of recovery, medical monitoring claims, medical studies, and more.

Mealey Publications, Reports: Drugs & Medical Devices, at [http://www.mealeys.com/rep\\_dmd.html](http://www.mealeys.com/rep_dmd.html) (last visited Aug. 12, 2005).

Dr. Wiznitzer noted that Mealey's is not a peer-reviewed publication. Tr. at 166. However, in his submission to Mealey's, Dr. Poser merely is quoting from accepted medical literature. Id. Dr. Wiznitzer testified that he believed that the quotes were accurate concerning vaccine reactions in certain circumstances. Id. Nevertheless, Dr. Wiznitzer cautioned that it was important to bear in mind that some of the pathology referenced by Dr. Poser was demyelinating in nature. Id. at 166-67. Moreover, Dr. Wiznitzer stressed that the paragraph written by Dr. Poser and relied upon by Dr. Cave did not discuss the DPT or MMR vaccines. Id. at 167. To the contrary, the article references reactions to live virus vaccines. Id. Although the MMR vaccine contains a live virus, Dr. Wiznitzer emphasized that it is biologically impossible to have a reaction to MMR within one day. Id. at 140, 167.



the nervous system, occur from the same pathogenetic mechanism as a virus. Id. at 54. However, as explained in more detail below, Dr. Wiznitzer explained that Dr. Poser's remarks are inapt vis-à-vis these facts. Id. at 167. Thus, Dr. Cave is not credible on this point.

2. Dr. Cave Argued that the Whole-Cell DPT Vaccine Joey Received Was from an Excessively Toxic Lot.

As explained above, one of the vaccines that Joey received on October 11, 1996, was the DPT vaccine. Dr. Cave claimed that the DPT vaccine administered to Joey was from "very toxic lot."<sup>37</sup> Id. at 40. Specifically:

This child did receive the whole-cell DPT. We've traced the lot number back. It was a very toxic lot. There was another death in that lot. And there were six other children who were hospitalized on record. I don't know anything about the hospitalizations.

But out of 77 possible lots that we looked into, there were only five that had greater than 24 reactions reported, and this was one of them. So this was actually one of the most toxic put out at that time.

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<sup>37</sup> Dr. Cave testified that she consulted the Vaccine Adverse Event Reporting System ("VAERS") to make the determination that Joey received a DPT vaccination from a toxic lot. Tr. at 61. VAERS is

a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Frequently Asked Questions About VAERS, at <http://vaers.hhs.gov/vaers.htm> (last visited August 6, 2005). Any person can file a report with VAERS. Id. According to Dr. Cave, only 10 percent of adverse vaccine reactions are actually reported to VAERS. Tr. at 61.

As an example of underreporting, Dr. Cave noted that Joey's death was not reported to VAERS. Id. Of course, because none of Joey's physicians believed that his tragic death was attributable to the vaccines, they would have no reason to report his death to VAERS. Dr. Cave also speculated, "But what if there were many other children who were not aware that [an adverse event were] linked to the vaccine? There may have been other deaths." Id. While it is an intriguing notion, Dr. Cave's speculation that other adverse events, including death, may have occurred, is an impermissible substitute for fact.

We stopped using whole-cell DPT because we saw more neurological problems with the children. It had more cellular components in it than the DTaP.<sup>38</sup>

And Japan had been using it since 1981. That was one of the reasons that they were actually seeing less in the way of neurological problems than we did. And we followed in the early 90s to incorporate this in—the DTaP, instead of the wholesale DTP.

Id. (footnote added). However, other than referencing the number of reports filed with VAERS, Dr. Cave was unable to provide any information showing that the reported death and/or hospitalizations were related to the alleged “toxic lot” of DPT vaccine. Id. at 76-79.

*A. According to the Petitioner, the Alleged Toxic DPT Vaccine Caused Joey’s Cardiorespiratory Arrest.*

Dr. Cave also thought it was significant that Joey received the whole-cell DPT vaccine because it has “10 times the safe level of ethylmercury, which can affect the neurological system and the immune system. It also had aluminum, which is a very toxic metal.” Id. at 41, 80. According to Dr. Cave, a then-recent study showed that there were two to three times more cardiovascular arrests in children who received the ethylmercury-containing whole-cell DPT vaccine. Id. at 43. Thus, she reasoned, Joey’s cardiovascular arrest could be attributed to his DPT vaccination. Id. Dr. Cave testified that “this child in essence had levels of ethylmercury that were 10 times EPA safe and FDA safe. Ethylmercury can cause cardiac arrhythmia. . . . If this child had 10 times [the safe] amount of ethylmercury in a heart that had problems already, he could certainly be pushed to cardiac arrhythmia with[in] 24 hours.” Id. at 179 (emphasis added). Dr. Cave explained that “[e]very child that has this level of ethylmercury doesn’t cardiac arrest. But I don’t think we can say in this child that there was no possibility of an arrest.”<sup>39</sup> Id. at 180.

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<sup>38</sup> DTaP is the abbreviation for diphtheria, tetanus, and acellular pertussis, and is “a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis.” Dorland’s Illustrated Medical Dictionary, *supra* note 2, at 1998.

<sup>39</sup> Unfortunately for petitioner, he cannot prevail merely by stating that something might be possible or by arguing that one should never exclude all possibilities. In Vaccine Program cases, a petitioner must demonstrate by a preponderance of evidence that the vaccine(s) in question more likely than not can cause and did cause an injury or death. Conjecture or speculation is insufficient.

As another example, Dr. Cave testified: “I had one week . . . where I had three patients [who] had a flu vaccine that ended up with pacemakers during the week of the their flu vaccine. I don’t think that was a coincidence. And we found elevated levels of mercury in their urine on

To support her theory that ethylmercury caused Joey's cardiac arrest, Dr. Cave relied upon an article by Mark Geier, M.D.,<sup>40</sup> which was based upon a review of certain VAERS data. Id. at 102-03, 191. Dr. Cave reported that Dr. Geier's article showed "a relative risk between two and three times for cardiac arrest in children that had the whole-cell DPT with thimerosal. And he was comparing it to the DTaP thimerosal-free." Id. at 102. Although it is true that the article purports to make a comparison between certain adverse effects allegedly resulting from thimerosal-containing DPT and DTaP vaccines and non-thimerosal-containing DTaP vaccines, the article is not helpful to petitioner. The numerator data used in the Geier article is derived from the VAERS database. Given the inherent limitations of VAERS,<sup>41</sup> one cannot use VAERS data to draw conclusions about vaccine safety. The mere fact that an adverse event report was filed does not force the conclusion that the vaccine in question caused the alleged injury. Thus, an analysis of VAERS data, while interesting, falls far short of adducing the proof necessary to show that the DPT or DTaP vaccines can cause and did cause injuries in specific cases.

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challenge." Tr. at 179. Although interesting, this information is not of sufficient caliber to adequately support Dr. Cave's theory that the ethylmercury in the vaccine played a role in Joey's injury and death. Nor, for that matter, was her theory concerning the toxic effects of ethylmercury sufficiently developed to support petitioner's claim. The best Dr. Cave could offer was:

So mercury's very toxic. It gets into every enzyme system in the body. It can abruptly change the action of enzymes. And, if you change enzymes, you change protein integrity, you can change any system in the body, including heart or brain. It's a very strong neurotoxin. And we see evidence of this constantly.

Id. at 180. There was no evidence, beyond Dr. Cave's unsupported assertions, that the ethylmercury in any of the vaccines adversely affected Joey.

<sup>40</sup>Mark R. Geier, M.D., Ph.D. & David A. Geier, Thimerosal in Childhood Vaccines, Neurodevelopment Disorders and Heart Disease in the United States, 8 J. Am. Physicians & Surgeons 6-11 (2003). This article was filed as Petitioner's Exhibit 27 at 167-72.

<sup>41</sup> According to the CDC and FDA, VAERS data has certain limitations, including: (1) most reports are voluntary, resulting in underreporting; (2) most reports are unverified; (3) many reports include multiple vaccinations, making it difficult to attribute a reaction to a single vaccination or a combination of a subset of the vaccinations; (4) reporting bias; (5) a lack of incidence rates in unvaccinated comparison groups; and (6) the reports merely show a temporal relationship and do not automatically prove a causative relationship. See <http://vaers.hhs.gov/search/README.txt> (last updated Oct. 2003).

*B. Petitioner Claims that the Alleged Toxic DPT Vaccine Caused a Hypoglycemic Event in Joey.*

In addition to causing cardiac problems, Dr. Cave testified that the DPT vaccine can cause a drop in blood sugar. Id. at 56-58. In this case, Dr. Cave hypothesized that the DPT vaccine could have caused a hypoglycemic reaction in Joey, which in turn could have led to his encephalopathy. Id. at 56-59. Dr. Cave based her theory on information contained in a paper published in the Third International Symposium of Pertussis.<sup>42</sup> Id. at 56-57. Dr. Cave claimed that the paper supported the notion that one of the side effects of the pertussis component of the DPT vaccine is a rise in blood insulin or a fall in blood sugar. Id. at 58-59. But, a review of the paper reveals that it does not discuss the magnitude of the insulin increase or sugar decrease, nor does it explain how the pertussis toxins cause the insulin or sugar level changes.

Dr. Cave believes it is significant that the medical records indicate that Joey's glucose level was at 51 after his collapse. Id. at 56, 59, 99. Dr. Cave explained that:

If the child's blood sugar drops to the point where it's 51 after glucose infusion,<sup>43</sup> it could have dropped to a level that would have taken him into an encephalopathic state.

If we can go back and find evidence that the pertussis vaccine itself can cause a rise in blood insulin or a fall in blood sugar, I think we have to say that it could be a possibility that it's a side effect of the DPT vaccine.

Id. at 59 (footnote added). Not only is this testimony pure conjecture, but Dr. Cave also conceded that, generally, a blood sugar level of 51 is not significant enough to cause death. Id. at 100. However, she added that there is no set time frame within which low blood sugar causes brain damage: "It depends on the patient and the biochemical setup of the patient. It doesn't take very long." Id. In general, Dr. Cave stated that brain damage would begin between five or eight minutes, depending on the patient, after being deprived of blood sugar. Id.

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<sup>42</sup> G.T. Stewart, Pertussis Vaccine: The United Kingdom's Experience, in Third International Symposium on Pertussis 262, 262-78 (1979). This article was submitted as Petitioner's Exhibit 23 at 7-22.

<sup>43</sup> Dr. Cave repeatedly testified that Joey's blood glucose level was 51 after an infusion of glucose. Tr. at 56, 59, 99-100. However, the paramedic records do not indicate a glucose infusion, or even a check of Joey's glucose level. Pet. Ex. 13 at 1-2. In fact, the first reported glucose check was at Marian Health Center—the result of this check was a level of 51. Pet. Ex. 14 at 4, 9. Joey was given intravenous glucose and his level increased to 395 less than one hour later. Id.

3. Petitioner Asserts that the MMR and OPV Vaccines, Which Contain Live Viruses, Overwhelmed Joey’s Compromised Immune System.

From Dr. Cave’s perspective, the DPT vaccine was not the sole culprit in Joey’s collapse and death. To the contrary, Dr. Cave testified that the MMR and OPV vaccines, which contain a total of four to five live viruses, overwhelmed Joey’s compromised immune system. Id. at 40-41. Dr. Cave also stated that the MMR vaccine was “contaminated with retroviruses.” Id.

With regard to the MMR vaccine, Dr. Cave explained:

We’ve found in some of the autistic children<sup>44</sup> that they actually—after the MMR, the ones who have the history, where they have an acute process going on following the vaccine—and it will be sometimes within 24 hours, sometimes within two days, sometimes five or six—we’ve found live viral particles, vaccine-type in the spinal fluid of these children, as well as in the bowel of these children.

...

If you have live viral measles particles in the spinal fluid, it can cause encephalopathy or encephalitis.

... [W]e don’t know if it goes into the spinal fluid in the first 24 hours following the vaccine. We really don’t have that information. But, you know, I would never say there’s no medical possibility this could ever happen.

Id. at 181 (footnote added). However, Dr. Cave’s theory is undercut in this case because there is no evidence that Joey had live viral measles particles in his spinal fluid—in fact, Joey’s spinal fluid was not examined after his October 11, 1996 MMR vaccination. Moreover, Joey did not react within the appropriate time frame; adverse reactions to the MMR vaccine typically occur between 10 and 14 days. Id. at 140, 167.

Despite Dr. Cave’s emphatic belief that Joey’s October 11, 1996 vaccinations caused his encephalopathy and subsequent death, Dr. Wiznitzer’s highly-credible testimony proves otherwise.

**Testimony of Respondent’s Expert: Max Wiznitzer, M.D.**

Dr. Wiznitzer performed his undergraduate work at Northwestern University in the honors program for medical education. Id. at 114. He received a bachelor of science in medicine and two years later, he was awarded his medical degree. Id. After medical school, Dr. Wiznitzer

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<sup>44</sup> There is no evidence that Joey was autistic.

trained in pediatrics (Children's Hospital Medical Center in Cincinnati, Ohio), developmental disabilities (Cincinnati Center for Development Disorders), and was awarded a child neurology fellowship at the Children's Hospital of Philadelphia. Id.

Dr. Wiznitzer also did a National Institutes of Health fellowship at Albert Einstein College of Medicine, where he dealt with disorders of higher cortical or cognitive function in children. Id. During this period, he received training in electrophysiology and gained additional knowledge about neurodevelopmental disorders. Id. Dr. Wiznitzer is board certified in pediatrics and in psychiatry and neurology, with special competencies in child neurology and neurodevelopmental disabilities. Id.; Resp't Ex. B at 4.

Dr. Wiznitzer currently has a clinical practice at Rainbow Babies and Children's Hospital in Cleveland, Ohio, which involves, among other things, seeing patients, performing electrophysiologic interpretation, and running the evoked potentials laboratory. Tr. at 115. Part of Dr. Wiznitzer's responsibilities as a practicing pediatric neurologist is to diagnose encephalopathies.<sup>45</sup> Id. at 116-17. And, he explained that like all physicians affiliated with a medical center, he supervises students and trainees. Id. at 115-16.

In addition to his education, training, and practice, Dr. Wiznitzer assisted with the rewriting of the criteria for encephalopathy, encephalitis, and multiple sclerosis for VAERS. Id. at 115. At the time of hearing, Dr. Wiznitzer was working with the Brighton Collaboration, a group of health care professionals developing standard criteria for helping define events that occur postvaccination. Id. He was asked to join the group to assist developing the criteria for encephalitis, encephalomyelitis, and acute disseminated encephalomyelitis. Id.

Dr. Wiznitzer has previously been involved in Vaccine Program cases, in three capacities. Id. at 117. He has reviewed cases and testified on behalf of respondent, he has testified on behalf of his own patients when he believed that their injury met the Table definition, and he has reviewed cases at the behest of a petitioner's counsel and the court. Id. at 117-18.

Given his education, training, experience, and his special competence in the field of pediatric neurology, Dr. Wiznitzer makes a very compelling witness. Throughout his testimony,

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<sup>45</sup> Dr. Wiznitzer explained that, sadly, in his practice, he commonly confronts situations in which a child is seemingly healthy one minute and then abruptly becomes seriously ill:

I'm the neurologist who has to come in afterwards and see these children and talk with family. . . . So, unfortunately, sir, I really have to deal with these kinds of circumstances, where you've got an otherwise healthy child looking okay. The next thing you turn around; the next thing you know you're in the hospital in the intensive care unit with a very sick child.

Tr. at 175-76.

Dr. Wiznitzer focused the full breadth of his knowledge and experience to explain in clear and concise terms how and why Joey did not suffer a vaccine-related injury that resulted in his death. For the purposes of rendering an opinion in this case, his testimony is entitled to great weight.

1. Joey Did Not Suffer a Table Injury that Resulted in His Death.

Dr. Wiznitzer explained that even though petitioner made allegations concerning the DPT, MMR, and OPV vaccines, given the facts of this case, a Table injury could only be shown in connection with the DPT vaccine. Id. at 119. This is so because the DPT vaccine is the only vaccine of the three Joey received that has a relevant injury listed on the Table for the appropriate time period. Id. The two relevant Table injuries for the DPT vaccine are anaphylaxis/anaphylactic shock and encephalopathy. Id. Dr. Wiznitzer dismissed anaphylaxis/anaphylactic shock because there was no evidence in the record of Joey experiencing that injury. Id. And, although recognizing that Joey suffered an encephalopathy,<sup>46</sup> Dr. Wiznitzer explained that it clearly was not vaccine-related and therefore not a Table injury:

[A]re there other factors that cause that encephalopathy?

In other words, is there some other information that would say encephalopathy is due to problem A, problem B, or problem C, and that we cannot relate it to the vaccination[?]

And here the records basically tell us clearly that there is an alternative causation for the encephalopathy.

The records—depending on the wording you use, either we have a hypoxic, ischemic event or an anoxic event that basically resulted in the evidence of encephalopathy that was detailed in the medical records.

So, in other words, we had an episode in which there was lack of adequate [oxygen] delivery to the brain.

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<sup>46</sup> With regard to Joey suffering an encephalopathy, Dr. Wiznitzer unambiguously testified that:

We have clear-cut evidence in the medical records that by the evening of the day after the administration of the vaccinations that Joey Nilson basically showed a significant impairment in consciousness with all the features that we would agree would be consistent with encephalopathy.

So I think that there's no question about that point.

Tr. at 119.

...

The records also tell us that Joey Nilson had a cardiorespiratory arrest and, as a consequence of that cardiorespiratory arrest did not have good circulation, which means he had ischemia.

Ischemia means inadequate circulation, which means there wasn't any blood flow to the brain, there wasn't adequate oxygen delivery to the brain, and the brain had an anoxic or hypoxic ischemic insult.

And that basically is the reason for the encephalopathy that is detailed in the medical records.

There is no evidence—as it has been basically stated before—there is no evidence in the medical records of any pre-existing encephalopathy prior to the onset of the cardiorespiratory arrest.

Id. at 120-21 (emphasis added). In sum, Dr. Wiznitzer testified that Joey experienced a cardiorespiratory arrest,<sup>47</sup> leading to a loss of circulation and a deprivation of oxygen to the brain. Id. at 120-21. The lack of oxygen going to the brain resulted in an anoxic or hypoxic insult that caused Joey's encephalopathy. Id. at 121. Thus, Dr. Wiznitzer characterized Joey's encephalopathy as toxic/metabolic. Id. at 122-23.

In support of his opinion, Dr. Wiznitzer testified that the record of Joey telling his grandmother that he did not need her help shows that he did not have any significant encephalopathy before he lost consciousness. Id. at 121. Dr. Wiznitzer opined that Joey lost

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<sup>47</sup> As Dr. Wiznitzer explained later in his testimony:

It doesn't matter to me, for the purposes of the Table, what caused the cardiorespiratory arrest. That's immaterial. The real question is, what caused the encephalopathy?

And the encephalopathy was caused by the anoxic or hypoxic ischemic insult to the brain that was a consequence of the cardiorespiratory arrest.

So we have encephalopathy; we have metabolic causation, lack of oxygen, and we have a triggering event, a cardiorespiratory arrest with the Table telling us, I don't have to tell you why that arrest occurred; that's immaterial from the point of the Table.

Tr. at 154-55.



consciousness due to his cardiorespiratory arrest—individuals who do not have circulation, lose consciousness. Id.

Because Dr. Wiznitzer concluded that Joey’s encephalopathy was caused by a toxic/metabolic disturbance, he found that Joey’s encephalopathy fell under an exception in the Table definition. Id. at 122-23. To supply additional support for his theory, Dr. Wiznitzer cited a chapter in a textbook submitted as evidence by Dr. Cave.<sup>48</sup> Id. The chapter specifically states: “If ischemia is rapid and severe, as in cardiac arrest, the patient will lose consciousness rapidly.” Id. at 123. Dr. Wiznitzer explained:

So, in other words, we know that cardiac arrest—in this case, cardiorespiratory arrest—can cause loss of consciousness, can cause ischemia. And we know the ischemia in itself will also cause loss of consciousness.

And so this reference and any other reference you would look in in any other book will list anoxic or hypoxic ischemic encephalopathy as being a toxic, metabolic encephalopathy.

Really, it’s really metabolic. . . . And it’s metabolic because you have lack of adequate oxygen delivery to tissue.

And because you have lack of adequate oxygen delivery to tissue, the tissue tries to make up for the deficit. It makes up for it in two ways. First, it switches to a metabolic system called anaerobic metabolism.

That means basically I’m holding my breath and I’m going to be using up the available sugar and other energy supplies that are available in the brain because I don’t have oxygen that’s present, and therefore, I cannot efficiently make energy.

However, you’re going to run out of those systems. A byproduct of using those other products in anaerobic metabolism is you develop a metabolic acidosis.

If those products by themselves are not sufficient to sustain the brain or if the insult lasts for too long of a period of time, you get irreversible damage such as what unfortunately happened with Joey Nilson.

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<sup>48</sup> Doris A. Trauner, M.D., Toxic and Metabolic Encephalopathies, in Neurology for Non-Neurologists 194 (Wigbert C. Wiederholt, M.D., ed. 1988). The chapter was submitted as Petitioner’s Exhibit 23 at 137-41.

And you get the classic pattern that he shows, which is, initially, his brain scan looks okay, because it was done right after the event, because it takes a while for the brain cells to show the extent of their injury.

And then, gradually, you show evidence of brain swelling. And he actually got up to the point where he had such severe brain swelling that he had brain herniation, according to what the medical records tell us.

And then studies that were done showed lack of blood flow to the brain in the ensuing days. This is the typical pattern unfortunately that we see in these events.

Id. at 123-25. The medical records clearly state that Joey was “unresponsive with no breathing and no pulse whatsoever.” Those same records also reflect that the ambulance came within minutes of Joey’s collapse.<sup>49</sup>

Further, Dr. Wiznitzer testified that Joey’s enlarged heart, i.e., a left ventricular hypertrophy, was not typical for an asthmatic child. Id. at 140. He explained that because asthma involves the lungs, an asthma sufferer may have problems with how his or her heart deals with the lungs. Id. But, Dr. Wiznitzer explained that unless the asthma is severe with low oxygen levels on a consistent basis, the patient will not have the left ventricular hypertrophy that was discovered at Joey’s autopsy. Id. at 140-41. Dr. Wiznitzer believes that the physicians would have noted in the records if they believed that Joey’s enlarged heart was due to asthma. Id. at 141.

Dr. Wiznitzer stated that based on the medical records, he would have concluded that Joey had a bronchospasm due to reactive airway disease or that Joey had a heart rhythm disturbance because of his abnormal heart. Id. at 159. Although arriving at opposite conclusions, Dr. Wiznitzer, like Dr. Cave, based his opinion concerning whether Joey suffered a Table encephalopathy on Joey’s clinical picture on the day of his collapse. However, unlike Dr. Cave, Dr. Wiznitzer opined that Joey’s ability to walk away from the merry-go-round demonstrated that he had not suffered an encephalopathy prior to collapse. Id. at 160. According to Dr. Wiznitzer, Joey’s collapse can be attributed to only two types of events: respiratory or cardiac— “There’s really nothing else that will do it.” Id.

Dr. Wiznitzer then testified that neither a respiratory nor cardiac event could be attributed to his vaccinations, explaining that: “[Joey had] a big heart. And, in fact, if you look in the

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<sup>49</sup> Dr. Cave originally testified that the paramedics did not arrive for 48 minutes after Joey’s, collapse. Tr. at 44-47. Later, she acknowledged that she was incorrect on that point, but that it did not alter or affect her opinion. Id. at 69-71, 128. Dr. Cave speculated that Joey was probably down for eight-to-ten minutes before he received emergency medical treatment from the paramedics. Id. at 71-72.

records, even the cardiologist was speculating, could he have had long QT syndrome?<sup>50</sup> However, it was difficult to opine because of his sick status. . . . [T]here's enough information in the records to support [this cause]." Id. (footnote added). Thus, Dr. Wiznitzer's testimony makes it clear that Joey's collapse on the playground was related to a respiratory or cardiac problem, neither of which was related to his October 11, 1996 vaccinations.

To further buttress his argument that there was no indication of encephalopathy in the history of Joey's illness at the playground, Dr. Wiznitzer explained that references to Joey staggering was not an indication of encephalopathy, delirium, or confusion.<sup>51</sup> Id. at 173-74. Dr. Wiznitzer reasoned that even though Joey might have exhibited some degree of staggering, he was able, nevertheless, to walk and talk. Id. at 174. From his perspective as a neurologist, Dr. Wiznitzer explained that if Joey had delirium or confusion, he would have been incapable of doing those things. Id. And, importantly, staggering is not a sign of significant change in mental status and, therefore, is not evidence of an encephalopathy. Id. at 174-75. Dr. Wiznitzer also testified that because Joey was just getting off of the merry-go-round, it was possible that Joey's staggering was attributable to a transient vestibular balance problem—the kind of problem that can follow when an individual is on a ride that goes in a circle and can cause dizziness. Id. at 176. As Dr. Wiznitzer explained, "[Dr. Cave] can't tell us which came first, encephalopathy or cardiorespiratory arrest. I can. The cardiorespiratory event preceded the encephalopathy." Id. at 163. Dr. Wiznitzer was far more credible and convincing in explaining these matters than Dr. Cave.

## 2. The Vaccines at Issue Were Not the Cause in Fact of Joey's Injury and Death.

As an initial matter, Dr. Wiznitzer disputed Dr. Cave's claim that Joey was immunocompromised. Id. at 136. Dr. Wiznitzer defined an immunocompromised person as someone "who's much more prone to serious infections in comparison to the general population." Id. He did not believe it was significant that Joey was on and off of steroids to manage his asthma: "From a neurology standpoint, I have several patients with neurologic conditions who are on steroid therapy. And they're quite healthy. They have not had any significant immune problems to my knowledge." Id.

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<sup>50</sup> Long QT syndrome is the "prolongation of the Q-T interval combined with [an atypical rapid ventricular rhythm] and manifest as several different forms; it may be acquired, usually due to metabolic or cardiac abnormality or to drug administration, or congenital . . . . It may lead to serious arrhythmia or and sudden cardiac death." Dorland's Illustrated Medical Dictionary, *supra* note 2, at 1823, 1850, 1924.

<sup>51</sup> Dr. Wiznitzer was firm in this view through his direct and cross examinations—he indicated that he was 100 percent certain. *Tr.* at 174. At one point on cross-examination, Dr. Wiznitzer explained with respect to the history of events on the playground, "So taking all the information we have available to us, not just the isolated feature that you're trying to pull out, you can't conclude that there's any evidence of encephalopathy. Yes. You can't conclude." Id.

*A. Petitioner’s Claim—that the DPT Vaccine Joey Received Was from a Toxic DPT Lot that Could Have Caused a Drop in His Blood Sugar Level and Resulted in an Encephalopathy—Is Not Well Founded.*

*I. There Is No Demonstrable Proof that the DPT Vaccine Joey Received Was from a Toxic Lot.*

Dr. Wiznitzer agreed with Dr. Cave that the DTaP vaccine is cleaner than the DPT vaccine, *i.e.*, that “it does not elicit as many of the unwanted reactions in comparison to DPT,” such as fever, swelling, and irritability. *Id.* at 141. Dr. Wiznitzer also acknowledged that there were reports of serious adverse reactions to DTaP, including rare reports of seizures. *Id.* Nevertheless, Dr. Wiznitzer discredited Dr. Cave’s opinion that, based on the VAERS reporting, the DPT vaccine that Joey received was from a particularly toxic lot. *Id.* at 134-35. To the contrary, Dr. Wiznitzer stressed that there was no scientific basis for Dr. Cave’s view because there was no information about the details of the claims filed about that vaccine lot. *Id.* Without that information, no conclusions can be drawn. As Dr. Wiznitzer explained, “There’s a lot of different things that can happen. . . . And we really want to be driven by good science and not by speculation. Speculation doesn’t get us anywhere.” *Id.* at 135. The missing link, in Dr. Wiznitzer’s view, is an examination of the underlying facts surrounding the alleged adverse reaction, to determine whether there is any merit to the claim.<sup>52</sup> *Id.* at 133. There could be numerous reasons for an illness or injury arising after vaccination, none of which may be attributable to the vaccine administered. VAERS was not intended to make specific causal links between vaccine and injury; rather, it is a passive reporting system, not an active surveillance system: “It’s supposed to just identify . . . problems that might be going on and warrant further investigation. And I think to some degree it meets that need. But we can’t draw any more information from it than that.” *Id.* at 135. Thus, Dr. Wiznitzer’s testimony that the DPT vaccination Joey received was neither contaminated nor toxic was more persuasive than Dr. Cave’s testimony to the contrary.

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<sup>52</sup> Dr. Wiznitzer has practical experience in this area. Specifically, when he helped rewrite the VAERS criteria for encephalopathy, encephalitis, and multiple sclerosis, Dr. Wiznitzer and his collaborators had the opportunity to review some of the original adverse reaction claims to VAERS. *Tr.* at 133. The purpose of their review was to test their proposed criteria. *Id.* Because the VAERS employees who take the claims are not trained physicians, Dr. Wiznitzer’s goal was to develop a checklist to facilitate the information-gathering process. *Id.* As the claims were reviewed and other causes and other reasons were considered, Dr. Wiznitzer and his colleagues determined that, in many cases, there was no relationship between the vaccine and injury. *Id.* Dr. Wiznitzer concluded that merely because reports are made to VAERS does not mean that a cause-effect relationship is definitely established. *Id.*

II. *Petitioner Failed to Prove that the DPT Vaccine Caused a Drop in Joey's Blood Sugar Level and Resulted in an Encephalopathy.*

In addition to discrediting petitioner's theory that Joey received a DPT vaccine from a toxic lot, Dr. Wiznitzer thoroughly rebutted Dr. Cave's theory that Joey could have suffered a hypoglycemic reaction from the DPT vaccine that could have caused his encephalopathy, calling this scenario "highly unlikely." Id. at 129. As a preliminary matter, Dr. Wiznitzer explained that the endocrinologist and metabolic specialist who examined Joey at McKennan Hospital, Dr. Keppen, considered and rejected the possibility that Joey's collapse was caused by a hypoglycemic event. Id. As Dr. Wiznitzer also explained, individuals "do not collapse like this suddenly with hypoglycemia to cause this level of severe brain damage." Id. Dr. Wiznitzer explained that a person can have:

a low blood sugar of 51 for a long time, for hours on end, and you're not going to get any permanent brain damage.

You really need to have a blood sugar so low—and it would probably be like zero or close to it—probably less than 10, for probably a period of a good hour—some people say hours—before it's going to lead to irreversible brain damage.

Hypoglycemia in older individuals is a very funny thing. And there's good literature that's been written on the subject describing good recoveries after very low blood sugars for long periods of time, which raises a whole bunch of questions about what the brain does when the sugar's not around and how it's able to function.

Id. at 143. Dr. Wiznitzer reiterated his point concerning the duration of low blood sugar and brain damage when he testified:

[Y]ou can be much, much lower in the critical range, and you don't get automatic brain damage.

Even then, it takes a period of time, which some people hypothesize to be an hour, two hours before you start getting irreversible brain damage due to the extremely low levels of blood sugar that actually cause brain damage.

It is not easy to damage an older person's brain. I mean older person means outside the neonatal time period—an older person's brain with low blood sugar. It takes quite a bit of effort.

Id. at 168. This testimony, from a credentialed neurologist, contradicts Dr. Cave's testimony that damage can occur within eight-to-ten minutes. See id. at 100.

Dr. Wiznitzer also rejected petitioner's use of the Stewart paper to support the theory that the DPT vaccine caused a hypoglycemic response in Joey. Id. at 138. Indeed, Dr. Wiznitzer testified that the Stewart paper failed to make a specific causal link between the DPT vaccine and a hypoglycemic response. Id. Dr. Wiznitzer also testified that although the paper claims that there is a fall in blood sugar, the author fails to explain the amount or degree of the decrease. Id. Furthermore, Dr. Wiznitzer's reading of the articles cited by the author revealed that they did not support petitioner's theory. Id. at 137-38. Thus, the article lends no support for petitioner's theory that the DPT vaccine caused Joey to suffer a hypoglycemic response, which in turn caused his encephalopathy.

Dr. Wiznitzer offered three reasons why Joey's encephalopathy was not caused by hypoglycemia. First, although hypoglycemia can impair consciousness, to reach the level of hypoglycemia that would cause irreversible brain damage, Joey's low blood sugar level would have had to remain constant over a long period of time. Id. at 129. Thus, contrary to Dr. Cave's testimony, eight-to-ten minutes would not be sufficient. Id. Second, the damage pattern reflected on Joey's CT scan was not consistent with hypoglycemia. Id. Dr. Wiznitzer stated that instead of seeing damage in the most metabolically-active areas of the brain, consistent with hypoglycemia, Joey's CT scan revealed diffuse brain swelling, consistent with a hypoxic-ischemic or anoxic event. Id. at 150. Finally, Dr. Wiznitzer stated that the evidence of significantly abnormal blood gases at the time Joey was brought to the hospital, *i.e.*, low oxygen level and elevated carbon dioxide level, is not consistent with pure hypoglycemic brain damage. Id. Once again, Dr. Wiznitzer's testimony was more credible than Dr. Cave's testimony regarding this issue.

The medical records clearly reflect the physicians' conclusion that Joey suffered a bronchospasm prior to his collapse. Id. at 130. According to Dr. Wiznitzer, even while he was in the hospital several days after his collapse, Joey "clearly showed evidence of the ability to have bronchospasms." Id. at 131. Dr. Wiznitzer also explained that it is possible to have a bronchospasm without coughing or wheezing. Id. Consequently, merely because Joey had an atypical asthma attack would not rule out bronchospasm as a cause of his collapse. Id. Additionally, there is no evidence in the medical records that Joey's encephalopathy was caused by anything other than a cardiorespiratory collapse with resultant anoxic encephalopathy. Id. at 131-32. Other potential causes, such as hypoglycemia, were investigated, but they were eliminated by the physicians. Id. Therefore, Dr. Cave's theory concerning Joey's hypoglycemia is not well founded and is rejected.

*B. There Was No Evidence that the MMR and OPV Vaccines' Live Viruses Harmed Joey.*

Dr. Wiznitzer disputed petitioner's contention that the article Dr. Poser wrote for Mealey's Litigation Report applies to the instant facts. Id. at 138-40. To the contrary, Dr. Wiznitzer explained that Dr. Poser was merely describing a mechanism found in measles as part of measles encephalitis or measles encephalopathy. Id. at 139. Dr. Poser was not describing the pathology associated with the DPT vaccine—rather, the focus of the article was the measles,

varicella, and rubella vaccines. Id. Indeed, Dr. Wiznitzer explained that the articles written about DPT vaccine-related autopsy studies “have been various and heterogeneous, with no clear-cut pathology ever ascribed—a central nervous system pathology ever ascribed to it.” Id. Dr. Wiznitzer further explained that:

We know that—just to put things in perspective, we all know that you can get an encephalopathy or an autoimmune encephalitis of some type after smallpox. It’s very rare, but it can happen. We know you can get phenomena like this with natural measles, very rarely with rubella.

Varicella—this is not the typical varicella response—you get more of a demyelinating process with varicella, which is chicken pox. But it’s purely speculative to take the quote that [Dr. Poser] has here and ascribe it specifically to this circumstance, because we have clear-cut evidence of a causal reason for the brain swelling that’s present. And that was the anoxic or hypoxic ischemic event, using the words interchangeably.

Id. at 139-40.

Although Joey did receive the MMR vaccine, Dr. Wiznitzer was emphatic that “[i]t’s biologically impossible” for the MMR vaccine to cause this type of reaction (i.e., brain swelling) 24 hours after vaccination. Id. at 140, 167. More time is needed, typically, 10 to 14 days. Id. at 140. Thus, Dr. Poser’s article fails to support petitioner’s argument that within 24 hours of administration, the live virus vaccines Joey received caused his collapse and ultimately his death.

### **Petitioner Has Not Met His Burden**

Petitioner argues that he has produced sufficient proof to prevail under both Table and causation-in-fact theories because he offered expert testimony by a credentialed physician and medical literature that he believes supports his theory of causation. The special master agrees that petitioner’s expert, Dr. Cave, is a board-certified family practitioner, but, that credential is not sufficient.<sup>53</sup> In this case, Dr. Cave’s theories of causation were effectively rebutted by a highly-credentialed pediatric neurologist, Dr. Wiznitzer, whose testimony was far more credible

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<sup>53</sup> In addition, respondent noted that Dr. Cave’s son handles Vaccine Act cases. Tr. at 73-74; Resp’t Closing Argument at 5. Further, Dr. Cave testified that she has testified before Congress to express her concerns regarding vaccine safety. Tr. at 36, 38, 193. Neither fact adversely influenced the special master’s view of Dr. Cave. One of the cherished blessings of living in our great Republic is citizens’ access to elected representatives. The fact that Dr. Cave testified about her concerns relative to vaccine safety is a credit to our free society.

and compelling.<sup>54</sup> The special master gives far greater weight to Dr. Wiznitzer's testimony because he spoke more knowledgeably about the vaccines in question and the relevant neurological issues. Dr. Wiznitzer's medical background and his participation in the development of definitions for possible vaccine-related neurological injuries made it clear that he was more knowledgeable about the underlying process that ultimately resulted in Joey's death. Dr. Wiznitzer's testimony left no room for doubt that Joey did not sustain a Table encephalopathy.

For purposes of his causation-in-fact claim, petitioner was not required to show that the DPT, MMR, and/or OPV vaccines were the sole cause or even the predominate cause of Joey's injury and death. However, petitioner did have the affirmative burden of establishing by a preponderance of evidence that but-for the administration of any one or combination of the three vaccines, Joey's injury and death would not have occurred. Petitioner was also required to show that, whether alone or in combination, the October 11, 1996 vaccinations were a substantial factor in bringing about Joey's injury and resulting death. As Dr. Wiznitzer's testimony highlighted, petitioner failed to make that showing.

To be clear, the special master is cognizant that the law does not require the rejection of a novel theory of causation. As the Supreme Court recognized in Daubert, the theory need rest only upon a reliable foundation of medical knowledge. 509 U.S. at 597; see also id. at 593 ("In some instances well-grounded but innovative theories will not have been published. . . . Some propositions, moreover, are too particular, too new, or of too limited interest to be published."). However, petitioner did not set out a logical sequence of cause and effect to carry his burden. And as explained above, the medical records that tie Joey's collapse and death to his chronic asthmatic bronchitis, combined with Dr. Wiznitzer's testimony, proved by a preponderance of the evidence that Joey's encephalopathy was caused by a factor unrelated to his vaccinations.

Based upon the forgoing reasons, this court finds that Joey did not suffer a Table injury. Dr. Wiznitzer's testimony clearly showed that Joey's encephalopathy was caused by a metabolic disturbance and therefore, pursuant to the clear terms of the Vaccine Act, the encephalopathy cannot be considered to be a Table injury. For the same reasons, this court also holds that Joey's October 11, 1996 vaccinations (any one or combination thereof) were not the cause in fact of his encephalopathy or death. Dr. Wiznitzer's testimony clearly demonstrated that (1) Joey did not

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<sup>54</sup> Expert testimony must be "supported by appropriate validation." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 590 (1993). Dr. Cave's expert testimony lacks appropriate validation and thus falls into the realm of speculation and conjecture. Thus, petitioner's theory of causation rests on "personal opinion, not science." See Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319 (9th Cir. 1995) (on remand from the U.S. Supreme Court). Regardless of how genuinely a theory is believed by an expert, the passion with which it is believed is no substitute for scientific support. In the absence of reliable medical evidence to advance a theory, petitioner cannot establish a claim by a preponderance of the evidence.



suffer an encephalopathy prior to his cardiorespiratory arrest; (2) Joey lost consciousness due to his cardiorespiratory arrest; (3) the DPT vaccine that Joey received was not from a toxic lot; (4) the vaccines did not cause a hypoglycemic event that lead to an encephalopathy; (5) the vaccines did not cause Joey's cardiac arrest; and (6) any ethylmercury, aluminum, or live viruses present in Joey's vaccinations did not cause his encephalopathy or death.

### **CONCLUSION**

Based upon a review of the medical records, medical literature, and expert reports, coupled with the testimony presented at hearing, the special master finds that the totality of evidence demonstrates that Joey's October 11, 1996 vaccinations did not cause his encephalopathy and resulting death. Not only did petitioner fail to establish a Table injury, he failed to prove by a preponderance of the evidence that those vaccinations were the cause in fact of Joey's collapse and death. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment accordingly.

**IT IS SO ORDERED.**

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Margaret M. Sweeney  
Special Master