

**OFFICE OF SPECIAL MASTERS**

01-230V

Filed: April 23, 2004

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**DEVON CORZINE, Administrator of the  
Estate of SARAH CORZINE, Deceased,**

Petitioner,

v.

**SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,**

Respondent.

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**To Be Published**

*Nicholas E. Bunch*, Cincinnati, Ohio, for Petitioner.

*Melonie McCall*, United States Department of Justice, Washington, D.C., for Respondent.

**ENTITLEMENT DECISION**

**FRENCH**, Special Master

**I. PROCEDURAL HISTORY**

On April 17, 2001, petitioner Devon Corzine filed a petition pursuant to the National Vaccine Injury Compensation Program<sup>1</sup> (hereinafter referred to as “the Program”), requesting compensation for the death of his infant daughter, Sarah Corzine (“Sarah”). Petitioner claims that an adverse reaction to six vaccines, including diphtheria, tetanus, pertussis (“DTaP”) and HiB, administered on April 21, 1999, caused a hypoxic seizure<sup>2</sup> that resulted in Sarah’s death on

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<sup>1</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 990660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-1 *et seq.* (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Further reference to individual sections will be to the relevant subsection 42 U.S.C.A. §300aa of the Vaccine Act.

<sup>2</sup> A seizure characterized by hypoxia, the reduction of oxygen supply to tissue below physiological levels despite adequate perfusion of the tissue by blood. *See, Dorland’s Illustrated*

April 22, 1999, less than 14 hours after her vaccinations.

In response, respondent's Rule 4(b) report recommends compensation be denied, maintaining that Sarah did not suffer a fatal seizure and that her death, more likely than not, was caused by a factor unrelated to the vaccine, Sudden Infant Death Syndrome ("SIDS"). Petitioner disputes respondent's ultimate conclusion. Respondent also considers the possibility of accidental overlay as an alternative cause.

The case required two evidentiary hearings.<sup>3</sup> The first hearing was conducted on February 7, 2003, in Cincinnati, Ohio. Evidence was presented in the form of written reports, contemporaneous medical records, and oral testimony presented by medical experts for each party. Pre-hearing reports from witnesses and medical experts were required to provide concise expositions of the parties' positions on the case. Conducted on September 26, 2003, the second hearing was telephonic, and limited to the testimony of Dr. Marcel Kinsbourne for petitioner and Dr. Max Wiznitzer for respondent. That hearing provided petitioner the chance to respond to one of respondent's central arguments, one not revealed until the close of the first hearing.

The record is now closed and the case is ripe for decision. This has been a difficult case, and a close one. On balance, however, after considering the totality of the evidence, the court finds petitioner has demonstrated by a preponderance of the evidence that Sarah's death was the result of a vaccine-related injury, and is therefore entitled to compensation.

## II. FACTUAL BACKGROUND

Sarah Corzine was born in Cincinnati, Ohio on February 18, 1999, two months premature at 31 4/7th weeks of gestation. Sarah's mother went into spontaneous labor and was treated with steroids and antibiotics – Betamethasone and Clindamycin – prior to delivery. Sarah's mother was found to have preeclampsia and hypertension. The infant, however, was delivered without complications and her APGAR scores were 6 and 9 at one minute and nine minutes, respectively. She weighed 3 pounds, 3 ounces at birth. During her first day of life, Sarah experienced respiratory distress and required positive airway pressure for one day. She was maintained on nasal cannula with 23 percent oxygen for the next few days. By her fifth day of life, she was stable on room air. A systolic murmur was detected on her fourth day of life. That problem was fully resolved three days later. She remained in the hospital for another two and one-half weeks, primarily for feeding and growth.

Sarah received a hepatitis B vaccination in the hospital on the day of her birth, February

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*Medical Dictionary* (27<sup>th</sup> ed.1988) at 810.

<sup>3</sup> The second hearing was necessitated by respondent's introduction of a theory rebutting petitioner's claim, without having identified the theory, or providing evidence in its support, prior to the first hearing.

18, 1999 and a Synagis vaccination on March 5, 1999. She was discharged on March 15, 1999, with a weight of approximately 4 pounds 3 ounces.

Drs. Libbey Spiess and Sharon Harp of Queen City Physicians, Ltd., provided Sarah's first pediatric office visit on the day after discharge from the hospital. Sarah was described as a vigorous infant and a "well newborn with good tone." Sarah had follow-up visits for weight checks. On April 7, 1999, and again on April 8, 1999, Sarah was experiencing episodes of choking on her formula. Her parents phoned the doctor but no office visit was required. Her last visit to the pediatrician's office was on April 21, 1999 when she was two months old. She was examined by Dr. Spiess who found her to have normal development and a weight of 6 pounds. On that same day, April 21, 1999, at 2:45 p.m., Sarah was given the following immunizations: a Diphtheria, Tetanus, acellular Pertussis Vaccine ("DTaP"), Inactivated Polio Vaccine ("IPV"), Hemophilus Influenza Type B (HiB), and Rotovirus vaccine. In all, six vaccines were administered on the same day, April 21, 1999. Sarah died the next day, April 22, 1999.

On April 22, 1999, less than 14 hours following her vaccinations, Sarah Corzine was found stiff and unresponsive in bed. According to petitioner, Sarah's mother was the first to go to bed at the end of the day, April 21, 1999. Mr. Corzine testified that he had fed Sarah, then went to bed himself, at approximately 11:30 p.m. At about 4:00 a.m. the next morning, April 22, 1999, he found Sarah not breathing. He attempted CPR while his wife dialed 911. The two parents received additional CPR instructions by telephone, and their efforts continued until the paramedics arrived. Sarah was pronounced dead at Children's Hospital Medical Center at 5:14 a.m. on April 22, 1999. An autopsy was performed. The autopsy report noted no abnormalities or unusual findings. The coroner's report and the death certificate list the cause of death as "undetermined -- Sudden Death in Infancy" (SIDS).

The investigation into Sarah's death began almost immediately. The Corzine residence was described as clean and well kept with evidence of prescription medications, bottles containing breast milk, and photographs. Sarah's mother told investigators that she and her husband slept with Sarah in their bed four to five nights a week, that they had an area in their bed for her, and that Sarah would sleep between them on her back, at approximately arm's length away from each parent. Mr. Corzine explained that he and his wife often slept with Sarah between them in their bed because they believed this would reduce the risk of SIDS. They had followed their standard procedure in which he and his wife slept on their sides with their knees bent and pillows between their legs in order to keep from rolling over onto Sarah. He told investigators that on that night, he had placed Sarah on her back, on or below his upper arm so that he could "keep tabs" on her, and that he was certain he didn't roll over her. At hearing, Sarah's father demonstrated the procedure followed routinely at bedtime. The demonstration revealed a sleeping position that provided a good deal of space between the parents.

### **III. STATUTORY PROVISIONS AND METHODS OF PROOF**

Causation in Vaccine Act cases can be established in two ways: either through a

statutorily prescribed presumption of causation or by proving what is commonly known as “causation-in-fact” or “actual causation.” Petitioners must prove one or the other, by a preponderance of the evidence, in order to recover under the Act. § 13(a)(1)(A). Thus, the trier of fact must “believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.” Hodges v. Secretary of HHS, 9 F.3d 958,963 (Fed. Cir. 1993) (Newman, J. Dissenting) (citing Concrete Pipe and Products of California, Inc. v. Construction Laborers Pension Trust for Southern California, 508 U.S. 602 (1993), quoting In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Certain injuries and conditions are listed on the Vaccine Injury Table (“the Table”).<sup>4</sup> If the injury has been observed or manifested within a prescribed time period following the immunization alleged to have caused the injury, the statute presumes causation and petitioner is entitled to compensation. §11 (c)(1)(C)(I), § 13 (a)(1)(A). This method of proof is designated a “Table” case. Once petitioner shows entitlement to a presumption of causation, the burden shifts to respondent to prove that the injury or condition “is due to factors unrelated to the administration of the vaccine described in the petition.” § 300aa-13 (a)(1)(A); § 300aa-11(c)(1)(C)(i).

If petitioner fails to satisfy the requirements under the Act for demonstrating a Table injury, compensation may be awarded for injuries not listed in the Table. Compensation is awarded if petitioner affirmatively demonstrates, by a preponderance of the evidence, that the vaccination in question, more likely than not, caused the alleged injury. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed.Cir. 1992). See also, §§11(c)(1)(C)(ii)(I) and (II). This standard is the same standard required in traditional tort litigation, proving a case by a preponderance of the evidence. To meet the traditional preponderance of the evidence standard, “[a petitioner must] show a medical theory causally connecting the vaccination and the injury.” Grant, 956 F.2d at 1148. A persuasive medical theory is shown by “proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). The logical sequence of cause and effect must be supported by “[a] reputable medical or scientific explanation” which is “evidence in the form of scientific studies or expert medical testimony.” Grant, 956 F. 2d at 1148; Jay, 998 F.2d at 984; See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. If petitioner is successful in establishing such proof, the burden shifts to respondent to prove that the injury or condition “is due to factors unrelated to the administration of the vaccine described in the petition.” § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(i). The actual causation method of proof has been the most common method pursued by petitioners in recent years, although it presents a

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<sup>4</sup> The Vaccine Injury Table was originally established by statute at § 300aa-14(a) and has since been modified administratively. The injury must be one specified on the table as a possible outcome of a specific vaccine, and occurring within the time period prescribed in the Table.

very heavy burden. While the Act relaxes proof of causation standards for on-Table injuries, it does not relax the standards for non-Table injuries. See, e.g., Whitecotton v. Secretary of HHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996); Grant, 956 F.2d at 1148.

The Federal Circuit has held that for a petitioner to establish a prima facie case of compensation based upon actual causation, petitioner must prove by a preponderance of the evidence that the vaccine was not only a “but-for cause of the injury, but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-1353. Petitioner does not meet the affirmative obligation to show actual causation by simply demonstrating an injury that bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also, H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Moreover, a petitioner does not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten-day period [following it]. . . . Without more, a proximate temporal relationship will not support a finding of causation”)); Hodges v. Secretary of HHS, 9 F.3d 958, 960. Nor does a petitioner demonstrate actual causation by solely eliminating other potential causes of the injury. See, e.g., Grant, 956 F.2d at 1149-1150; Hodges, 9 F.3d at 960. Petitioner pursues this case as one of causation-in-fact and the court will analyze it as such.

#### IV. THE ISSUES

Petitioner asserts that the administration of the DTaP vaccine resulted in a seizure that caused Sarah Corzine’s death. See, Pet. at 1. Respondent’s position is that Sarah did not suffer a fatal seizure, nor was capable of doing so, and that her death was caused by a factor unrelated to the vaccine, SIDS.

The seminal issue, therefore, is whether an infant of Sarah’s age could suffer a fatal seizure. Second, if so, did she suffer a seizure that caused her death? Next, did the vaccine cause that seizure and its sequella - death? Finally, the court must consider whether SIDS is a legally reasonable alternate cause of death.

##### A. **Could an infant of Sarah’s age and development suffer a fatal seizure?**

Petitioner’s claim rests on evidence that purportedly demonstrates Sarah Corzine suffered a fatal seizure less than 14 hours after receiving a DTaP vaccination. Testifying for respondent, Dr. Max Wiznitzer<sup>5</sup> insists that a seizure could not have occurred here because a very young

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<sup>5</sup> Dr. Wiznitzer is certified by the American Board of Pediatrics, the American Board of Psychiatry and Neurology with special qualification in child neurology, the National Board of Medical Examiners, and the State Boards of Ohio, Pennsylvania and New York. He has served as assistant professor of various medical disciplines at Case Western Reserve University, and has

infant is not capable of mounting a fatal seizure. Testifying for petitioner, Dr. Marcel Kinsbourne,<sup>6</sup> challenges Dr. Wiznitzer's contention. Having viewed the witnesses and considered their testimony, the court finds that Dr. Kinsbourne's explanation of why an infant of Sarah's age and development could suffer a fatal seizure is more credible than Dr. Wiznitzer's argument that the occurrence is not possible.

Asked whether Sarah could have a seizure at her age and development, Dr. Kinsbourne answered in the affirmative, noting that there are many different kinds of seizures and that it is absolutely possible for a child of any age to have a seizure. There was further disagreement between the parties as to whether Sarah's age is determined by the date of her birth or by another formula. Dr. Kinsbourne explained that there are two methods of computation and that both are correct. First, there is the chronological age, the time elapsed between her birth and the present. Using this standard, Sarah was two months old. Alternatively, if one wished to determine how much the baby has developed, the time between the date of conception and the present would be considered. At the time of Sarah's death, slightly more than nine months passed from the time of conception. Were she not born prematurely, that number would be eleven months. The significance of these numbers goes to Dr. Wiznitzer's contention that a very young infant could not mount a fatal seizure, and that a nine-month-old, by this measure, is a very young infant.

Dr. Wiznitzer maintains that seizure in a newborn is not actually a seizure but is associated with identifiable pathology of the brain, none of which was evidenced upon autopsy here. Tr. at 180. He concludes that Sarah could not have suffered a generalized tonic seizure. Tr. at 182-186. Yet Dr. Wiznitzer equivocates in his testimony. At times he insists that a seizure is not possible in a newborn, that although newborns can present with seizure-like symptoms, they cannot sustain actual seizures. See, e.g., Tr. at 168, 180. At other times he states that seizures in newborns are rare. See, Tr. at 168. Furthermore, in his statement filed prior to the second hearing, Dr. Wiznitzer adamantly denies ever having said that newborns cannot sustain seizures. R. Ex. T. This equivocation impacted Dr. Wiznitzer's credibility.

Dr. Wiznitzer argues that Sarah's developmental age is critical in determining whether she suffered a seizure because that age determines how long her nervous system had to grow. He measures Sarah's at nine months. Dr. Kinsbourne argues that her chronological age must be

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served in several well-known hospitals, working in pediatrics and neurology. He has published many articles in these fields. R. Ex. F. Dr. Wiznitzer's initial expert report was filed October 25, 2001, as R. Ex. E.

<sup>6</sup> Dr. Marcel Kinsbourne is a pediatric neurologist in Cambridge, Massachusetts and a distinguished expert in the field of neurology, well known in medical and academic circles relating to vaccines and to the Vaccine Injury Program itself. It is his opinion to a reasonable degree of medical certainty, that Sarah Corzine's death resulted from a seizure, and that the seizure was caused by the pertussis component of the DTaP vaccine administered to Sarah on April 21, 1999. P. Ex.15.

considered. The disagreement has two elements. One is how mature her nervous system was, and that is critical in determining whether or not an infant of Sarah's age and development could have a seizure that results in death. The other is whether the amount of time since birth affects the possibility of seizure.

The court finds Dr. Kinsbourne's argument more credible. It is counter-intuitive to discount the almost two months during which Sarah Corzine lived outside the womb. There is no disagreement that Sarah's nervous system is less mature than would be that of a full-term two-month-old, but Dr. Wiznitzer has not convinced this court that the discrepancy is of major consequence here. At time during his testimony, his contentions seem predicated on the assumption that a very young infant cannot sustain a fatal seizure. At other times, he concedes that this can happen, but rarely does. The seizures that Dr. Wiznitzer describes as being possible in a newborn, are simply not relevant to this case. More persuasive is Dr. Kinsbourne's rebuttal that Sarah Corzine, two months post birth, could not have suffered the non-fatal seizures discussed by Dr. Wiznitzer, because, as both parties admit, those seizure are induced by stress, particularly birth-trauma.

Dr. Wiznitzer states that, as a neurologist, "really, my job is to address the neurological issues here. So. . . the bottom line question here is did this child have a seizure . . . [on] that point I can say with 100 percent certainty that could **not** have occurred here." (emphasis added). Tr. at 164-165, 186. He insists that a generalized tonic seizure could not have occurred in an infant this age. Tr. at 165-167. Dr. Wiznitzer testified that the literature demonstrates a generalized tonic event, in which the child apparently stiffened all over, is not an epileptic seizure, as it is not associated with epileptiform discharges on an electroencephalographic monitoring ("EEG"). When a child is having this kind of a stiffening spell, "I do not see seizure discharges on the EEG." Tr. at 167.

Dr. Kinsbourne contests Dr. Wiznitzer's position regarding newborns and seizure. He states, "There simply isn't the literature on it. There isn't any literature which says a child who is two months old, but was born two months premature, can or cannot have a tonic seizure. [T]hat just doesn't appear anywhere." Tr. 2<sup>nd</sup> at 19-20.<sup>7</sup> Dr. Kinsbourne maintains that it is absolutely possible for a child of Sarah's age and development to have a seizure. Tr. 2<sup>nd</sup> at 10. First, he refutes Dr. Wiznitzer's contention that Sarah should be considered a newborn, not a two-month-old infant. He explains that having been born two months prematurely, Sarah has a central nervous system that has matured for only nine months since conception. She, has, however, lived two months since the time she was delivered, the significance being that for Sarah to have sustained a non-epileptic seizure, the immature nervous system would have to have experienced extreme stress.

Dr. Wiznitzer testified that seizures in a child of Sarah's age are not necessarily the same

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<sup>7</sup> To provide context, testimony from the first hearing will be cited at "Tr. at \_\_\_." Testimony from the second hearing will be cited as "Tr. 2<sup>nd</sup> at \_\_\_."

or have the same kind of presentation you might see in older children, and he maintains that the newborn brain is more difficult to provoke into seizure and is not very good at mounting such seizure. Dr. Wiznitzer asserts that Sarah could not have had a seizure that would be likely to cause death, because it was not an epileptiform seizure, explaining that seizures in young infants are usually due to the difficulties of childbirth, most often occurring on the day of birth.

Dr. Kinsbourne agrees that non-epileptical seizure could only be provoked by such stress and that when these seizures are observed in newborns, that stress is related to the actual birth process – to the delivery:<sup>8</sup> Tr. 2<sup>nd</sup> at 14-16. But, he explains why discussion of non-epileptiform seizure is not relevant to Sarah’s death:

[T]he significance is that the descriptions of neonatal seizures are not applicable to Sarah Corzine, because . . . these seizures that are described so fully in various texts and in literature submitted [by respondent], all have to do with interaction between an immature nervous system and significant neurological stress, and as I’ve discussed, although Sarah did have an immature nervous system, she did not have significant neurological stress. Tr. 2<sup>nd</sup> at 17.

Dr. Wiznitzer uses the word “spell” or an “event” to describe seizure-like behavior in so young a child. Yet, he concedes that one simply cannot identify ‘epileptiform activity’ seizure without modern technology that could identify a true seizure by observable discharge on an EEG. The court notes that no one actually observed Sarah’s death, and the technology needed was not in place at the time of death. Moreover, as stated earlier, any seizure activity will not be revealed upon autopsy. Therefore, there is little substance to Dr. Wiznitzer’s argument that the child **could not** have died in seizure because there is no evidence that she sustained the kind of seizure capable of provoking death. Accordingly, neither is there substance to his argument that the components contained in the vaccines most probably had nothing to do with the child’s death.

As to Dr. Wiznitzer’s observation that none of Dr. Kinsbourne’s references provide definitive support for his theoretical position, the court emphasizes that the standard of proof in vaccine cases does not require definitive support. See, Knudsen, 35 F.3d at 548-49. (Petitioners must produce affirmative evidence supporting medical probability rather than certainty, to meet their burden of proof.)

The referenced literature includes early clinical investigations into the classification of indexing seizures, notably differentiating between epileptic and non-epileptic seizures. Dr. Wiznitzer insists the significance of the distinction is that the seizure activity claimed in this case is only correctly identified as seizure if it has been classified as an epileptic seizure identifiable by an EEG. Tr. at 166-167. In other words, according to Dr. Wiznitzer, whatever it was that caused the child’s death could not have been a seizure, as described by petitioner’s experts, with any degree of

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<sup>8</sup> Two months had passed since Sarah Corzine experienced the birth process.



certainty.

The undersigned reviewed diligently the many medical articles and texts concerning these issues.<sup>9</sup> The tenor of these articles appears to relate to the classification of five major types of seizures defined in newborns, distinguishing epileptic seizures from non-epileptic seizures. The distinction is relevant to any decision in this case because Dr. Wiznitzer insists that if an “episode” does not meet the criteria of an “epileptic seizure,” as determined by evidence of epileptiform activity, the child is not having a seizure, but a kind of “stiffening spell.” Dr. Wiznitzer clings to his belief that only epileptic events could cause Sarah’s death in seizure, maintaining that it would be very rare for an infant of Sarah’s age to mount a generalized seizure when the brain is so immature.

Much of the material filed did little to support the thesis that an infant of Sara’s age could not mount a fatal seizure. For example, an article published in the *New England Journal of Medicine*, “Risk of seizures after Receipt of Whole-cell pertussis or Measles, Mumps and Rubella Vaccine,” is irrelevant inasmuch as the issue of risk is not determinative here. The vaccine program does not rely upon the issue of statistical risk and that article explored statistics rather than explain causation, providing little regarding age and seizures.<sup>10</sup> Careful review of another article, from *Neonatal-Perinatal Medicine: Diseases of the Fetus and Infant*, added little to support Dr. Wiznitzer’s argument relevant to this case.

In short, the court was not favorably persuaded by Dr. Wiznitzer’s testimony. Moreover, the Doctor’s bias against theories of causation attributing injury to vaccines seemed to color much of his testimony. For example, he questions whether deaths that occur two days after an immunization are “a rise statistically more than we would expect to see, or is this just part of the normal background noise, and it’s an unfortunate coincidence that it occurred.” Tr. at 177. Dr.

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<sup>9</sup>The articles provided were: *Pediatric Epilepsy: Diagnosis and Therapy* (John M. Pellock, M.D. et al. “Neonatal Seizures, co-authored by Eli Mizrahi, M.S., and Peter Kellaway, Ph.D (Respondent’s Exhibit O); *Rudolph’s Pediatrics* (Abraham M. Rudolph, M.D. ed., 20<sup>th</sup> ed., 1996) Chapter 23: “The Nervous System” and “Neonatal Seizures” (Respondent’s Exhibit P); Eli M. Mizrahi, M.D., “Neonatal Seizures and Neonatal Epileptic Syndromes,” *Epilepsy*, Vol. 19, No. 2, May 2001, (Respondent’s Exhibit Q); Barlow, William E., et al., “Risk of Seizures After Receipt of Whole-Cell Pertussis or Measles, Mumps and Rubella Vaccine,” *N. Eng. J. Med.*, 2001; 345:656-661; *Neonatal-Perinatal Medicine: Diseases of the Fetus and Infant*. (Avroy Fanaroff, M.D., F.R.C.P. et al. eds., 7<sup>th</sup> ed., Vol. 2, 2002), Part Six “Seizures in Neonates.”

<sup>10</sup> The court acknowledges that statistical information may be considered in vaccine cases. See, e.g., Hart v. Secretary of HHS, 2003 U.S. Claims LEXIS 398. It is not, however, a critical, or even necessary consideration. But the court will not rely upon a body of evidence that is comprised, for the most part, on statistics, in determining causation. See also, Knudsen, 35 F.3d at 548. (Statistics alone do not defeat a case.)

Wiznitzer does acknowledge that vaccines have adverse events, but opines that other than encephalopathy and anaphylaxis, he finds little evidence that vaccines cause other injuries, including those that cause what he refers to as “spontaneous death.” Tr. at 177-178.

In sum and substance, the court finds Dr. Kinsbourne’s theory to be better reasoned and more persuasive than Dr. Wiznitzer’s and finds that Sarah Corzine could have suffered a tonic epileptic seizure at her age and level of development.

## **B. Did Sarah Corzine suffer a fatal seizure?**

Petitioner asserts that Sarah mounted a hypoxic seizure. Respondent rejoins, arguing a lack of evidence that she suffered a seizure. The court finds that respondent’s position is without convincing support and the undersigned considers the petitioner’s experts in this issue more credible. Experts from both sides agree the posture in death is significant to the question of seizure. Dr. John J. Shane,<sup>11</sup> for petitioner, explained that rigor fixed the body in its position at death. Tr. at 125. He explained that bodies do not assume different positions after death; that Sarah’s posture was the result of contracture, flexed muscles, and that contracture was due to a seizure. *Id.* He states that rigor sets in the position at the time of death, “there is not a lot of movement after death.” Tr. at 126. Finally, he opines that contracture prior to the time of death would be more consistent with seizure and more aptly accounts for Sarah’s posture than does rigor mortis, “where this relaxed baby now flexes into this position.” Tr. at 127.

At the hearing, Dr. Shane testified that, in his opinion, Sarah’s death was not a SIDS death. Sarah was found in a tense position, with fists clenched. This child, he reasons, does not meet the criteria of a “normal relaxed child who dies in the peaceful sleep that we expect in sudden infant death.” Tr. at 47. He believes that clenched fists and flexed posture are indicative of seizure. Tr. at 50. He attributes this posture to muscle physiology, explaining that “infants deplete muscle reserves of energy very quickly . . . associated with the breakdown products of muscle metabolism . . . [that] contribute [sic] to the fixation in that position.” Tr. at 51. A seizure, he reasons, would deplete those energy reserves.

Dr. Shane describes the mechanism of physical findings that tonic seizure would precipitate. First, one would expect arrhythmia, a slowing of the heartbeat accompanied by bradycardia (an abnormal rhythm) accompanied by pulmonary congestion. These conditions create a reasonable likelihood of, or, *more* certainly, a cause, of death, and the testimony persuades the court that not only did Sarah Corzine suffer a seizure, but that the seizure caused her death. He

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<sup>11</sup> Dr. Shane is a cardiovascular pathologist practicing in Allentown, Pennsylvania. He is an adjunct professor of pathology at Hahnemann University, serving as a clinical professor of pathology, chairman of pathology, and medical director at several laboratories. He is well-published in his field. He is board certified in pathologic anatomy and clinical pathology, including chemistry and toxicology. P. Ex. 18.

testified that Sarah had no heart problem prior to vaccination, but had suffered pulmonary congestion, as found on autopsy in minor amounts, a veritable sign of heart failure, indicating that an acute event occurred at some time during the night of April 21. Tr. at 48-50.

Dr. Shane considers this to be the cause and outcome of Sarah's problem. The mechanism he described is "a kind of part-shock, lung, and hemodynamic instability" that produced vaccine-related congestion. Tr. at 49. Dr. Shane bases his explanation on years of service as a cardiovascular pathologist, "almost exclusively for acute care hospitals with a huge pediatric service." Tr. at 48. He maintains that the position of clenched fists and flexed posture is consistent with a tonic convulsive seizure that led to an untimely death. He concurs with Dr. Kinsbourne that the seizure was most likely precipitated by the pertussis composition of the DTaP.

Dr. Shane disagrees with respondent's experts' opinion that the heavy lungs found on autopsy in this case are well within the range of what is found in most autopsies of both children and adults:

[T]his is a very small baby. I'll point you to the fact that the weight of the lungs . . . in this case is over a hundred grams. That is over twice the limit of normal for the weight of lungs in a six-pound baby. They are heavy by anyone's definition . . . It is an abnormal finding at the time of autopsy. And if there are abnormal findings of significance at the time of autopsy, they must be explored and explained prior to this ever being considered a sudden infant death syndrome. Tr. at 45.

He argues that all of the organs other than the lungs showed no significant abnormalities, including the heart. Tr. at 46. The diffusely subcrepitant<sup>12</sup> lungs with significant congestion indicate a "significant pathologic finding." Tr. at 47. Dr. Shane attributes the condition of the lungs to bradycardia, a condition that reduces cardiac output substantially, explaining that seizures produce bradycardia. Tr. at 49. Of particular interest is his statement that in SIDS, "you may have a small amount of pulmonary congestion and edema. It's a very small amount. It is not significant. If it were, it wouldn't be sudden infant death . . . You have an explanation. You have pulmonary congestion." Tr. at 50.

Under cross-examination, Dr. Shane further explained his position:

I think there are anatomic findings that you find in SIDS deaths, and they are reliable findings. And you should be looking for them. And as that science has evolved, even over the past decade, people have become much, much more aware of findings in SIDS. What has evolved is that SIDS is a multi-system disease. So when you

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<sup>12</sup> Dr. Shane explains, "diffusely subcrepitant means firm, they don't exhibit, they don't have the sponginess of the normal crepitant lungs to palpation, and there are no areas of the lung that are clear. It is diffuse throughout."

look at these findings, they spread over multiple sites. And the thing is, there is no single site that explains death. Which is why, if you get the extent of pulmonary edema and congestion that is present here, it's no longer SIDS. It's a congestive death. Tr. at 68.

Testifying for respondent, Dr. Virginia Anderson<sup>13</sup> challenges Dr. Shane's opinion that there are reliable anatomic findings apparent in SIDS deaths, stating that although there have been many articles written by those trying to find pathologic markers for SIDS, none have withstood the test of time. Tr. at 75. Once again, the court finds Dr. Shane's testimony persuasive, as definitive proof is not required in vaccine cases. See, Knudsen, supra at 548-49.

Dr. Shane adds that seizures in very small children are usually very subtle and not associated with much clonic activity. The alarming clonic seizures seen in adults are very uncommon in infants, particularly very small infants. Tr. at 51. The court views this testimony as a credible rebuttal to respondent's position that had Sarah suffered a seizure while in bed with her parents, they would have been roused by the event.

Dr. Kinsbourne supports Dr. Shane's testimony regarding SIDS, asserting that not only is Sarah's posture indicative of a seizure, but that her posture is not typical of a SIDS death. He notes that a careful search of the SIDS literature has not yielded a description of a similar posture. See id; Tr. at 131. The deceased child's posture, he explains, reflects the posture at the time of death, and rigor mortis serves to perpetuate that posture. P. Ex. 15; Tr. at 133. He asserts that Sarah's posture indicates she died in a tonic seizure. In support of his opinion that Sarah sustained a seizure, he explains, "The pivotal observation on which I rely is the posture in which the baby was found by her father. . . ." Tr. at 130.

Dr. Kinsbourne finds significant support in the fact that after autopsy, the coroner, Dr. Dean, believed that "the description of Sarah's flexed arm, clenched fists, rolled back eyes and tongue, are all consistent with death following a seizure." P. Ex. 16 (Affidavit dated March 15, 2001 at 1-2). Critical to the significance of this testimony, and specifically stated by Dr. Kinsbourne at hearing, is that none of the professionals attending to Sarah up until the moment she was pronounced dead, described or referred to her as being in rigor mortis.<sup>14</sup> Tr. at 132. "So anything I say from here on out is predicated on the court accepting that this child was not in rigor [when she was found not breathing] . . ." Id. Having ruled out rigor mortis as an explanation for

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<sup>13</sup> Dr. Virginia Anderson is a pediatric neurologist and pediatric-pathologist-neurologist, is an associate Professor of Clinical Pathology at Kings County Hospital Center in Brooklyn, New York. She is certified by the Board of Medical Examiners, The American Board of Anatomic Pathology, American Board of Pediatrics, and the American Board of Pathology with Special Qualification in Pediatric Pathology.

<sup>14</sup> Respondent's expert, Dr. Marzouk, argues that Sarah's position is the result of muscle contraction that sometimes occurs when rigor mortis sets in.

Sarah's posture, Dr. Kinsbourne opines that, "The position is consistent with, and to my mind, only explicable by a tonic seizure present at the moment of her death." Tr. at 132-133.

Dr. Kinsbourne further explained his conclusion that Sarah had a tonic epileptic seizure that obstructed her breathing, resulting in her death, by discussing the two types of tonic seizures:

The word 'tonic' basically means stiff. During a tonic seizure, certain muscles in the body are held rigid and immobile. Now the difference between focal and generalized tonic seizures is a matter of which muscles are held stiff and immobile . . . if the tonic seizure is generalized, then the muscles on both sides of the body are held stiff, and when that is the case, then the muscles that move the chest of the child . . . makes [sic] it impossible for the child to breathe and obviously if the child can't breathe, then ultimately the child will die. Tr. 2<sup>nd</sup> at 18.

Dr. Kinsbourne argues that "the evidence of [tonic epileptic seizure] was the posture of the baby when found dead and the fact, as discussed by the pathologist,<sup>15</sup> that it is a highly unusual posture for a SIDS death and does indeed indicate that the child died in seizure." *Id.* He then explains why DTaP vaccine is the most likely cause of seizure in this case. Tr. at 133.

Testifying for respondent, Dr. Marzouk<sup>16</sup> refutes Dr. Shane and Dr. Kinsbourne, opining that rigor **caused** the position in which Sarah's body was found. He testifies:

In the old times when they had people dead and they leave [sic] them in their homes, and suddenly they sit up, do you remember those old stories of somebody dead, and they are at a wake, and they put them on a table in the kitchen and they suddenly sit up? That is because of rigor mortis. The muscles shrink or shorten. They won't contract, because contraction is a live phenomenon. But that's why. You get a lot of shortening and rigor mortis even if you are flaccid like that. Tr. at 128.

Dr. Wiznitzer, maintains that Sarah's posture in death is that normally found in a healthy,

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<sup>15</sup> As discussed supra, Dr. Dean testified that Sarah's posture and some autopsy results are characteristic of seizure. *See* Tr. at 24.

<sup>16</sup> Dr. AbuBakr A. Marzouk, Col, USAF, MC, FS for Respondent serves as Acting Chairman, Department of Armed Forces Medical Examiner, Armed Forces Institute of Pathology in Washington, D.C. He is board-certified in forensic and anatomic pathology by the American Board of Pathology, and in forensic medicine by the American Board of Forensic Medicine. In his position as medical examiner and aircraft accident investigator, Dr. Marzouk has published a number of articles and abstracts in his field.

sleeping baby. Considering these explanations for Sarah's position in death, the court finds Dr. Shane's more credible than either Dr. Wiznitzer's or Dr. Marzouk's. It is simply more likely that Sarah's position was caused by seizure-induced contracture than by extreme post-death movement. Moreover, the coroner's observations support petitioner's contention that the posture is consistent with seizure.

Dr. Dorothy Dean<sup>17</sup> testified for respondent that after considering every possible cause of death, it is likely that the child's death was due to either SIDS or an accidental suffocation caused by overlying. Tr. at 23-24. She acknowledges, however, that the position in which the baby was found is also consistent with a seizure that led to her death, but added that seizure can't be diagnosed by autopsy alone. Tr. at 23-24. Dr. Dean found no other possible causes; the baby had no medical problem that she could find. When asked if she thought it likely that the baby had a seizure, Dr. Dean said, "we can't make a diagnosis of seizure on the autopsy alone; we can't say that the baby had a seizure definitely." Tr. at 25. "[But] you can't have a seizure by itself. A seizure has to be caused by something else." *Id.* The court notes that Dr. Dean ignores the fact that pertussis vaccine has been known to cause seizure, finding nothing upon autopsy that could be considered an objective cause of death. Her final diagnosis, therefore, "within a reasonable degree of medical probability," was SIDS. *Id.* Although Dr. Dean felt it prudent to find Sarah Corzine's death to be more likely than not attributable to SIDS, the court finds in Dr. Dean's testimony critical evidence that strongly suggests Sarah's death was the sequella of a vaccine-related seizure.

In February 2001, at the request of petitioner, Dr. Dean reviewed the autopsy report, the case history, photographs, and microscopic slides pertaining to Sarah Corzine's death. She reviewed Sarah's pediatric records from Queen City Pediatrics, Ltd., the Cincinnati Children's Hospital records from April 1, 1999, and a copy of the Vaccine Injury Table utilized under the National Vaccine Injury Compensation Program. As a result of both her examination and review of the documents, Dr. Dean seemed to revise her opinion. Dr. Dean came to the opinion, to a reasonable degree of medical probability, that there was no anatomic evidence of any significant natural disease that would account for Sarah's death, and that her death was consistent with a hypoxic seizure following administration of the vaccination or vaccinations that had been administered less than 14 hours prior to death. She bases her opinion on Sarah's curiously flexed arm, clenched fists, and rolled back eyes and tongue, which Dr. Dean found to be an unusual and significant posture for a baby. She concluded that posture to be consistent with death following a seizure. Pet. Ex.16. Yet, at the hearing, Dr. Dean testified that we can't say the baby had a seizure, definitely. Tr. at 26.

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<sup>17</sup> Dr. Dean serves as coroner in the Franklin County Coroner's Office in Columbus, Ohio. She is certified and licensed as a Diplomat of the American Board of Pathology in Anatomic and Clinical Pathology, and of the American Board of Pathology in Forensic Pathology. Dr. Dean has also been employed as deputy coroner in Hamilton County, Ohio since 1998. On April 22, 1999, Dr. Dean served in that position to perform a postmortem examination on the body of Sarah Corzine.

Petitioner does not need definitive proof to prevail. Evidence that an injury is vaccine-related need not be definitive. *Id.* It need only indicate, when considering the totality of circumstances, that it is more likely than not that the vaccine caused the injury. Therefore, the dichotomy between Dr. Dean’s medical finding and the court’s legal finding is not problematic here. Dr. Dean, like the court, is charged with considering the circumstances surrounding the death, but without positive evidence of an alternative cause, she was bound to indicate SIDS as the cause. In *Knudsen*, the Federal Circuit found that “identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” 35 F.3d at 549. Accordingly, this court does not require petitioner to produce absolute medical proof in order to prevail. “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.” *Knudsen, supra*, at 548. The trier of fact is required to weigh the evidence accordingly and the undersigned has done so.

Attempting to further the position that Sarah Corzine did not suffer a seizure, respondent offers the testimony of Dr. Marzouk. His arguments do not impress the court. Dr. Marzouk observes that a seizure could not have occurred here for several reasons: First, a seizure death must have a cause, and he finds nothing in Sarah’s case that could cause a seizure. Curiously, Dr. Marzouk seems to have overlooked the administration of six concurrent vaccines known to be associated with, and capable of causing, seizures. He notes that in death associated with seizure, “we sometimes find evidence of injury to the tongue, implying that the tongue moves forward, not backwards, though non specific. No trauma to the tongue was found that would identify injury.” He speculates however, that resuscitation by an inexperienced person, Sarah’s father, for example, might mask trauma to the tongue. The court notes that respondent’s own expert, Dr. Robert Pfaltzgraf,<sup>18</sup> testified that trauma would be unlikely if the child has no teeth to cause injury to the tongue.

[P]athologists can’t diagnose seizures at autopsy without “certain things.” And so again, without an eyewitness report of seizure, or having certain injuries such as a bite mark on the tongue. But infants don’t have teeth so they can’t bite tongues. R. Ex. G at 2; Tr. at 16-17.

Moreover, he believes that the occurrence of a tonic seizure would have been recognized by parents sleeping close by, as they consistently did according to their testimony. The court finds that point effectively challenged by Dr. Shane’s testimony that seizures in infants do not conform with the extreme body motion exhibited in adult seizures. Moreover, Dr. Marzouk’s argument that trauma to the tongue would be apparent had there been a seizure, is refuted by respondent’s own expert, Dr. Pfaltzgraf.

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<sup>18</sup> Dr. Dean’s supervisor, Dr. Robert Pfaltzgraf, was present at the autopsy. Dr. Pfaltzgraf is the Chief Deputy Coroner and Director of Forensic Pathology at Hamilton County Coroner’s Office. He did not assist in the autopsy but served as supervisor, as is required by his office. Tr. at 10-11. He signed off on the autopsy report, and was later called to testify at the hearing, which he did by telephone conference call.

Dr. Dean's acknowledgment that Sarah's posture was indicative of seizure supports Dr. Kinsbourne's theory that the infant sustained a seizure that resulted in her death. Therefore, the undersigned considers Dr. Dean's testimony tantamount to the proverbial feather<sup>19</sup> required to satisfy petitioner's burden of proof – by a preponderance of the evidence. Accordingly, the court finds that Sarah Corzine mounted a hypoxic seizure fewer than 14 hours following her DTaP vaccination.

### **C. Did the DTaP vaccine cause the seizure that resulted in death?**

Having found that petitioner has demonstrated that Sarah suffered a seizure that led to her death, the court now looks to petitioner to establish a causal link between the vaccine and that seizure and its sequella. Dr. Kinsbourne maintains that according to the medical literature, "Convulsions appear to be the most common serious reaction observed following a pertussis vaccination, which Sarah received in the group of vaccines administered less than 14 hours prior to her death." He adds, "DPT is well known at times to cause a seizure."<sup>20</sup> In support of that statement, Dr. Kinsbourne cites well-known experts in vaccine matters, including Dr. Cody.<sup>21</sup> Dr. Cody and colleagues have documented the fact that seizures are well-known reactions to certain vaccines, including the DPT and DTaP vaccine. The DTaP has become the preferred vaccine for several reasons, but can cause seizures, although less commonly than does DPT. Tr. at 133. Sarah received the DTaP vaccine.

Dr. Kinsbourne maintains that death in the course of a seizure is not common, but is a well-documented event.<sup>22</sup> P. Ex. 15. In Sarah's case, he explained, the tonic seizure presumably impeded her breathing. Her rolled-back tongue would further obstruct airflow. More likely than not, her presumably impeded breathing and the factor of her rolled-back tongue made it very difficult for the infant to get necessary oxygen. *Id.* No other adverse event was witnessed between the administration of the six vaccines and her death, 14 hours later.

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<sup>19</sup> To prevail, petitioner must demonstrate causation by a preponderance of the evidence, at least 50% and a feather. *See, e.g., Kuperus v. Sec'y HHS*, 2003 U.S. Claims LEXIS 397; *Degrandchamp v. Sec'y HHS*, 2003 U.S. Claims LEXIS 150.

<sup>20</sup> DPT and DtaP both contain the antigens carried in the pertussis vaccines. Sarah received the DtaP, now considered the preferred vaccine

<sup>21</sup> Cody, et al. "Nature and rates of adverse reactions associated with DTP and DT immunization in infants and children." 68 *Ped.*, at 65, 660 (1981).

<sup>22</sup> As discussed in the previous section, Dr. Wiznitzer does not contest that seizures can cause death, but that these fatal seizures cannot be mounted by a very young infant. The court is emphatic in its finding that Dr. Kinsbourne's successfully rebutted that assertion.



Petitioner has demonstrated, to the court's satisfaction, the three critical elements of proof in this case: First, that an infant of Sarah's age and development can suffer a fatal seizure. Second, that she did suffer a fatal seizure as evidenced by her posture in death. Third, that the pertussis component of the DTaP vaccine can cause seizures, and did cause the seizure that resulted in Sarah's death. The Federal Circuit has held "that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." See, Shyface, 165 F.3d 1344, supra. Clearly, petitioner's proof meets that standard.

## V. THE QUESTION OF ALTERNATIVE CAUSATION

### A. Accidental Overlay

Before continuing with the discussion, the court now addresses the question of accidental overlay. The court is satisfied that the likelihood of accidental overlay is mere speculation. There is simply no reliable evidence to support overlay as the cause of Sarah's death; the coroner found no evidence at autopsy that would even suggest overlay. The body did not show evidence of an infant tangled in covers, nor was her face smothered by bedding. No marks on her body indicated any bruising that would suggest pressure from significant weight.

Testifying for petitioner, Dr. Shane dismisses out of hand the likelihood of overlay. He maintains that the possibility of overlay is mere speculation, explaining that an asphyxial death due to overlay while a child sleeps between parents would have resulted in cerebral edema due to cerebral hypoxia, and this condition was not evident at autopsy.

Petitioner's testimony and demonstration were credible, and it is unlikely that the parents would have changed the usual sleeping arrangement they followed consistently at least four or five times a week. The experts agree that overlay is possible, but none of the experts in this case brought forth any physical evidence of overlay or was willing to consider accidental overlay as the probable cause of death.

### B. SIDS

"A successful showing of legal causation **or** causation-in-fact does not end the question" of compensation (emphasis added). Jay, 998 F.2d at 984, citing, Grant, 956 F.2d at 1149. The court in Jay emphasized that the Act provides that "after a petitioner establishes legal causation (table injury) or causation-in-fact, there still remains the statutorily separate inquiry under 42 U.S.C. § 300aa-13(a)(1)(B) whether an alternative causation has been proved by HHS. Id. Accordingly, the court next addresses respondent's contention that Sarah Corzine died of SIDS.

At hearing, each of respondent's experts seemed to agree that SIDS is the most probable cause of Sarah's death, but provided different reasons. Dr. Anderson reasons that Sarah's condition meets the criteria for a SIDS death. Dr. Marzouk's reasoning is based primarily on statistical probability, as SIDS is a far more common cause of infant death than is seizure. He

adds that the new DTaP would be less likely to cause seizure than the old vaccine. He insists that seizures usually have a cause, but finds nothing in this case that could cause a seizure or fever, ignoring the fact that the vaccinations Sarah received, particularly the pertussis component, have been known to result in seizure. Furthermore, much of his reasoning is statistical in nature and lacks merit because statistics are not considered dispositive in vaccine cases. The court is looking for scientific information that will help it understand the complexities of this case. This is not to say that statistical information is not useful, but to emphasize that more than statistics was needed here.

The court notes further that SIDS is not a disease, nor is it a cause of injury. SIDS is a diagnosis of exclusion, a catchall definition used when the cause of death in a previously healthy infant cannot be identified because no cause is apparent. In other words, when the doctors, pathologists, and other experts are at a loss for possible causes of death, they rely on SIDS as a diagnosis. Dr. Marzouk leans toward a SIDS death in this case without acknowledging the well-established possibility of seizure following pertussis vaccination. With interest, the court notes that respondent's experts also insist that a seizure must have a cause, supporting petitioner's argument that the vaccine caused a seizure. Respondent deigns to overlook the most likely cause of seizure here . . . that is, the toxins in the six different vaccines administered less than 14 hours before the child was found dead. This court cannot ignore the fact that the toxins in the very vaccines Sarah received are known to cause seizures, and although the DTaP is less reactogenic than the earlier DTP, it is still capable of causing adverse reactions. Moreover, the testimony holding that an autopsy would not reveal evidence of seizure supports the thesis that Sarah could easily have suffered a seizure while her parents slept, an occurrence that belies the testimony that this child's death is without explanation.

Under the Act, SIDS cannot qualify as a factor unrelated to the vaccine, and therefore cannot defeat petitioner's claim. Respondent may rebut a presumption of causation by establishing that the injury or death is due to factors unrelated to the administration of the vaccine. "The statute provides that the term 'factors unrelated' does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause." Cummings v. Secretary, HHS, 1996 U.S. Claims 182, 184, citing § 13(a)(1)-(2)(A). SIDS, by definition, pertains to a sudden and unexplained death. See, Dorland's, supra. Accordingly, it cannot be considered a "factor unrelated" by virtue of its idiopathic nature. See, Hossack v. Secretary, HHS, 32 Fed. Cl. 769, 771 n.4 (1995); Morris v. Secretary, HHS, 20 Cl. Ct. 14, 22 n. 7 (1990). Therefore, this court is prohibited from denying compensation to the petitioners on the basis that SIDS was an alternative cause of Sarah Corzine's death. See, Carraggio v. Secretary, HHS, 38 Fed. Cl. 211, 223 (1997). Moreover, it is well established that "factors unrelated" are pertinent to causation-in-fact cases, not only to the presumption of causation afforded petitioner in Table cases.

## VI. CONCLUSION

Sarah Corzine died on the night of April 21, 1999. She received her DTaP vaccination that day and died approximately 14 hours later. Temporal association of the onset of the injury

with the vaccination, although probative, is not sufficient in and of itself to establish causation-in-fact. Grant, 956 F.2d at 1148); See, Strother, 950 F.2d 731. Temporal association and lack of alternative cause are factors that figure greatly in all such cases. To wit, petitioner argues that although temporal association must be considered here, it is not the substance of the vaccine-causation argument. Seizure is the substantive cause and the court finds that Sarah's posture upon death bears evidence to that. Respondent, however, clings to the argument that petitioner's case rests merely upon temporal association and lack of alternative cause. It is Dr. Dean's testimony that tips the balance in petitioner's favor at this juncture.

Although the temporal relationship in this matter cannot be ignored, the court does not rely on it in reaching a decision. Mere temporal association is not enough to relate a vaccine to injury or death; something more is needed in a causation-in-fact case to tip the scales. See, O'Leary v. Secretary of HHS, 1997 U.S. Claims LEXIS 98. That "something more" in this case is the position in which the child was found in death, a posture the experts have effectively shown to be indicative of seizure. The court finds, after considering the entire record in this case, that Mr. Corzine is ENTITLED to compensation under the Vaccine Act.

By presenting a preponderance of evidence supporting his claim, Mr. Corzine has met his burden for prevailing in a causation-in-fact case. He showed that an infant Sarah's age could mount a fatal seizure, that she did, in fact mount a seizure and that the seizure caused her death, that the pertussis vaccine can, and in this case did, cause seizure, and finally, that SIDS is not an alternate cause. This logical sequence of cause and effect brings the court to the conclusion that "but for" the administration of the DTaP vaccine, Sarah Corzine would not have suffered a seizure on the night of April 29, 1999, and that the vaccine was a "substantial factor" in triggering a seizure that caused her death.

For these reasons, the court finds that it is more likely than not that a vaccine-induced seizure caused Sarah Corzine's tragic death. The court has reviewed the records in this matter and finds that, pursuant to 42 U.S.C. §300aa-15(a)(2), petitioner is entitled to an award of \$250,000.00.

In the absence of a motion for review filed pursuant to RCFC Appendix B,<sup>23</sup> the Clerk is directed to enter judgment in accordance with this decision.

**IT IS SO ORDERED.**

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E. LaVon French  
Special Master

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<sup>23</sup> Pursuant to Vaccine Rule 11(a), entry of judgment may be expedited by each party filing a notice waiving the right to seek review.