OFFICE OF SPECIAL MASTERS

No. 99-998V

Filed: July 20, 2005

<u>James A. Pagliuca</u>, Woodbridge, New Jersey, for petitioners.

<u>James Andreas Reistrup and David Levon Terzian</u>, United States Department of Justice, Washington, D.C., for respondent.

DECISION¹

GOLKIEWICZ, Chief Special Master

PROCEDURAL BACKGROUND

On December 14, 1999, petitioners filed a claim on behalf of their daughter, Brianna Guzman [hereinafter Brianna], under the National Vaccine Injury Compensation Program

¹Because this decision contains a reasoned explanation for the special master's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, as provided by Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. <u>Id.</u>

[hereinafter "the Act" or "the Program"].² Petitioners claim that Brianna suffered seizures and an acute encephalopathy as a result of the administration of a Diptheria-Pertussis-Tetanus [hereinafter DPT] vaccination she received on January 24, 1997. Petition [hereinafter Pet.] at 1. Petitioners aver that symptoms of an encephalopathy³ were apparent within 72 hours of Brianna's DPT vaccination, manifested by a significantly decreased level of consciousness lasting for at least 24 hours, and followed by a chronic encephalopathy, persisting for more than six months from the time of vaccination. See generally, Pet.; Respondent's Rule 4(b) Report [hereinafter R. Report] at 11. Respondent does not challenge these basic facts relating to Brianna's injury; rather, respondent alleges that the injury was caused by trauma – not the vaccine. R. Report at 11.

Prior to addressing the issue of causation, vaccine versus trauma, an initial legal issue must be addressed; who bears the burden of proving or disproving the trauma as a cause for the baby's injury? ⁴ At issue is the interpretation of two sections of the Vaccine Act – § 13(a)(1)(B) and § 14(b)(3)(B). Under section § 14(a) of the Act, if it is determined that the first symptom or manifestation of an encephalopathy occurred within three days (72 hours) following a DPT vaccination, a rebuttable presumption arises that the injured person is entitled to an award under the Program. Thus, if a special master finds based on the record as a whole, "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," compensation shall be awarded. § 13(a)(1)(B). That section puts the burden squarely on respondent to prove that trauma was in fact the cause of Brianna's injuries. See Whitecotton v. Secretary of the Department of Health and Human Services, 17 F.3d 374, 376 (Fed. Cir. 1994). Petitioners are therefore entitled to a presumption of vaccine-causation, unless respondent rebuts the presumption by presenting evidence that the injury was due to factors unrelated to the administration of the vaccine.

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-1 et seq. (West 1999 & Supp. 2000). Hereinafter, individual section (§) references will be to 42 U.S.C.A. § 300aa of the Act.

³An encephalopathy is "any degenerative process of the brain." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 550 (27th ed. 1988); see § 14(b)(3)(A) for the definition of encephalopathy under the Vaccine Act.

⁴ Specifically, the following briefs and responses were filed by the parties to address this legal issue: 1) The Respondent Should Bear the Burden of Proving a Factor Unrelated, filed May 19, 2003 [hereinafter P. May 19 Brief]; 2) Petitioners Bear the Burden Establishing a Table Encephalopathy: Respondent's Memorandum in Support, filed May 9, 2003 [hereinafter R. May 9 Brief]; 3) Respondent's Reply to Petitioner's Memorandum: A "Table" Encephalopathy Has Not Been Established in this Case, filed May 30, 2003; and 4) Petitioner's Rebuttal to Respondent's Memorandum, filed June 25, 2003.

However, as pointed out by respondent, another section of the Act, § 14(b)(3)(B), muddies the otherwise clear waters. That section states that if it is shown by a preponderance of evidence that the encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances, the encephalopathy shall **not** be considered to be a condition set forth in the Table. § 14(b)(3)(B); 42 CFR 100.3 (b)(2)(3) (emphasis supplied). While the language for these four identified pathologies mimics the "factor unrelated" language of § 13(a)(1)(B), respondent argues that petitioners, not respondent, are obligated to rule out trauma as part of petitioners' proof of a Table case. The statutory route of respondent's argument begins with § 13(a)(1)(A), which requires petitioner to prove the elements of § 11(c)(1). Of relevance here, § 11 (c)(1) requires proof of a "condition set forth in the Vaccine Injury Table." § 11(c)(1)(C)(i). The Vaccine Injury Table, found at § 14(a), the initial Table, and at 42 C.F.R. 100.3 (b)(2)(3), as revised, contains the covered vaccines, the list of injuries, and the appropriate time frames for onset of the injuries - issues not in dispute here. However, critical to the dispute here is § 14(b), "Qualifications and Aids to interpretation," which "shall apply to the Vaccine Injury Table." Respondent argues that by taking together the clear wording of these provisions, petitioner is not entitled to the Table presumption for an encephalopathy unless and until petitioner proves that the encephalopathy was not due to one of the factors listed in § 14(b)(3)(B).

Reading these two sections of the Act and trying to understand their interplay, it is difficult to reconcile them practically. In fact, respondent's initial Rule 4(b) report conceded that Brianna's injuries satisfied the statutory requirements for a prima facie Table case. In that report, respondent argued that trauma was the in-fact cause, thus a factor unrelated pursuant to § 13(a)(1)(B). R. Report at 11. Thus, respondent accepted the legal burden of proving trauma as the actual cause. Respondent later changed that position, arguing subsequently that the petitioners did not establish a Table case. R. May 9 Brief at 2. Respondent's present argument "denies that Brianna sustained a vaccine-related injury," arguing "that the contemporaneous medical evidence establishes that Brianna's condition was diagnosed and treated as a 'traumatic brain injury,' specifically excepting it from the regulatory definition of encephalopathy under the Table." R. May 9 Brief at 1. In essence, respondent now contends that petitioners bear the burden of disproving trauma as the cause of Brianna's injuries, citing § 14(b)(3)(B). Respondent's argument continues that since petitioners have not ruled out trauma as the cause, petitioners have not proven the Table injury of encephalopathy as defined by the "Qualifications and Aids to interpretation," and thus are not entitled to the presumption of causation.

If respondent is correct in his reading of the Act, it would seem that much of respondent's burden of establishing a factor unrelated in Table cases would be eviscerated by § 14(b)(3)(B). This is because petitioners would have to disprove the alternative causes of infection, toxins, trauma, or metabolic disturbances as part of their proof of a Table injury. In an effort to understand Congress' intent behind the two provisions, the undersigned reviewed the legislative history. Unfortunately, it is sparse and essentially unhelpful in answering the question of burden. It states:

Subsection (b) provides various descriptions and definitions that the Committee intends be used in interpreting the meaning of the Table. In addition, the subsection also restates in specific terms the general rule described in Section 2113 and provides that if the cause of an encephalopathy is an infection or another condition not related to the vaccine, the encephalopathy is to be considered compensable if other conditions (including specified time of initial onset) are met.

H.R. Rep. No. 99-908, at 19 (1986). In restating the general rule, Congress arguably placed the same burden of addressing alternative causes, at least for the four identified processes, to the vaccine on both parties: § 13(a)(1)(B) on respondent and § 14(b)(3)(B) on petitioner. A review of past case law cited by the parties and provided through the undersigned's own research provides limited discussion of the issue.

However, as the undersigned related to the parties prior to trial, the Federal Circuit discussed indirectly this issue in <u>Knudsen v. Secretary of Health and Human Services</u>, 35 F.3d 543 (Fed. Cir. 1994). In <u>Knudsen</u>, it was undisputed that the petitioners' child suffered an encephalopathy within the appropriate time frame and thus was presumptively entitled to compensation. <u>Id.</u> at 547. However, the court noted that the inquiry does not end there as the claim can be defeated by the government proving by a preponderance of the evidence that the injury was in-fact caused by factors unrelated to the vaccine. <u>Id.</u> (citing <u>Whitecotton v. Secretary of the Department of Health and Human Services</u>, 17 F.3d 374, 376 (Fed. Cir. 1994)).

In arguing that a viral infection was the cause of the encephalopathy, the Federal Circuit noted that:

[T]he government relies on two sections of the Vaccine Act. First, the Vaccine Act provides that "factors unrelated to the administration of the vaccine" which can defeat a petitioner's right to recover *may* as documented by . . . material in the record, include *infection* . . . which ha[s] no known relation to the vaccine involved, but which in the particular case [is] shown to have been the agent or agents principally responsible for causing the petitioner's illness disability, injury, condition, or death. Id. §300aa-13(a)(2) (emphasis added). Second, the table of injuries expressly states that if "it is shown by a preponderance of the evidence that an encephalopathy was caused by *infection* . . . the encephalopathy shall not be considered to be a condition set forth in the table." Id. § 300aa-14 (b)(3)(B) (emphasis added).

Knudsen, 35 F.3d at 548 (emphasis in original).

Thus, in <u>Knudsen</u>, which involved analogous issues to the case at issue, <u>i.e.</u>, of alternate causes to the Table injury, respondent did not argue that $\S 14(b)(3)(B)$ placed the burden on petitioner to show that the encephalopathy was **not** caused by a viral infection before receiving the Table presumption of causation, but instead argued that $\S 14(b)(3)(B)$ buttressed

respondent's argument that the viral infection was a factor unrelated under § 13 (a)(2). While rejecting on other grounds respondent's argument of a factor unrelated, the Federal Circuit adopted respondent's legal analysis. <u>Id.</u>

Thus, as the undersigned explained to the parties at the hearing, Tr. at 22-23, 267-68, the undersigned believes that the most reasonable interpretation of the Act is that, as explained in the legislative history and supported by Knudsen, § 14(b)(3)(B) merely restates in specific terms the proposition that if another cause unrelated to the vaccine is shown to be the actual cause of the injury, petitioner's Table case is defeated. By restating this proposition in the legislative history, there is no indication that Congress intended to shift the burden of proof. The burden of proving alternative causes is the respondent's burden. Whitecotton, 17 F.3d at 376. Respondent has accepted that burden under both §§ 13 (a)(2) and 14 (b)(3)(B). Knudsen, 35 F.3d at 548. The Federal Circuit has concurred. Id. The undersigned agrees and also notes that to the extent the Federal Circuit has spoken on the issue, the undersigned is duty-bound to follow its construction.

Lastly, it should be noted that in the undersigned's seventeen years of experience deciding cases under this Act, this is the first case before the undersigned where respondent has raised this issue. These provisions have been in the statute from its initial passage, with minor changes not impacting the issues raised in this case. The undersigned's experience includes two previous "shaken baby" cases, where in both instances respondent conceded petitioners' Table injuries and accepted as respondent's legal burden the duty to show that trauma was in-fact the actual cause of the injury. It is, to say the least, surprising that such a potentially critical legal issue has arisen at such a late date in this manner. However, in the final analysis of this case, this legal issue became a non-issue. This is so because no matter whose burden it is to prove or disprove the alternate cause to the vaccine, the undersigned finds by far greater than a preponderance of the evidence that Brianna's injuries were not due to trauma.

The undersigned arrived at the determination that petitioners are entitled to compensation after reviewing all of the evidence before the court. This evidence included depositions that were taken by both parties as well as a hearing that was held on January 13, 14, and 15 of 2004. At the hearing, petitioners presented factual testimony from Mr. and Mrs. Guzman, as well as Mrs. Guzman's mother, Nancy Schirmer, with expert testimony provided by Drs. Peter Carmel and James Goodrich.⁵ Drs. Gilbert Vezina, Robert Zimmerman, David L. Chadwick, and Arnold Gale testified on respondent's behalf. Following the hearing, the parties continued to brief the difficult medical issues presented in this case. Petitioners' experts maintained that the vaccine caused Brianna's encephalopathy. Respondent's experts contended that Brianna was shaken, resulting in her brain injury.

⁵Petitioners also intended to present Dr. Steven Schonfeld, a neuroradiologist, as a witness on their behalf, but declined to call him at the hearing. See Order, filed December 15, 2003 at 2; Tr. at 495.

Shortly following the evidentiary hearing, without benefit of the transcript, the undersigned conveyed to the parties tentative thoughts and conclusions regarding the evidence. Order, filed January 23, 2004. Several key observations and findings were made in the Order:

- it was found that based upon Dr. Zimmerman's and Dr. Vezina's testimony that subdural blood was shown on the CT scans;
- it was observed that, except for Dr. Gale, the experts could not conclude based upon that blood that trauma was the cause;
- it was agreed that Brianna suffered an anoxic injury;
- it was agreed that the vaccine could cause an anoxic injury; and
- it was agreed that the anoxic injury would not cause retinal hemorrhaging.

Based upon these observations, the undersigned found that: Dr. Zimmerman's testimony regarding the presence of blood on the scan cannot be dismissed; however, Drs. Carmel, Goodrich, and Bruce's conclusion that this is not "shaken baby syndrome" [hereinafter SBS] could not be dismissed solely on the basis of Dr. Zimmerman's testimony regarding the blood seen on the scans. Thus, after summarizing the evidence and the experts' positions, the undersigned requested the experts to address the following "postulation":

Brianna received her vaccination, suffered a seizure which led to/caused an anoxic event. The father, in an effort to get his daughter to breathe, "jostled" or "shook" her and thereafter performed CPR. The anoxic event resulted in severe brain damage, while the "shaking" and possibly the CPR resulted in the retinal hemorrhaging and brain bleed.

Order, filed January 23, 2004 at 3.

Petitioners' experts Drs. Carmel and Goodrich filed responses to the undersigned's request on April 15, 2004 agreeing with the "postulation." See P. Exs. 106, 107. Respondent's experts Drs. Zimmerman, Chadwick and Gale filed responses on April 12, 2004 disagreeing, more or less, with the "postulation." See R. Exs. II, JJ, KK.

On May 26, 2004, the court issued an Order memorializing counsels' representations that the record was complete. The Order indicated that the case was ripe for decision at that time. Subsequently, on August 20, 2004, the undersigned issued a Damages Order indicating that the undersigned had "finished a complete and thorough review of the entire record of this case" and that the "undersigned finds that petitioners are entitled to compensation under the Act." Order, filed August 20, 2004 at 1. The undersigned indicated that a "full opinion shall issue at a later date." Order, filed October 20, 2004. Pursuant to that Order, a full discussion follows.

FACTUAL BACKGROUND

Brianna Guzman was born on November 21, 1996, following an uneventful pregnancy. P. Ex. 2 at 1, 2-11. On December 7, 1996, when she was approximately three weeks old, she was hospitalized for four days with a possible viral infection, fever, and right otitis media. P. Ex. 3 at 5. The otitis media and possible viral infection were successfully treated with antibiotics. Id. Brianna was found to be a normally developing child at the four "well baby" pediatrician visits prior to the administration of the DPT vaccine on January 24, 1997. See P. Ex. 4 at 1-6.

On January 24, 1997, when Brianna was eight weeks old, Mrs. Guzman and her mother, Nancy Schirmer, took Brianna to the pediatrician's office for a check up and vaccinations. Tr. at 105, 126; P. Ex. 4 at 1. Mrs. Guzman and Ms. Schirmer testified that they asked the pediatrician whether it was safe for Brianna to be vaccinated, considering that she was congested at the time. Tr. at 105. The doctor checked Brianna and said she was fine, with no chest congestion, and was healthy enough to be vaccinated. <u>Id.</u> at 105-106, 134. Brianna received her first administration of DPT at approximately 12:00 noon, on January 24, 1997, in her pediatrician's office in Old Bridge, New Jersey. <u>See</u> P. Ex. 4 at 1; Tr. at 105, 134.

Ms. Schirmer testified that when she was about to feed Brianna that evening, at approximately 5:30 p.m., Brianna refused her bottle and screamed in an alarming manner. Tr. at 136. Ms. Schirmer had never seen her granddaughter scream like that and assumed she was reacting to the vaccine. <u>Id.</u> The pediatrician advised her and her daughter that should Brianna seem uncomfortable, they could give her some Tylenol. <u>Id.</u> at 106. Ms. Schirmer did so, walked around with Brianna in her arms, and the infant relaxed enough to be fed. <u>Id.</u> at 137. Brianna fell asleep in her grandmother's arms. <u>Id.</u> at 137-38. Mr. Guzman came home from work at approximately 6:30 p.m., at which time he showered. <u>Id.</u> at 138. When he came down half an hour later, Brianna was in her swing, and Ms. Schirmer left to go out for dinner. Id. at 138-39.

Mr. Guzman testified that soon after his mother-in-law left the house, Brianna was asleep in the swing. Id. at 156. He took her from the swing and put her in her crib. Id. Soon after, he heard Brianna screaming and went to check on her. Id. at 157. He described the screams as very high-pitched and unusual. Id. When she wouldn't stop, he turned her from her back to her side, and patted her back a little, calling her name. Id. Mr. Guzman said that Brianna suddenly "stopped screaming and she went like stiff.... And at that moment I didn't know what - because she looks like stiff, and I pick her up." Tr. at 158. Responding to a question, Mr. Guzman said he didn't know if Brianna was breathing at that time, but that his impression was that she was not breathing. Id. He picked her up and put her on his shoulder, at which point her body went limp. Id. "And I just put her in front of me and I called her: Brianna, Brianna, but she was like, you know." Id. Mr. Guzman testified that at that point, Brianna's eyes were closed and he was supporting her head. Id. at 158-59. Needing help, he called his brother-in-law and brother-in-law's girlfriend, Kelly, who were present in the house. Id. at 159. They came

⁶ Otitis media is an inflammation of the inner ear. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 1202.

downstairs and Mr. Guzman told them to call 911. <u>Id.</u> Because Kelly was making the phone call from Ms. Schirmer's room, Mr. Guzman put Brianna down on Ms. Schirmer's bed so that he could listen for the instructions on how to proceed until help arrived. <u>Id.</u> at 159-60. In the course of the next few minutes, Kelly called 911 and Mr. Guzman attempted CPR. <u>Id.</u> at 160. He had never trained to perform CPR, nor performed CPR on anyone before, let alone a small baby. <u>Id.</u> Eventually the police and paramedics arrived at the house and Brianna was breathing at that time. <u>Id.</u> at 160-61. Fitting her with an oxygen mask, the paramedics took her to the hospital where she was admitted. Id. at 161.

After examination by several physicians, Brianna was diagnosed with focal seizures and was noted to have suffered global encephalopathy as the result of an anoxic⁷ or hypoxic⁸ injury to the brain. P. Ex. 9 at 2, 16, 147, 153. In addition, she presented with bilateral retinal and vitreous hemorrhages.⁹ P. Ex. 9 at 4, 164. Based upon these findings, Dr. Steven Kugler, a neurologist, and Dr. Mark Engel, a pediatric ophthalmologist, were called into the case; both doctors wrote consultation reports opining as to the cause of Brianna's injuries including their opinions as to whether SBS had occurred.¹⁰ See P. Ex. 9 at 164-65; R. Ex. Q at 15-17; R. Ex. R

[An] acceleration or deceleration of the head associated with flopping back and forth probably . . . most of the time in the direct plane of far and aft, front to back, where the head flops back, actually hits the back, and flops forward, and the chin impinges on the chest, and that happens perhaps through a few cycles, nobody knows how many, at high velocity, and with great energy that the brain within the skull . . . sloshes; the brain is gelatinous and it isn't rigid, so it sloshes within the dura and within the skull. And it produces torsional effects within itself that are damaging, and it produces shear along the plane of the dura or the surface of the brain and down within the folds of the brain, down in the inner hemispheric fissure. That movement of the brain tears the veins.

The venous drainage, the veins that come out of the brain and go down the sinuses, . . . [and] they cross through the dural space, and with this movement some of those veins can be torn a lot. It could be just one big one. It could be a lot of little ones, and it varies case to case, but there is tearing of the bridging veins. Then there is bleeding into the subdural space, but meanwhile before that ever happens the event itself produces brain damage by the tearing of nerve cells, particularly the long fibers of nerve cells that do the conductions, because they go over long, large spaces, and they are more exposed.

The axonal damage, those are called axons, . . . are the way the nervous cells conduct messages from one part of the brain to another, or from the brain out to the body. So there is axonal damage within the brain and possibly within the upper part of the spinal cord as well.

⁷ Anoxia is the total absence of oxygen. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 94.

⁸ Hypoxia is a reduction of oxygen supply. Dorland's Illustrated Medical Dictionary at 810.

⁹ Retinal and vitreous hemorrhage is bleeding into the innermost of the three tunics of the eyeball and further into the vitreous body of the eyeball. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 1846.

¹⁰Dr. Chadwick, one of respondent's expert witnesses on SBS, see infra p. 11, described SBS as:

at 11. After referral by Brianna's treating physicians at the hospital, P. Ex. 9 at 4-5, an investigation was conducted by the Division of Youth and Family Service [hereinafter DYFS] to determine whether Mr. Guzman had in-fact hurt his daughter. See, e.g., P. Ex. 23¹¹, R. Exs. EE, FF, GG. While the investigation occurred, DYFS allowed Brianna to be released to her family only on the condition that Mr. Guzman not spend time alone with her. Tr. at 163; see R. Ex. PP at 128. Ultimately, the charges of child abuse were found to be without merit, and no grand jury was ever convened. Tr. at 208.

Experts Presented

Petitioners in this case presented two expert witnesses in support of their position: Dr. Peter Carmel and Dr. James Goodrich, both neurosurgeons. Respondent presented four expert witnesses in support of his position: Dr. Gilbert Vezina and Dr. Robert Zimmerman, both neuroradiologists; Dr. Arnold Gale, a neurologist; and Dr. David Chadwick, a pediatrician with an expertise in child abuse. The testimony was of the highest quality. The undersigned found each of the experts, except Dr. Gale, as discussed at p. 17 *infra*, to be highly credible. A short discussion of each of their respective backgrounds and qualifications follows.

Dr. Peter Carmel for Petitioners

Dr. Peter Carmel is board-certified in adult and pediatric neurological surgery. Tr. at 31; P. Ex. 93 at 2. He is the chairman of the Department of Neurological Surgery at the New Jersey Medical School, a Level 1 trauma center. Tr. at 29; Pet. Ex. 93 at 2. He is also chairman of the Department of Neurological Surgery, the director of the neurosurgical resident training program, and chief of the neurosurgical services at that hospital. Tr. at 32. Dr. Carmel has served on 3 editorial boards and published over 100 peer-reviewed articles. Id. at 33. He testified that 70% of his clinical practice is dedicated to children and that he still performs pediatric brain surgery and often reads CT and MRI scans. Id. at 33-34. Dr. Carmel testified that he has read "thousands" of CT scans and MRIs throughout his career. Id. at 34.

Tr. at 236-238.

¹¹Petitioners apparently filed two exhibits labeled as "Exhibit 23." One was filed on September 10, 2001 and contains documents that relate to the DYFS investigation regarding Brianna's injuries. The other exhibit was filed on December 14, 1999, and appears to be a discharge document from the Children's Specialized Hospital. Unless otherwise noted, when the court refers to Exhibit 23, the court is referencing the document relating to the DYFS investigation.

¹²Trauma centers are designated as Levels 1 through 4 by the American College of Surgeons' Committee on Trauma, with Level 1 centers providing the highest and most comprehensive level of care. Level 1 trauma centers also tend to be teaching hospitals. See, e.g., http://www.henryfordhealth.org/113498.cfm.

Dr. James Goodrich for Petitioners

Dr. Gilbert Vezina for Respondent

Dr. Vezina is a pediatric neuroradiologist, board certified in diagnostic radiology in the United States and in Quebec, Canada in 1987 and 1988, respectively. R. Ex. BB 1-2. Dr. Vezina graduated from McGill Medical School in 1983, which is located in Quebec, Canada. Id. at 1. Subsequently, he undertook a radiology residency from 1984 through 1987 at Massachusetts General Hospital in Boston. Id. at 1; Tr. at 426. He then performed a two-year fellowship in neuroradiology at Massachusetts General and stayed on as a junior staffer there until 1990. Tr. at 426. Subsequently, he moved to Washington, D.C. where he completed a one-year fellowship in pediatric neuroradiology at Children's National Medical Center. Id. In addition to his certification in diagnostic radiology in the United States, Dr. Vezina has also been certified as a neuroradiologist since 1998. R. Ex. BB at 3. In 2001, Dr. Vezina served for a term as President of the American Society of Pediatric Neuroradiology. Tr. at 427. He testified that he has been practicing exclusively pediatric neuroradiology since 1990. Id. at 428.

Dr. Vezina testified that of the radiologic film he reviews daily, approximately 10-20 percent of them deal with trauma. <u>Id.</u> He testified that every time he reviews a trauma induced injury of an infant, he considers whether it could be SBS. He estimates that since he began at the Medical Center, he has seen one hundred cases of confirmed SBS. <u>Id.</u> at 429. As a neuroradiologist, he consults with neurologists and/or neurosurgeons every day. Id. at 430.

Dr. Robert A. Zimmerman for Respondent

Dr. Zimmerman is a neuroradiologist who specializes in pediatric neuroradiology. Tr. at 497. Dr. Zimmerman is board-certified in diagnostic radiology since 1970 and in neuroradiology since 1995. R. Ex. HH at 4. Dr. Zimmerman received his medical degree from Georgetown University School of Medicine in 1964. <u>Id.</u> at 1. From 1964-65 he interned at Georgetown University Hospital and subsequently from 1965-69, did his radiology residency at the Hospital of the University of Pennsylvania, in Philadelphia, Pennsylvania. <u>Id.</u> Dr. Zimmerman was a full professor the Hospital at the University of Pennsylvania in the Department of Radiology as well

as in the Department of Neurosurgery from 1981-89; thereafter, he moved to Children's Hospital of Philadelphia, where currently he has been Chief of the Pediatric Neuroradiology unit since 1988. Tr. at 497-98; R. Ex. HH at 2-3. As an extension of his expertise, Dr. Zimmerman has published in the field of SBS a number of times. Tr. at 553-54. His most recent piece in the area of SBS focused on the state of research and knowledge in non-accidental trauma for infants and children, and was presented for a program at the National Institute of Health. <u>Id.</u> He wrote the neuroradiology section of the presentation, which was published by the American Academy of Pediatrics. Tr. at 554. Dr. Zimmerman testified that he has been practicing pediatric radiology since 1974 – over thirty years. <u>Id.</u> at 499. He also testified that there is no board certification in the area of pediatric neurology because there are "not enough people to have a board." <u>Id.</u>

Dr. David Chadwick for Respondent

______Dr. Chadwick is board certified in pediatrics. R. Ex. B at 1. He earned his medical degree from the University of California, San Francisco School of Medicine in 1949. Id. Dr. Chadwick is currently Director-Emeritus for the Center for Child Protection at the Children's Hospital in San Diego. Id. Dr. Chadwick also currently provides "medical consultation about child maltreatment," in which he 1) does program development for hospitals; 2) provides expert testimony in cases of alleged child abuse; and 3) develops and provides educational materials regarding child abuse. Id. Dr. Chadwick testified that he has had "hands-on" participation in approximately 100 to 200 SBS cases. Tr. at 227. In addition, Dr. Chadwick is the author of numerous articles on child abuse and SBS. See R. Ex. B at 8-11.

Dr. Arnold Gale for Respondent

Dr. Gale is a board-certified pediatrician. Dr. Gale received his medical degree from Johns Hopkins University School of Medicine in 1976. Tr. at 334. After completing an internship and residency in pediatrics at Massachusetts General Hospital in Boston, Massachusetts, from 1976-78, Dr. Gale subsequently completed a fellowship in pediatrics from 1979-80 at Johns Hopkins University School of Medicine and Hospital in Baltimore, Maryland. R. Ex. T at 1. Following this, Dr. Gale was a resident in neurology at Hopkins from 1979-81, and then Chief resident of child neurology from 1981-82. <u>Id.</u> Dr. Gale currently is a staff neurologist at Stanford University Medical Center, where he has been since 1982. <u>Id.</u> at 2.

In addition to his professional credentials, Dr. Gale also has extensive involvement with academia. For example, he was an assistant professor of pediatrics and neurology at the George Washington School of Medicine in Washington, D.C. from 1982-89. Id. During that time, Dr. Gale was also director of the neurology training program at the Children's Hospital National Medical Center, also in Washington, D.C. Tr. at 335. As noted above, he is currently a member of the clinical faculty as associate clinical professor of pediatrics and neurology and neurological sciences at Stanford University in Stanford, California. Id. Dr. Gale claims that he has testified for the vaccine program as many as "60 to 80 different times." Id. at 336.

Deposition Testimony

In addition to the hearing testimony, the above witnesses along with several treating physicians were deposed. Drs. Carmel, Goodrich, Zimmerman, Vezina, Chadwick, and Gale were deposed by petitioners' and respondent's counsel. See R. Exs. Y, L, K, DD, J, CC. Several of Brianna's treating physicians were also deposed by both counsel, including Drs. Castello, Kugler, Engle, and Weiss. See R. Exs. M, R, Q, N. The undersigned read and considered each of the depositions.

DISCUSSION

Standard of Review – Table Cases

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.¹³

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. §300aa-14(a). To demonstrate a table injury, a petitioner must show that the individual who was given the vaccination suffered an injury listed on the table within the Table's prescribed time periods. §300aa-14. Thus, if a petitioner can show by a preponderance of the evidence that a table injury was sustained within the required time period, then there is a presumption that the petitioner is entitled to compensation, unless the respondent can show, by a preponderance of the evidence, that the injury was caused by factors unrelated to the administration of the vaccine. Carraggio v. HHS, 38 Fed. Cl. 211, 218 (1997) aff'ing 1997 WL 74964 (Fed. Cl. Spec. Mstr. Jan. 31, 1997); but see, discussion, *supra* pp. 2-5 regarding burden of proving or disproving alternate causes. DPT is included on the Vaccine Table; encephalopathy and residual seizure disorder are listed as DPT Table injuries. Accordingly, petitioners are pursuing their claim as a Table case.

Analysis

This case presents many complex emotional and medical issues. There were two important areas of agreement among the experts. Drs. Carmel, Goodrich, Zimmerman, Gale, and Chadwick all agreed that an anoxic event caused Brianna's resultant brain damage, i.e., the encephalopathy, and that the DPT vaccine can cause an anoxic event. P. Exs. 106, 107; Tr. at

¹³ A preponderance of the evidence standard requires a trier of fact to "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." <u>In re Winship</u>, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

542-43; R. Ex. CC at 45; Tr. at 292, 296-97. However, this is as far as the agreement goes; there was virtually no unanimity among the doctors except that Brianna Guzman suffered a devastating injury with lifetime consequences.

Thus, clearly this case presents a medical dilemma for the undersigned too. While it is undisputed that Brianna suffered an anoxic event which led to her brain injury, 14 it is also undisputed that the DPT vaccine and shaking a baby can cause an anoxic event to occur. Therein lies the problem in deciding this case; what caused the anoxia? Not surprisingly, the parties have differing views as to the root cause of the anoxic event. Petitioners' experts, for a variety of reasons, believe that the anoxia occurred as a result of the vaccine. Respondent's experts believe that based on the presence of blood on the CT scans and MRI films as well as the severe retinal hemorrhaging seen in Brianna's eyes at the time of her injury, no other diagnosis but SBS could be possible. Thus, the undersigned must decide between these opposing views in order to determine whether petitioners are entitled to compensation.

To the undersigned, there are several key issues that need to be considered in order to determine whether Brianna suffered a Table injury or if she is a victim of SBS. First, was there blood apparent on the CT scans and MRI films? According to Dr. Carmel, doctors look for "evidence of blood in the brain or around the brain" when suspicions of trauma arise. Tr. at 40. He further testified that doctors normally look for blood in the brain on the frontal lobes and inside the temporal lobes because "with trauma those are the portions of the brain that are smacked up against the surface of the skull and they bruise." Id. at 41.

All of the doctors – except Dr. Gale – testified that blood must be present on the scans in order to conclude that trauma occurred. Petitioners' experts testified that there was no blood present on the scans. Respondent's experts testified that there was a small amount present. As described at pp. 14-15 *infra*, the court finds that respondent has demonstrated a presence of blood on the CT scans and MRI films.

However, does a finding of blood on the CT scans and MRI films mean necessarily that there was intentionally inflicted trauma? The experts disagreed about the answer to this question. Drs. Carmel and Goodrich testified that even if there was blood, that there was simply not enough to correlate with the severity of the injury in this case. In rebuttal, respondent's experts testified that there is no correlation between the amount of blood found on a scan and the severity of the injury.

Lastly, what was the cause of Brianna's severe retinal hemorrhaging and did it relate to her brain injury? Similar to the reading of the scans, the experts disagreed as to the cause because of the severity of the injury. Petitioners' witnesses attributed the damage to artificial resuscitation efforts by Mr. Guzman. Respondent's witnesses testified that hemorrhaging as

¹⁴See Tr. at 44, 190, 292, 296-97, 508-09.

severe as in Brianna's case could only be attributed to SBS. Dr. Gale even went as far as to proffer that the retinal hemorrhaging in this case was dispositive for a diagnosis of SBS.

In essence, two mutually exclusive factual and medical scenarios are presented: 1) the DPT vaccination caused Brianna to experience an anoxic event, causing her to become unconscious and to suffer a catastrophic encephalopathy. The subdural and retinal bleeds were not caused by the anoxic event, but resulted from the father's efforts to revive her, including intentionally shaking her; or 2) Brianna's father violently and intentionally shook her, causing her to experience an anoxic event, which ultimately resulted in her brain injury. Thus, the simple issue is what caused the anoxic event? If the undersigned finds that scenario one more likely occurred, petitioners win; if scenario two is more likely, petitioners lose.

As will be seen later in this decision, the medical evidence alone was not enough for the undersigned to make a determination whether Brianna Guzman suffered SBS. The undersigned thus looked at other evidence available in the record, including evidence from the DYFS investigation, psychological profiles of Mr. Guzman, lay witness testimony, as well as the undersigned's own personal observation of the family. After a thorough review of the *entire* record, the undersigned finds that petitioners have satisfied their burden that Brianna suffered a Table injury because there was no SBS¹⁵; thus, the Act's presumption applies and petitioners are entitled to compensation. The relevant analysis follows.

Of paramount importance in this case is the determination of whether there is blood on the scans and films – as all the experts, except Dr. Gale¹⁶, testified that if there is <u>no</u> blood, there can be no trauma. Thus, petitioners would be entitled to compensation due to the presumption that the vaccine caused the seizure-induced anoxic encephalopathy. However, if there is blood, there must be a further inquiry as to whether SBS occurred and caused Brianna's injuries. It must be remembered that anoxia alone does not explain the subdural blood. Approximately three-hundred pages of testimony related to this issue. The undersigned considered all of this testimony and has come to the conclusion that there was blood present on the scans, albeit as conceded by respondent's experts, very little.

In a January 23, 2004 Order, the undersigned tentatively found that "subdural blood was found on the CT scans." Order, filed January 23, 2004 at 2. The undersigned reiterates that finding in this Decision. Dr. Zimmerman is recognized as preeminent in the field of pediatric neuroradiology and testified cogently and credibly. Tr. at 79; 212. Dr. Vezina, also a pediatric neuroradiologist, is similarly a well-credentialed, credible expert witness. Although petitioners' experts are highly credentialed neurosurgeons, respondent's experts have the clear edge on this

¹⁵Thus, as mentioned *supra* pp. 2-5, there is no need to discuss the legal issue regarding the burden of proof required for respondent to establish a "factor unrelated" to the vaccine as the cause for Brianna's injuries.

¹⁶As discussed *infra* p. 17, the court was not persuaded by Dr. Gale's testimony. To the extent that it differed from the other experts' testimony, whose testimony the undersigned found highly credible, Dr. Gale's testimony was disregarded.

issue as they read and interpret pediatric scans almost exclusively. <u>Id.</u> at 82; 516. The depth of knowledge, experience, and explanation of the CT and MRI issues was patently clear from Drs. Zimmerman and Vezina's testimony. In addition, the actual scans were shown at trial, with Drs. Zimmerman and Vezina simultaneously showing the areas of blood as they testified. While Drs. Carmel and Goodrich have extensive experience reading scans as neurosurgeons, the ultimate responsibility for interpreting the scans lies with the radiologists. That greater knowledge that comes from that greater professional responsibility was apparent in Dr. Zimmerman's and Dr. Vezina's testimony. Thus, the court finds that there was blood on the scans as testified to by the respondent's experts.

However, as the experts testified, it does not necessarily follow that the blood was a result of trauma; that is the reading of the scans is not pathognomonic – the finding of blood on the scans does not necessarily equate with answering the question as to what caused the blood. As described by Dr. Zimmerman, the presence of the blood could indicate trauma or "some other dramatic indication, like hemophilia, or . . . something that could produce bleeding with less trauma. . . ." Id. at 515; see also id. at 507-08. Thus, Dr. Zimmerman described the limited value of the CT scans in stating: "Well, I think that's the story. There is subdural bleeding and there is brain injury." Id. at 510.

Having determined that the subdural bleed is not dispositive, the next question presented is what explains the retinal hemorrhages. This may have been the most difficult medical issue presented, and expectedly, the testimony reflected that difficulty. Again, like the subdural blood, it must be understood that the anoxic event alone could not cause the retinal hemorrhages.

The experts including both Drs. Carmel and Goodrich, agreed that retinal hemorrhaging is generally seen as an indicator of SBS. <u>Id.</u> at 49, 198, 247-48, 350. However, all but Dr. Gale were reticent to testify that the retinal hemorrhages alone were diagnostic of trauma.

Petitioners' experts Drs. Carmel and Goodrich struggled with this medical factor. <u>See id.</u> at 88-89, 216-17. In fact, Dr. Carmel testified that the retinal hemorrhaging in this case was more severe than he has seen in "practically anything." <u>Id.</u> at 89. However, he argued that if Brianna was a shaken baby, he would "expect to see a similar kind of bleeding in the places in the brain that are typical of [SBS]." <u>Id.</u> at 51. He suggested other causes of vitreous and retinal hemorrhaging and maintained that Brianna was not a victim of child abuse. Id. at 88-89.

On the other hand, Dr. Chadwick, an expert on SBS, opined that there is a correlation, albeit not one-to-one, between the amount of retinal hemorrhaging and the amount of brain damage. <u>Id.</u> at 322. Dr. Chadwick noted that there are many causes of such hemorrhaging, but that "when the retinal hemorrhage is very severe, the more severe it is, the more it tends to be associated with the acceleration/deceleration kind of event that we associate with shaken baby syndrome." <u>Id.</u> at 248. Dr. Chadwick observed that Brianna's retinal hemorrhages were very severe, and that is not necessarily correlated with the amount of blood in the subdural space, but is associated with SBS. <u>Id</u> at 248-49. Dr. Engel, Brianna's consulting ophthalmologist at Robert Wood Johnson Hospital, provided a diagnosis of "vitreous hemorrhages, retinal hemorrhages."

R. Ex. Q at 17. With this evidence in support of the finding of blood on the scans, Dr. Chadwick concluded with ninety-nine percent certainty that Brianna was a victim of SBS. Tr. at 252.

In contrast, although certain of his diagnosis, Dr. Engel would not opine as to whether the hemorrhages were caused by SBS. R. Ex. Q at 30. In fact, he stated that retinal hemorrhaging is not absolutely specific for the diagnosis of SBS. Id. at 23-24. Dr. Engle also explained that CPR could cause the type of retinal hemorrhaging similar to that seen in Brianna Guzman. Id. at 23. Dr. Chadwick agrees with Dr. Engle that CPR could cause retinal hemorrhaging, although he states that such injury under those circumstances is very rare and with special conditions. Id. at 303. Dr. Chadwick does not think CPR caused retinal hemorrhaging in this case. Id. at 305. However, Dr. Chadwick, in response to the undersigned's post-trial postulation, Order, filed January 23 at 3, conceded that with respect to accidental SBS by the father, while trying to resuscitate the baby, "[t]his may not be a question that is answerable by any medical expert. Who can say what someone (including the entire population) might do?" R. Ex. JJ at 2 (emphasis added).

Brianna's treating doctors also considered the retinal hemorrhages as part of their medical analysis of her injuries. The occurrence of the ophthalmic hemorrhaging led some doctors to conclude that Brianna was a *potential* victim of SBS. Among those doctors was Dr. Frank Castello, Director of Pediatric Intensive Care at Robert Wood Johnson Hospital, and the doctor who first saw Brianna after her injury, R. Ex. M at 9; Dr. Lynne Weiss, a pediatric nephrologist and attending physician at the Robert Wood Johnson Hospital, who discharged Brianna, R. Ex. N at 8; Dr. Mark Engel, Brianna's ophthalmologist, R. Ex. Q at 6; and Dr. Steven Kugler, a neurological consult in Brianna's case, R. Ex. R at 6.

Dr. Castello was the director of the pediatric intensive care unit and was Brianna's attending physician at the Robert Wood Johnson University Hospital where she was brought the night of the injury. Dr. Castello subsequently referred this case to the New Jersey Department of Youth and Family Services. Dr. Castello testified in a deposition taken by respondent that his diagnosis of SBS was based on his clinical examination of Brianna in the emergency room. R. Ex. M at 12, 34. Dr. Kugler concurred with that diagnosis, specifically that Brianna's injuries were more likely than not caused by SBS, but there was some confusion because "part of it has to do with the confusing scan readings, that people read scans differently. That's one aspect. The other aspect is the timing, the fact that this occurred the day of the DPT." R. Ex. R at 73. In addition, Dr. Weiss had no professional opinion as to whether SBS occurred to Brianna. R. Ex. N at 15. And as explained in the preceding paragraphs, Dr. Engle would not opine as to whether Brianna was a victim of SBS.

Respondent's witness, Dr. Gale, was alone in proffering the unequivocal opinion regarding the hemorrhaging. He opined that "when the ophthamological findings are added to the clinical picture . . . [he] think[s] overwhelmingly the diagnosis would be trauma. [He] cannot imagine another cause in this case for Brianna Guzman's clinical encephalopathy other than trauma." Tr. at 345. Although he acknowledged that retinal hemorrhaging can result from extremely rigorous cardiopulmonary resuscitation, he stressed that it is very uncommon. <u>Id</u>. at

349. Even in the absence of subdural bleeding, notwithstanding that resuscitation can cause the hemorrhaging and that an ophthalmologist could not opine that SBS occurred, Dr. Gale would find a diagnosis of trauma in this case due to the ocular findings. <u>Id.</u> at 350. He stressed that the issue in this case is not whether or not the films indicate subdural bleeding, but the significance of the ocular findings. <u>Id.</u> at 351. On a scale from 1 to 100, Dr. Gale places the diagnosis of trauma at between 90 and 100. <u>Id.</u> at 353.

To the undersigned, the only testimony the court found questionable was that of Dr. Gale. Dr. Gale has testified before the undersigned on numerous occasions and his testimony has been relied upon for a number of determinations. He is unquestionably a highly intelligent, knowledgeable, and articulate expert. However, as has become increasingly clear to the undersigned, his close association with the respondent is coloring his testimony. Dr. Gale termed himself a "consultant for the [P]rogram," having testified for respondent in at least 60-80 cases over his 13-year association. Id. at 336, 359.

No expert, including the ophthalmologist, Dr. Engle, would diagnose SBS based *solely* on the ocular findings. Only Dr. Gale makes so bold a determination. His objectivity is questionable – his certainty is not. He disagreed on some level with every expert, including those testifying, like himself, for respondent. He called one doctor's opinion "laughable," another's "curious." <u>Id.</u> at 370, 402. He injected slanted facts into his report, such as those from the DYFS referral, while leaving out balancing information from the same source that Brianna's custody was given back to the Guzman's and that no grand jury was ever convened. <u>Id.</u> at 384-86. His parrying with counsel, not seen with any other expert, is viewed as an effort to provide information that supports his position, not providing helpful information to the court. <u>See</u>, <u>e.g.</u>, id. at 358-361. The undersigned discredited Dr. Gale's testimony.¹⁷

At this point, it is clear what medical issues must be resolved to decide this case, but unfortunately despite the many highly qualified, highly credentialed experts reviewing this case, the medical judgments alone cannot answer the pivotal question presented in this case. What caused the anoxic event? Unlike the experts, whose testimony focused almost exclusively on the medical tests – which as stated earlier are not pathognomonic – the undersigned is obliged to consider the entire record. When that additional information, consisting of lay witness testimony, police reports, and psychological reports is factored into the medical information, the undersigned confidently finds the evidence of trauma is far below the preponderance necessary to defeat petitioner's claim of a Table encephalopathy.

To begin, the undersigned considered the deposition testimony as well as contemporaneous medical records provided by Brianna's treating physicians. Because of the

¹⁷For a description of the accepted standards of conduct regarding expert testimony provided by physicians, <u>see</u> The American Medical Association. Opinion 9.07, "Medical Testimony." AMA Code of Medical Ethics Current Opinions with Annotations 2004-2005 ed. Chicago: AMA Press; 2004:272. Available at: <a href="http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-9.07.HTM&&s_t=&st_p=&n th=1&prev_pol=policyfiles/HnE/E-8.21.HTM&nxt_pol=policyfiles/HnE/E-9.01.HTM&.

severe nature of her injury, the treating doctors were concerned about possible SBS in this case. However, only Dr. Castello opined ultimately that SBS was the cause and referred the case to DYFS. Equally probative to the undersigned was evidence obtained by DYFS in the subsequent investigation of whether Brianna was abused. A short summary of the DYFS process follows.

On January 25, 1997, the day Brianna's injury occurred, based on the referral of Dr. Castello, Brianna was evaluated by the Child Protection Center for medical findings consistent with SBS. See Vol. B, Part I at 2. 18 After some investigation, on February 20, 1997, DYFS filed a complaint with the family court in New Jersey for custody of Brianna due to alleged child abuse. See Vol. A, Part IV at 15. The family court subsequently ordered that legal custody of Brianna Guzman be awarded to DYFS, but that physical custody remain with Mrs. Guzman. Mr. Guzman was only allowed supervised visitation with his daughter. Id. at 46, 51, 52. In the course of the investigation, DYFS required a psychological evaluation of Mr. Guzman. See R. Ex. PP. Ultimately, however, the charges of child abuse against Mr. Guzman were found to be without merit and the case was closed. See P. Ex. 23 at 3.

Of all the evidence seen related to the DYFS investigation, the court finds highly probative a "psychological evaluation" written by psychologist Rachel Modiano, Psy.D., filed at the request of DYFS. In her report, Ms. Modiano makes the following assessment of the circumstances surrounding Brianna's injury, as well as the culpability of Mr. Guzman:

In short, there are three possibilities in this case. The first is that Mr. Guzman did, indeed become frustrated and angry with the baby's irritability and crying (it is noted that Mrs. Guzman described the baby as moody) and in a moment of rage, shook the baby. The second possibility is that Mr. Guzman shook the baby but did so out of shock and distress because the baby had some kind of a seizure and not because he was angry. The final possibility is that there was, in fact, some rare reaction to the vaccination.

¹⁸Two volumes of records from the DYFS investigation were filed, but no exhibit numbers were given. The court will refer to these documents as "Vol. A" and "Vol. B."

At this point, it appears that prevailing medical opinion, offered by two leading centers in the diagnosis of child abuse, rests with the first two possibilities. Given Mr. Guzman's psychological profile, the **second possibility seems more likely** as there is no data to suggest that he is a chronically angry, violent individual. If anything, he is more used to talking his way through a conflict than using aggression. While we cannot decisively conclude Mr. Guzman did, in fact, hurt his child, we must also look at the available data and opt to err on the side of caution with regard to recommendations for the future.

R. Ex. PP at 126-27 (emphasis added).

The psychological evaluation presented by Ms. Modiano of DYFS was viewed by the undersigned in tandem with a generic psychological profile of a child abuser discussed by respondent's expert witness, Dr. Chadwick, during cross-examination. Petitioners' counsel inquired about an article written in part by Dr. Chadwick entitled "Diagnostic and Treatment Guidelines on Child Physical Abuse and Neglect," published by the American Medical Association in March 1992 [hereinafter "Guidelines"]. Tr. at 313. This article lists predisposing factors for child abuse. According to the paper, the following are "child and family characteristics [that] may be risk factors for child abuse and/or neglect." Guidelines at 5. The "child characteristics" are listed as: 1) premature birth; 2) the child has disabilities or abnormalities; and 3) the child exhibits behaviors common in infancy, such as persistent crying. Id. at 6. The "family characteristics" are listed as: 1) other violence in the home (in particular, the father abuses the mother or siblings abuse one another); 2) substance abuse, including alcohol abuse by the parents or caretakers; 3) the parents or caretakers lack the necessary maturity to care for the child; 4) parental expectations are inconsistent with the child's developmental abilities; 5) the caretaker is socially isolated (i.e. has no external support systems); 6) the family is experiencing high levels of stress from events such as loss of a job, increased financial burdens, serious illness, death in the family, separation or divorce; and 7) adult members of the family have themselves been abused as children, either physically or sexually. Id. In addition to the above factors, the paper points out that:

Although some studies have indicated a correlation between child abuse and factors such as income, race, education, and marital status, some of these studies may have been subject to bias since physicians may be more likely to consider child abuse when the family has a lower income or is non-white.

<u>Id.</u>

¹⁹Although the parties did not file this article as an exhibit, the parties referenced the article extensively at the hearing in January 2004. The article was obtained at www.ama-assn.org/ama1/pub/upload/mm/386/childabuse.pdf.

First, with respect to the "child characteristics," the record indicates that Brianna was born normally, and but for an ear infection, was a normal child. With respect to the family characteristics, Mr. Guzman does not seem to fit the psychological profile of a child abuser. For instance, Mr. Guzman testified that he was never physically or emotionally abused by his parents, nor to his knowledge were any of his siblings ever abused by anyone in the family. Tr. at 152. Moreover, there were never any drug or alcohol abuse problems in the family, nor did he ever need any counseling. Id. Mr. Guzman's parents have been happily married for 44 years and have a "slew of grandkids," some of which Mr. Guzman took care of by feeding and bathing. Id. at 150.

In addition, Mr. Guzman is an educated person – he testified that he earned a college degree in tourism in Costa Rica. He first met his wife Kim in 1995 in Costa Rica, and married her a year later in 1996. When he came to the United States after marrying Mrs. Guzman, he "was working on the third day" that he came to this country. <u>Id.</u> at 154. Mr. Guzman also testified that he had been alone in taking care of Brianna "several" times and had no problems taking care of her. <u>Id.</u> In addition, because Mr. and Mrs. Guzman lived with Mrs. Guzman's mother and brother at that time, they had a solid family unit to help them take care of the baby.

In the court's view, DYFS's psychologist, Ms. Modiano's, report as well as Dr. Chadwick's "profile" of factors that are linked to child abusers do not support the postulation that Adolfo Guzman shook his child in a fit of rage. Rather, the evidence points to a loving, caring, and devoted father that probably shook his child out of fear and an adrenaline rush when he picked her up and she was not breathing.

In addition, the psychologist's evaluation is consistent with the court's own observations at the January 2004 hearing. Mr. Guzman was seen actively caring for his daughter — he was observed to be involved in her feeding as well as in tending to her basic needs. The family unit seemed cohesive and very supportive of each other in caring for the child. Moreover, Mr. Guzman testified that he loves his daughter, and liked having her. Tr. at 154. In addition, Ms. Schirmer testified credibly that no one ever abused Brianna physically, emotionally, or in any other type of abuse and that the "child was loved to death." <u>Id.</u> at 144. Brianna's mother also testified that Mr. Guzman had "absolutely not" ever abused Brianna in any way. Tr. at 122.

In the final analysis, as stated several times previously, this case presented an amalgam of complexities, tragedies, and emotions seen in vaccine cases. Except for Dr. Gale's testimony, the expert testimony was of the highest quality, but on its own it was not dispositive. Based upon the entire record, including the medical tests, the psychological reports, and the undersigned's assessment of the witnesses, the court is convinced that an anoxic event followed the vaccination, which caused Brianna's encephalopathy. The anoxic event in turn led to an induced head trauma by Mr. Guzman in trying to revive Brianna, which caused the eye damage and, most likely, the subdural bleeding. Although there is a possibility that the eye injuries were caused by CPR, the experts are not of the opinion it could cause the bleeding in the brain. The undersigned agrees. The evidence points to aspects of Brianna's injuries, namely the retinal hemorrhages, to have been caused by induced trauma – shaking. Mr. Guzman admits to having shook his daughter in

an attempt to revive her. P. Ex. 23 at 52-53. Mr. Guzman explained that he picked his daughter up and determined she was not breathing, and shook her, crying her name. It is well within the realm of possibility that a parent, upon discovering their infant unconscious and not breathing, would make every conceivable effort to revive the child. As Dr. Chadwick stated in his supplemental expert report, "[w]ho can say what someone (including the entire human population) might do?" R. Ex. JJ at 2.

In addition, this sequence of events comports with the undersigned's view of the witnesses and the legal conclusions comport with the Federal Circuit's teachings in <u>Knudsen</u>, 35 F. 3d at 550:

It is entirely plausible, and contemplated by the statute, the DTP may cause an encephalopathy at the same time that a virus or something else causes non-encephalopathic symptoms or injuries. So long as it has not been shown that the virus or other unrelated factor caused the encephalopathy or injury complained of, compensation is not foreclosed.

Id.

This complex case was summarized succinctly by Dr. Goodrich. He stated that when he looks at the whole picture, the gestalt of this case, he doesn't see the various pieces fitting together. "I couldn't see anything else in that picture that would go along to explain why that serious injury [retinal and vitreous hemorrhaging] is there, and there is nothing else to go along with the brain injury other than what I see as an anoxic event." Tr. at 211. He maintains that SBS would not present with the hemorrhaging alone, that there would be signs of additional injury. There is no head fracture or soft tissue contusion. <u>Id.</u> at 214.

The court is satisfied with a multi-event explanation for the devastating injuries suffered by this little girl. There is a preponderance of evidence that the encephalopathy Brianna suffered on January 24, 1997 was presumptively caused by the vaccine. There is simply no persuasive evidence that the father shook his child in a fit of rage. The fact that the shaking was severe does not rule out uncontrolled or frantic shaking to revive his child during an extraordinarily stressful period. The informative testimony of a cadre of highly regarded specialists, leads the undersigned to these answers, and accordingly to the conclusion that the DPT vaccine set off a series of events beginning with anoxia and ending with Mr. Guzman shaking Brianna to revive her. Even Dr. Gale admitted that after receiving such a DPT vaccination, a set of circumstances could come into play where a person trying to revive a baby after an anoxic event could exacerbate the condition. R. Ex. CC at 45.

CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that petitioners are entitled to compensation under the Vaccine Act. The parties hopefully will continue working toward negotiating a life care plan that will provide the services Brianna needs in light of her injuries.

IT IS SO ORDERED.

Gary J. Golkiewicz Chief Special Master