In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-941V

June 1, 2007

Published

MELINDA SIMON, Parent of DEVIN SIMON, Deceased	*	Complex Febrile Seizure; DTaP Vaccine; DTP Literature Does Not Support DTAP Causation; Fever; Epilepsy; Death
Petitioner,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Craig Homer, Conway, Homer, and Chin-Caplan, P.C., Boston, MA, for petitioner.

Michael Patrick Milmoe, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master.

On August 26, 2005, petitioner, Melinda Simon (Ms. Simon), filed a petition on behalf of her son, Devin Simon (Devin), pursuant to the National Vaccine Injury Compensation

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this order on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 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. Id.

Program[2] ("the Act" or "the Program") alleging that Devin suffered an encephalopathy and seizures, as a result of the Diphtheria-Tetanus-acellular-Pertussis (hereinafter "DTaP") vaccination he received on March 18, 2003. Petition (Pet.) at 1. In addition, Ms. Simon alleges that Devin died on December 31, 2004 from his seizure disorder developed as a result of his March 18, 2003 DTaP vaccination. *Id.* On February 1, 2006, respondent filed a Rule 4 Report contending, that compensation was inappropriate. Respondent's Report, filed Feb. 1, 2006. To elicit expert testimony, a Hearing was held on November 30, 2006. Petitioner presented Marcel Kinsbourne, M.D., as an expert witness. Respondent presented Arnold Gale, M.D., as an expert witness. On December 6, 2006 the undersigned indicated to the parties in a reasoned Order that based upon the information in the record to date, he viewed the "evidence preponderating in petitioner's favor" and suggested it was "not necessary and productive to continue proceeding in this case." See Order filed December 6, 2006. A telephone status conference was held on December 21, 2006 in follow-up to the undersigned's December 6, 2006 Order, during which the parties' respective counsel indicated they would present no further evidence and the record would rest as it stood.

After reviewing the entire record and considering the testimony of both experts, and for the reasons set forth below, the court finds petitioner has met her burden of proof required under the Act, and thus is entitled to compensation. A summary of the findings follow.

Statement of the Facts

The parties agree on the following underlying facts of the case. Devin was born on November 7, 2002. Petitioner's Exhibit (Pet. Ex.) 3 at 10. Devin appeared developmentally normal on March 18, 2003 when he received a vaccination for DTaP. Pet. Ex. 10 at 1. *See generally* Pet. Ex. 5. That evening Devin experienced a fever and then a seizure at home and was brought to the emergency room (ER) by ambulance where he continued seizing. Pet. Ex. 8 at 2, Pet. Ex. 10 at 2, Pet. Ex. 6 at 7,13, 18, 23-24. A neurology consult conducted on March 19, 2003, documented that Devin was in status epilepticus for 50 minutes. Pet. Ex. 6 at 23. Devin was diagnosed as having experienced a complex febrile seizure. Pet. Ex. 6 at 1, 18, 23, 24.

Devin suffered multiple seizures, subsequent to his initial seizure on March 18, 2003, including one on April 23, 2003 and two on May 10, 2003. Pet. Ex. 10 at 2, Pet. Ex. 6 at 102-104, 113, 117-122. On June 19, 2003, Devin was seen by Dr. David Franz at Cincinnati Children's Hospital who began to monitor and treat Devin in an attempt to control his seizures. Pet. Ex. 7 at 1-5. Devin's seizures increased in severity and frequency during June and July of 2003. Pet. Ex. 10 at 2-4, Pet. Ex. 7 at 5-7. Devin was found dead on December 31, 2004 after

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

having been put down for a nap. Pet. Ex.6 at 310-313, Pet. Ex. 9 at 1, Pet. Ex. 10 at 5-6. Resuscitation attempts failed and an autopsy report declared Devin's cause of death to be his seizure disorder. Pet. Ex. 9 at 3.

Issue

The sole issue presented in this case is whether the initial seizure Devin suffered on March 18, 2003 was caused in fact by the DTaP vaccination Devin received on March 18, 2003. Respondent's expert conceded that Devin's initial seizure which occurred within 12 hours following his DTaP vaccination is medically connected to Devin's subsequent epilepsy and death. Transcript of November 30, 2006 Hearing at 52-53 (Tr. at 52-53).

Experts' Testimony[3]

Respondent's expert, Dr. Arnold Gale, opined in his expert report filed March 20,2006, and testified at the November 30, 2006 Hearing that Devin was predisposed to suffer from epilepsy. Respondent's Exhibit (Resp. Ex.) A at 2-3, Tr. at 70-71. In Dr. Gale's opinion, Devin would have developed epilepsy in the same way had he not received the DTaP vaccination on March 18, 2003. Tr. at 70-71. Dr. Gale did state, however, that "when you receive a vaccine, you can experience a fever with it. And it may be that the fever had something to do with that first seizure occurring." Tr. at 98-99. Dr. Gale testified that in his opinion the epileptic syndrome evidenced by Devin's medical records most closely resembles Severe Myoclonic Epilepsy of Infancy or SMEI. Tr. at 86- 87. Dr. Gale speculates that Devin had a SCN1a gene abnormality. However, Dr. Gale concedes he did not evaluate Devin and thus cannot diagnose Devin as suffering from SMEI, nor can he confirm that Devin had an gene abnormality as DNA analysis was never preformed on Devin. Id. at 87-89.

Petitioner's expert, Dr. Marcel Kinsbourne, opined in his expert report filed July 18, 2006, and testified at the November 30, 2006 Hearing that "Devin's neurological impairments were caused by, or substantially contributed to by, the acellular pertussis vaccine." Pet. Ex. 16 at 3, Tr. at 39-40. Dr. Kinsbourne based his opinion on the close temporal relationship between Devin's March 18, 2003 vaccination and his initial seizure suffered 12 hours later, the medical literature, the nature of the injury, and lack of any alternative causation for the injury. Tr. at 40. Dr. Kinsbourne testified that it was possible Devin was predisposed to epilepsy, however that possibility does not change his opinion that the DTaP vaccination was the cause of Devin's seizure disorder. Tr. at 54. Dr. Kinsbourne testified that he would not classify Devin as having suffered a febrile seizure, but rather a fever with a seizure. Tr. at 59. Dr. Kinsbourne's testified to two possible cause and effect sequences to explain Devin's seizure disorder, as follows:

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[3]In deciding this case, the experts' experience and credibility were not factors. Both experts are well-known to the undersigned and are highly respected for their knowledge and testimony.

1)Devin's March 18, 2003 DTaP vaccination caused a fever which in turn caused his initial seizure;[4] or alternatively 2)Devin's DTaP vaccination caused a seizure which in turn caused fever, but that the pertussis toxin in the DTaP vaccine was the cause of the initial seizure activity that was experienced by Devin. Tr. at 40-42, 65-66.

Discussion

As the petitioner alleges an "off-table" case, the petitioner must prove that the vaccine in-fact caused Devin's injury, a so-called "off-Table" case. To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. 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). To meet this preponderance of the evidence standard, in Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioner's burden is to produce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Further, the Federal Circuit stated, "The purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id.

The Federal Circuit reiterated Althen's three-part test in Capizzano III , Pafford v. Secretary of HHS, 451 F.3d 1352 (Fed. Cir. 2006); and most recently in Walther v. Secretary of HHS, - - - F.3d - - - (Fed. Cir. 2007). The panel in Pafford, explained that the three prongs in Althen "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355.

Moreover, the Federal Circuit in Althen and Capizzano III indicated special consideration

[4]As was the opinion of Devin's treating physician Dr. Krueck, although Dr. Krueck diagnosed Devin as having suffered a complex febrile seizure which but for the fever would not have occurred.

should be given to the opinions of the treating physicians and medical records. "*Althen III* explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the cause of the injury.'" Capizzano III, 451 F.3d at 1326 *citing* Althen, 418 F.3d at 1280.

In the case at hand, Devin's medical records indicate he received the DTaP vaccination at 10:00 am on March 18, 2003. Pet. Ex. 5 at 1-4, Pet. Ex. 10 at 1. Devin's mother, Melinda Simon (Ms. Simon) reported in her affidavit and in histories memorialized in the contemporaneous medical records that Devin had a slight fever of 101 degrees when she put him down for a nap that afternoon. Pet. Ex. 8 at 2, Pet. Ex. 10, Pet. Ex. 6 at 13, 18. When Devin awoke at 9:00 pm Ms. Simon noted he was very hot and she gave him a half dosage of Tylenol; Devin then began to seize. Id. After fifteen to twenty minutes an ambulance arrived to transport Devin to the emergency room. Devin continued to seize throughout this period. Pet. Ex. 10 at 2, Pet. Ex. 6 at 7, 23, 24. Devin was in status epilepticus upon arriving at the emergency room. Pet. Ex. 6 at 4, 13, 18. Devin's initial seizure lasted for 50 minutes. Pet. Ex. 6 at 23. Devin was transferred to the Pediatric Intensive Care Unit where he remained until he was discharged on March 20, 2003. Pet. Ex. 6 at 24, 73, 80. Pet. Ex. 10 at 2. Devin's initial seizure was diagnosed as a complex febrile seizure per the records at Children's Hospital, Columbus. Pet. Ex. 6 at 1, 18, 23, 24. Devin's treating physician, Dr. Katherine Krueck, upon examining Devin subsequent to his release from Children's Hospital associated Devin's seizure as secondary to receiving the DTaP vaccination on March 18, 2003 and mandated that he was to receive no aP (pertussis) vaccination in the future. Pet. Ex. 5 at 13. Dr. Krueck diagnosed Devin as suffering from "epilepsy, felt to be triggered by fever related to DTaP" on June 23, 2003. Id. at 23.

This fact pattern is seen frequently in vaccine cases. An otherwise healthy petitioner receives a vaccination, the vaccine causes a fever, which in turn causes or triggers a complex febrile seizure. Complex febrile seizures are "seizures lasting longer than 15 minutes, occurring more than once in a 24 hours, or having focal features." Gregory L. Holmes, M.D., Diagnosis and Management of Seizures in Children, 228 (W.B. Saunders Staff eds., 1987). As discussed by Dr. Holmes, if the first febrile seizure is complex, the risk for developing epilepsy increases significantly. Id. at 228-229; See also Jean Aicardi, M.D., Epilepsy in Children, 231 (Joseph French et al. eds. 1986).[5] In addition, while recognizing that the impact of febrile seizures on intellectual and motor development "has been an area of controversy,"citing numerous studies Holmes reported that prolonged or complex seizures are recognized as the antecedent of sequelae. Holmes, supra, at 227-228; see also Aicardi, supra, at 231.

In this case, there is much agreement between the experts. Dr. Gale agrees that the DTaP is capable of causing seizures. Tr. at 128. He also agrees that Devin's subsequent seizures are related to his initial seizure following vaccination. Id. Finally, Dr. Gale agrees that Devin's

[5] The Holmes and Aicardi literature was filed into the record pursuant to the undersigned's Order dated December 14, 2006.

death was a sequelae of his epilepsy. Id. The experts diverge on what caused the initial seizure; thus presenting the issue to be decided in this case. Answering that question requires a certain amount of highly educated speculation, because as Dr. Gale recognized, we will never know the exact medical cause of Devin's epilepsy. Tr. at 126; see also Holmes, supra, at 226 ("Unfortunately, when a child first has a seizure with fever, there is no definitive way to determine whether the seizure is secondary to the fever or his first manifestation of epilepsy.").

Thus, we are faced with two working suppositions: as the petitioner contends, the vaccine caused a fever which caused the seizure (or the vaccine caused the seizure which caused the fever), the first seizure being a complex febrile seizure which presents a greater risk of developing epilepsy, Devin goes on to develop epilepsy and subsequently dies from factors related to his seizures; or as respondent argues, Devin was predisposed to having epilepsy prior to his vaccination and unfortunately followed that course of epilepsy to his death.

As Holmes noted, there is no definitive answer to this question of what caused Devin's epilepsy. However, the scales of justice are based upon a preponderance of evidence, not medical certainty. In this case, what we do know is that Devin received a DTaP vaccine. The experts agree vaccines, including the DTaP vaccine can cause fevers. The experts further agree that fevers can trigger seizures. The experts agree that Devin's initial seizure is connected to Devin's subsequent seizures, his epilepsy and death. Tr. at 52-53. Based upon Devin's medical records, the affidavit of Ms. Simon, the testimony of the experts, and the medical literature the undersigned finds that petitioner has proven by more than a preponderance of the evidence the following: that Devin received a DTaP vaccination on March 18, 2003; Devin experienced a fever within twelve hours of receiving the DTaP vaccination; Devin experienced a complex febrile seizure within twelve hours of receiving the DTaP vaccination; Devin as a result of his initial complex febrile seizure went on to develop epilepsy; and, Devin died on December 31, 2004 as a result of epilepsy. Finally the undersigned concludes that "but for" Devin having received the DTaP vaccination on March 18, 2003 he would not have suffered a fever on that date which triggered the complex febrile seizure he suffered that same day. This conclusion is supported by the treating physicians, the experts, and the medical literature. Thus the undersigned finds that petitioner has met her burden under the three part test of causation articulated in Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005) and is entitled to compensation.

Faced with a strikingly similar set of facts, my colleague reasoned the same in Cusati v. Secretary of HHS, No. 05-5049V, 2005 WL 4983872 (Fed. Cl. Spec. Mstr. Mar. 9, 2006). In that case, a one year old child, Eric Cusati, developed a fever of 102 degrees and was not responsive to his mother four days after received an MMR vaccination. Id. at *3. The following day Eric experienced seizures that were diagnosed as "complex febrile seizure activity" by one of Eric's treating physicians. Id. at *3-4. Eric developed epilepsy subsequent to his initial seizures and died as a result of his seizure disorder on September 10, 1999. Id. at *5. Based upon these essential facts and the expert testimony, Special Master Edwards found that:

> Dr. Kinsbourne [petitioner's expert] and Dr. Kohrman [Respondent's Expert] agree that before his November 5, 1996 MMR immunization, Eric was predisposed probably to suffer seizures. . . . Dr. Kinsbourne and Dr. Kohrman agree that MMR vaccine causes fever. . . . Dr. Kinsbourne and Dr. Kohrman agree that fever causes seizures. . . . In fact, Dr. Kohrman declared that fever in a child who is susceptible to seizures will make the child's seizures "much worse." . . . Dr. Kinsbourne and Dr. Kohrman agree that Eric's November 5, 1996 MMR immunization was a logical source of Eric's fever associated with Eric's initial complex febrile seizure. . . . Dr. Kinsbourne and Dr. Kohrman agree that a child who suffers a complex febrile seizure has a greater chance of developing epilepsy. . . . As a consequence, Dr. Kinsbourne and Dr. Kohrman agree that Eric's initial complex febrile seizure and Eric's subsequent intractable seizure disorder were related.

[internal citations omitted] Id. at *9. Based upon this expert testimony and applying the preponderance of evidence standard, Special Masters Edwards found that the MMR vaccine caused the fever, which caused the complex febrile seizure which was associated with the intractable epilepsy which led to Eric's unfortunate death. Id. at *10. The undersigned concurs with that reasoning.

In finding for petitioner in this case, the undersigned does not dismiss Dr. Gale's testimony cavalierly. Dr. Gale is highly regarded, although at times his testimony is colored by requiring a higher level of proof for causation. He has been criticized by the undersigned and others for such testimony. In this case, despite recognizing that the vaccine can either cause a fever which can cause a seizure, or that the vaccine can cause a seizure, Dr. Gale disputes the vaccine's role in any further seizures. On cross-examination, Dr. Gale agreed that the reason he contests the vaccine's role is because he believes an underlying epilepsy is the cause. Tr. at 128. However, there is no evidence of the underlying epilepsy, Tr. at 130, we will never know the cause of Devin's epilepsy, Tr. at 126, and there is no way to determine if the seizure was caused by the fever or was a manifestation of the epilepsy. Tr. at 137. So on what evidence is Dr. Gale's opinion based?

Dr. Gale relied on three medical factors for his opinion that Devin's brain was predisposed to seizures: the age of onset, the focal nature of the seizures and the presentation initially as status epilepticus. Tr. at 72-76, 131-32. However, Dr. Gale conceded that each of the three factors he relied upon can be seen with febrile seizures. First, Dr. Gale contended that Devin's age of onset, four months, argues against a febrile seizure and for epilepsy. However, Holmes defined a febrile seizure as occurring between three months and five years. Holmes, supra, at 226; see also Aicardi, supra, at 212 ("The Consensus Development Panel on febrile convulsions has defined febrile seizures as 'an event in infancy or childhood usually occurring between three months and five years of age. . .'"). Dr. Gale conceded that "[i]t can happen, but it

doesn't happen often." Tr. at 134. Secondly, Dr. Gale stated that the focal nature of Devin's seizures argued against febrile seizures. But again, reading from Holmes, the undersigned noted that the risk of febrile convulsions developing into epilepsy is greatest with focal seizures. Id. Dr. Gale agreed and agreed that focal seizures as part of febrile seizures is "not unknown." The final predicate for Dr. Gale's opinion that Devin's brain was damaged prior to the vaccination is that febrile convulsions are a benign disorder. However, Holmes notes that if the febrile seizure was complex, the risk of developing epilepsy is increased significantly. Tr. at 137-138; see also Aicardi, supra, at 213. Thus, it is clear to the undersigned that each of the factors that Dr. Gale used to rule out a febrile seizure was not dispositive in Devin's case, but was based, in essence, upon statistical likelihoods. The Federal Circuit rejected such statistical based expert testimony. See Knudsen v. Secretary of HHS, 35 F.3d 543, 550 (Fed. Cir. 1994). In fact, based upon Dr. Gale's testimony the undersigned asked the question: ". . . why is it not possible here that . . . this vaccine caused the fever, which may have triggered the first seizure which was a complex febrile seizure, which has a greater chance of developing epilepsy. . ."? Tr. at 138. Dr. Gale while by no means agreeing that the posited question was a likely occurrence, responded that ". . . it's possible, but it's certainly not very likely." Id.

What we face in this case is an unprovable event, unprovable utilizing the higher standard of medical certainty. However, on a probability scale, it is reasonable to conclude that where the vaccine is associated with fever and seizure and the seizure is of a complex nature, in the absence of proof of an alternative cause, it is the vaccine that is legally responsible for a subsequent epilepsy and residual sequelae. See Cusati v. Secretary of HHS, No. 05-5049, 2005 WL 4983872 (Fed. Cl. Spec. Mstr. Mar. 9, 2006). Accordingly, the undersigned finds that petitioner has proven by a preponderance of the evidence her right to compensation in this case.

Lastly, the undersigned finds that Respondent has not identified an alternative theory of causation for Devin's fever, which led to his initial complex seizure which resulted in his seizure disorder and death. The undersigned finds unsupported Dr. Gale's theory that a predisposition to seizures was the legal cause of Devin's injury death. Further the undersigned notes that while Dr. Gale theorizes Devin suffered from SMEI, none of Devin's treating physicians diagnosed him with SMEI, and Dr. Gale himself concedes he cannot make such a diagnosis based upon the record.[6]

While finding for petitioner, the undersigned is compelled to comment on some of petitioner's expert's testimony. Specifically, the undersigned finds unpersuasive Dr. Kinsbourne's theory based upon the National Childhood Encephalopathy Study of 1981,[7] the ten

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[6]Even if Respondent proved that Devin was predisposed to having epilepsy, a significant legal issue would remain, that is whether a predisposition could constitute a factor unrelated. See §13(a)2.

[7]R. Alderslade, et al., The National Childhood Encephalopathy Study. Whooping Cough:

(continued...)

year follow up to that study,[8] and the 1994 report issued by the Institute of Medicine,[9] that the pertussis toxin in the DTaP vaccine was the cause of the initial seizure activity that was experienced by Devin. Tr. at 27. Dr. Kinsbourne testified the NCES study demonstrated a strong correlation between a child receiving DTP vaccine and a child suffering an encephalopathy or seizure lasting greater than thirty minutes within three days of vaccination, as the relative risk of these events was found to be five to seven times more likely than in the control group. Tr. at 28. Dr. Kinsbourne further testified that the follow-up study ten years later found that the children who had experienced severe seizures at the time of the NCES study were likely to have developed epilepsy in the intervening time period. Tr. at 29. However, the aforementioned studies and report concerned the DPT vaccine not the DTaP vaccine. Dr. Kinsbourne acknowledged that the DTaP vaccine was developed in response to the DTP vaccine reaction rates found in the NCES study. Dr. Kinsbourne testified that studies involving the DTaP demonstrate the same types of reactions documented following the DTP vaccine are occurring following the DTaP vaccine. Tr. at 35. However, the neurological events following the DTaP vaccination are greatly reduced to only around 30-40 percent of the reaction rate seen following the DTP vaccination. Tr. at 30-31. Thus, it appears to the undersigned that the NCES and the ten year follow-up study cannot be utilized to support DTaP causation. The undersigned does not dispute that both vaccines may result in the same neurological reactions, however as Dr. Kinsbourne noted these events do not occur with the same frequency. Accordingly the relative risks of an adverse event from a DTP vaccine found in those DTP related epidemiological studies do not attach to a DTaP vaccine. Dr. Kinsbourne gave no convincing explanation to the contrary. Thus, it appears that the DTP studies cannot be used to support DTaP causation. See Grace v. Department of HHS, 2006 WL 3499511, at *9 (Fed. Cl. Spec. Mstr. Nov. 30, 2006) (Special Master Hastings noted the distinction between the DTaP and the DTP vaccines stating "[t]he theory of Dr. Jacobson, then seems to be that any evidence concerning possible harmful effects of the DTP vaccine can be automatically extrapolated to apply to the DTaP vaccine. However he simply failed to explain why that would be so.").

Conclusion

The undersigned has considered the entire record as a whole at length. As discussed

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[7](...continued)
Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccine and Immunizations. (Her Majesty's Stationery Office 1981); Pet. Ex.16(A).

[8]Nicola Madge, et al., The National Childhood Encephalopathy Study: A 10-year Follow-up: A Report on the Medical, Social, Behavioural and Educational Outcomes After Serious, Acute, Neurological Illness in Early Childhood, in Developmental Medicine and Child Neurology Vol. 35, No. 7, Supp. No. 68 at 1-117 (July 1993).

[9]Stratton et al. DPT vaccine and chronic nervous dysfunction: A new analysis. Institute of Medicine, Washington DC. (National Academies Press 1994); Pet. Ex.16(C)

above, it is found that Ms. Simon has established by a preponderance of the evidence that Devin's March 18, 2003 DTaP vaccination was the legal cause of his epilepsy that resulted in Devin's death. The undersigned finds that there is not a preponderance of the evidence that the legal cause of Devin's death was due to factors unrelated to Devin's March 18, 2003, vaccination. Accordingly, in the absence of a motion for review, the Clerk shall enter judgment in favor of petitioner, Ms. Simon, for $250,000.00.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master