

OFFICE OF SPECIAL MASTERS

(No. 95-0652V)

(Filed July 19, 1999)

JESUS and JUANA CASTILLO, as the
Legal Representatives of their minor son,
MICHAEL CASTILLO,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Respondent.

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Curtis R. Webb, Twin Falls, Idaho, for petitioners.

Glenn A. MacLeod, United States Department of Justice, Washington, D.C., for respondent.

DECISION

WRIGHT, Special Master.

On September 28, 1995, petitioners filed a claim on behalf of Michael Castillo ("Michael") under the National Vaccine Injury Compensation Program (hereinafter "Vaccine Act" or the "Act").⁽¹⁾ Petitioners claimed that Michael sustained an insult to his brain resulting in a seizure disorder and learning disabilities which were caused-in-fact by a diphtheria-tetanus-pertussis ("DPT") vaccination administered on September 29, 1992.

I.

PROCEDURAL BACKGROUND

On February 20, 1996, respondent filed a report in this matter recommending compensation be denied since contemporaneous medical documentation did not support petitioners' claim. An evidentiary hearing was held in this matter on November 20, 1997, in La Jolla, California and continued telephonically on October 19, 1998. Petitioners presented the testimony of Jesus and Juana Castillo, Michael's parents, as well as Dr. Sheldon Gross and Dr. Thomas Schweller, both pediatric neurologists. Testifying for the respondent was Dr. Albert Spiro, also a pediatric neurologist. Petitioners filed a post-hearing brief on January 14, 1999. Respondent filed her brief on January 22, 1999. Petitioners filed additional medical records on April 19, 1999, April 26, 1999, and May 3, 1999. The record is now closed and the case is ripe for decision.

II.

FACTUAL BACKGROUND

The following evidence is contained in the record in this matter:⁽²⁾

Factual Testimony

According to Mrs. Juana Castillo, Michael was born on October 7, 1990, following an uneventful pregnancy. Mrs. Castillo recalled that Michael walked when he was one year and one month old and was very soon running. Tr. at 12. Mrs. Castillo recalled that before his September 29, 1992, DPT vaccination, Michael could speak in short sentences.⁽³⁾ Tr. at 13-14, 57.

Following his September 29, 1992, DPT vaccination, Michael was crying and acting fussy during the car trip home from the doctor's office. Tr. at 15-17. All of a sudden, Michael "collapsed to the back and he started having a seizure, a convulsion." Tr. at 16. Mrs. Castillo testified that Michael's hands were

clenched, he was shaking and trembling, and appeared pale. Tr. at 16-17. According to Mrs. Castillo, the incident lasted through two traffic intersections or approximately four to five blocks.⁽⁴⁾ Tr. at 17-18, 36. The Castillo's took Michael to the office of Dr. Villarreal, Mrs. Castillo's physician. Tr. at 19-20. Dr. Villarreal checked Michael and then made arrangements to have Michael admitted to the hospital. Tr. at 21.

Mrs. Castillo recalled that when they took Michael to the hospital he was still pale, weak, and black around his lips. Tr. at 22. According to Mrs. Castillo, Michael did not respond to her while he was in the hospital until the day he was discharged, and then he did not respond to her as he had before the seizure.⁽⁵⁾ Tr. at 23, 25. Mrs. Castillo recalled that Michael was not active in the hospital; he did not walk and he was not talking at all. Tr. at 24, 27. After discharge from the hospital, according to Mrs. Castillo, Michael did not walk again until two weeks after the seizure. Tr. at 27.

According to Mrs. Castillo, Michael continued to have problems walking and speaking following his hospitalization. Tr. at 27-28, 34. Mrs. Castillo testified that when she took Michael to see Dr. Seals, a pediatric neurologist, she felt that he did not understand Michael's condition and dismissed it as a breath holding spell. Tr. at 29-30. Mrs. Castillo testified that Michael did not have a tantrum and did not hold his breath. Tr. at 30.

Mrs. Castillo recalled Michael's second seizure in March 1993. At that time, Michael collapsed backward and started trembling with his arms clenched. The episode lasted for a couple of seconds. Tr. at 30. According to Mrs. Castillo, Michael could not walk again following this seizure until the next day. Tr. at 30. Michael was then started on Depakene for his seizures. Tr. at 31. Mrs. Castillo recalled that Michael's speech regressed further. Tr. at 32. Mrs. Castillo testified that none of Michael's seizures were associated with breath holding.⁽⁶⁾ Tr. at 89.

On November 20, 1997, the date of the first evidentiary hearing, Mrs. Castillo testified Michael had not suffered a seizure since May 1995.⁽⁷⁾ Tr. at 33. His doctors stopped his anti-convulsant medication in May 1997. Tr. at 34. However, Mrs. Castillo testified, Michael continued to have problems walking and has episodes during which he cannot walk at all. Tr. at 34. For that reason, according to Mrs. Castillo, Michael cannot play outside with other children because he tires easily. Tr. at 37.

Medical Records

Medical records indicate an uneventful pregnancy and delivery. Throughout the first two years of his life, Michael was taken to hospital emergency rooms on a number of occasions for acute pharyngitis,

bronchitis, and gastroenteritis. P. Exs. 2, 4 and 5. On September 29, 1992, Michael received his third DTP vaccination. P. Ex. 6 at 3, 6. Later that same day, Michael was seen by Dr. Villarreal with complaints of a seizure. Dr. Villarreal arranged to have Michael admitted to the hospital for observation and studies.⁽⁸⁾ P. Ex. 6 at 3. The hospital admission note indicated that approximately a half hour after Michael received his immunizations he experienced a seizure consisting of his eyes rolling back into his head. Michael became very pale and his extremities were tight and flexed. P. Ex. 2 at 38. The admission record also noted that Michael's primary language was Spanish, that he had difficulty expressing himself and "doesn't know many words 2 years old." P. Ex. 2 at 38. The record indicates that the information was supplied by Michael's mother. P. Ex. 2 at 38.

During his hospital stay, Michael underwent a CT scan of his head which was found to be normal. P. Ex. 2 at 35. Michael also had an EEG performed which was thought to be abnormal due to "potential epileptiform activity." P. Ex. 2 at 36. Throughout his hospital stay, Michael was described by the nursing staff as active and alert. P. Ex. 2 at 59-60. On October 2, 1992, Michael was described as alert and oriented and able to follow verbal commands. P. Ex. 2 at 71. On October 3, 1992, Michael was discharged from the hospital with a diagnosis of seizures of unknown etiology. P. Ex. 2 at 26.

A Vaccine Adverse Event Reporting System form was completed for Michael which noted that following his vaccination he experienced crying, unconsciousness, convulsions and a temperature of 101°. The report also indicated that a CAT scan was within normal limits and Michael recovered from the incident. P. Ex. 7 at 3.

On October 5, 1992, Mrs. Castillo called the clinic to report the events following Michael's DPT immunization. She indicated that Michael was "very active." P. Ex. 7 at 5. On October 23, 1992, Michael was seen by Dr. Seals, a pediatric neurologist, for a consultation. P. Ex. 11 at 1. Dr. Seals recorded the following information:

According to the parent, on 9-29-92 approximately 1 hour 20 minutes after receiving immunizations, he was riding in the car and began acutely crying. After a very brief crying episode, he went into a generalized seizure with trembling and eyes rolled back. This was heralded by acute inspiratory breath holding. He became pale and cyanotic. The episode lasted approximately 15-20 seconds, followed by spontaneous and complete recovery. An evaluation in McAllen apparently demonstrated some epileptiform activity on EEG. He was begun on Phenobarbital medication.

* * *

IMPRESSION: 1. Seizure episode associated with breath holding spell.

P. Ex. 11 at 1.

A history and physical by Dr. Ramirez dictated November 2, 1992, indicates the following:

This is a two-year old with seizures plus immunization. This infant male was admitted directly from Dr. Villarreal's office because of the child having had immunizations and 24 hours later had seizure activity that lasted about three seconds to 45 seconds as stated by the parents. *Since then, the child has been okay.*

P. Ex. 2 at 27 (emphasis added).

On March 4, 1993, Michael was seen for fever and diarrhea and was noted to have had a febrile seizure earlier that day. P. Ex. 5 at 10. On April 23, 1993, Michael was seen by his pediatrician who noted that his mother was concerned that he was not eating. The pediatrician recorded the following, "Explained she needs to ignore him - needs to stop him from having temper tantrums." P. Ex. 5 at 12. His last seizure was noted to have been two months earlier. P. Ex. 5 at 12.

Michael was diagnosed with an umbilical hernia on May 12, 1993. P. Ex. 5 at 13. On November 15, 1993, Michael saw his pediatrician who noted that he had not taken valproic acid since March and had no recurrent seizures. P. Ex. 5 at 14. His pediatrician also noted, "Mom states child is very aggressive." P. Ex. 5 at 14. On November 26, 1993, Michael fell and hit his head and experienced a possible seizure or fainting spell. P. Ex. 5 at 14.

Michael again saw his pediatrician on November 30, 1993, after sustaining a head injury. P. Ex. 5 at 15. On December 2, 1993, Michael's pediatrician recorded that Michael's mother had concerns about his seizures. P. Ex. 5 at 15. The record indicates, "parent education specified that there is no effect [with] seizures on his learning disability. Explained to mother that [patient] is ADD." P. Ex. 5 at 15. Over the following months, Michael was seen numerous times by his pediatrician and other health care providers for ear infections, pharyngitis, bronchitis, conjunctivitis, tonsillitis, and upper respiratory infections. P. Ex. 5.

A March 4, 1994, pediatric record notes that Michael had speech and developmental delays. P. Ex. 5 at 18. A letter from Dr. Gurden, a pediatric neurologist, dated September 30, 1994, indicates that Michael

was experiencing both petit mal and grand mal seizures and had been taking Depakote since 1992. Dr. Gurden noted that Michael was diagnosed as having attention deficit disorder and hyperactivity. Dr. Gurden recorded the following, "The mother was rather vague as to his milestones. Apparently he is not talking normally at this point in time however. On examination the child wouldn't talk with me very much but his strength and coordination, reflexes, and cranial nerves all seemed normal." P. Ex. 9 at 1.

On December 14, 1994, Michael again saw Dr. Seals for a follow-up consultation. P. Ex. 11 at 3. Dr. Seals noted Michael had been placed back on seizure medication because he experienced seizure activity after his Phenobarbital was discontinued. At the time of the visit, Michael was noted to be "doing quite well" on his medication dosage. His general neurologic exam was "entirely within normal limits." P. Ex. 11 at 3. Michael underwent further EEGs on December 29, 1994, and on October 26, 1995, which were both interpreted as normal. P. Ex. 11A at 1-2.

Michael saw Dr. Seals again for follow-up on December 9, 1995. During this visit, Dr. Seals noted that Mrs. Castillo felt that Michael was doing well although he had some breakthrough seizures over the past several months. P. Ex. 11A at 4. Dr. Seals further noted that Michael was in the Head Start Program and doing satisfactorily. Dr. Seals recorded, "Some mild behavioral difficulties with hyperactivity and aggressiveness have continued." P. Ex. 11A at 4. At an April 11, 1996, visit, Dr. Seals recorded that there was some concern with Michael's hyperactivity and aggressive behavior. P. Ex. 11A at 6. Dr. Seals also noted Michael was having some difficulty with school but it was not a "major issue" at that time. *Id.* On May 1, 1996, Michael had another normal EEG. P. Ex. 11A at 7. On November 8, 1996, Dr. Seals recorded that Michael was having difficulty in academic performance due to poor writing and recall, as well as excessive aggressiveness. Michael was noted to be receiving speech therapy in school. P. Ex. 11A at 8. Michael's November 14, 1996, EEG was reported as normal. P. Ex. 11A at 9.

Dr. Marco Gutierrez saw Michael in February 1997 and described him as "very hyperactive." Dr. Gutierrez concluded that Michael had Attention Deficit Disorder "with a very poor attention span." P. Ex. 37 at 3. In March 1997, Dr. Gutierrez noted, "Patient has possible Attention Deficit Disorder by history. I've asked for a note from his teachers, but they have not sent me anything." P. Ex. 37 at 2.

On February 2, 1999, Michael was taken to the McAllen Medical Center emergency room with a history of two seizures that day following a head injury. P. Ex. 36. Michael was administered seizure medication and given stitches for his head wound. An EEG was ordered. A February 4, 1999, EEG was noted to be abnormal "with demonstration of lateralized and focal spike wave activity consistent with benign rolandic epilepsy." P. Ex. 35 at 4.

On February 15, 1999, Dr. Wilson Sy, a pediatric neurologist examined Michael and indicated in his report that Michael's motor strength and coordination were both normal and that his gait was normal for his age. Dr. Sy noted Michael's history of seizures "about every three months" beginning in 1992 after this DPT shot until 1995. P. Ex. 35 at 1. The report indicates Michael's anti-seizure medication was discontinued in 1997 and that he had been seizure-free until about two weeks previously, when he had

two seizures in one day, lasting about 20 to 30 seconds each. He related, "The seizure was described as generalized tonic clonic in character," and that Michael had been prescribed Depakote. P. Ex. 35 at 1. The report also noted that Michael "had a recent EEG done which showed that he has evidence of a focal seizure coming from the right temporal area."⁽⁹⁾ P. Ex. 35 at 1. Dr. Sy continued:

This is a young boy who has evidence of partial seizure with rapid generalization. He also has evidence of learning disability. The possibility that he might have ADHD can not be totally ruled out also.

P. Ex. 35 at 1. Follow-up visits on February 25, 1999, and March 9, 1999, indicated no further seizures. P. Ex. 35 at 3.

Expert testimony

Dr. Sheldon Gross

Testifying for petitioners was Dr. Sheldon Gross, a pediatric neurologist.⁽¹⁰⁾ Dr. Gross examined Michael Castillo on March 3, 1998, and spoke with Mrs. Castillo about Michael on two occasions.⁽¹¹⁾ Tr. at 153. He also ordered a series of blood and urine tests as well as a chromosomal analysis. All tests were negative and did not provide any explanation for Michael's current problems. Tr. at 153-54. Dr. Gross found Michael's seizure disorder to be in remission, but found Michael to have some cognitive problems, especially in the areas of speech and language. Dr. Gross related that some of Michael's teachers strongly suspected that Michael may have some attention deficit disorder ("ADD"). Tr. at 154. Dr. Gross did not find any weakness in Michael's extremities and found no neuromuscular deficits. Tr. at 163-64.

Dr. Gross believes the onset of Michael's current problems was the brief seizure he experienced following his September 29, 1992, DPT vaccination. He bases this primarily on Mrs. Castillo's description to him of immediate developmental regression in Michael's speech following the vaccination, signifying a neurologic sign or symptom that the event was "more than simply a brief seizure with no long-term sequela."⁽¹²⁾ Tr. at 155. He believes all of Michael's deficits are attributable to the same underlying problem. Tr. at 158, 165. He testified, "It's my opinion that [Michael] had a seizure shortly [after his DPT vaccination] and based on the history that the family gives me, they saw evidence of changes in his language function associated with it. So, I think, based on those two pieces of history, I would say, yes, something happened." Tr. at 165. When asked if he believed to a reasonable degree of medical probability that the DPT immunization was the cause of Michael's current condition, Dr. Gross replied, "You know, I don't know how else to answer that, other than to say the evidence points to that." Tr. at 166. When pressed to give a "yes" or "no" answer, Dr. Gross responded, "I would say in this particular case, *yes, I probably believe it.*" Tr. at 166 (emphasis added).

Dr. Gross also examined Michael's medical records and testified he saw no history of any developmental problems before the vaccination in question. Tr. at 156. He conceded, however, that Michael's speech delay may have predated his vaccination but he added, "You can't be 100 percent sure."⁽¹³⁾ Tr. at 162.

Dr. Thomas Schweller

Also testifying for petitioners was Dr. Thomas Schweller, a pediatric neurologist.⁽¹⁴⁾ Dr. Schweller believes that Michael suffered a complex seizure within 15 to 30 minutes following his DPT immunization that lasted several minutes. He believes, based on the parents' descriptions, that there was a "marked difference" in Michael's before- and after- seizure status, particularly in the areas of language and walking. Tr. at 110-11. He testified that if some particular ability is lost for a period of time following a seizure, in this case language ability, it suggests that the language centers in the brain may have been impaired during the seizure event. Tr. at 111-12. He testified further he believes the seizure constituted an encephalopathic event based on the reported regression in Michael's skills, signifying a "change in the . . . brain's coordination in certain areas, both in speech, language and in some of the balance, some of the foot, leg activities . . ." Tr. at 113. Dr. Schweller believes Michael suffered a serious neurologic event following his DPT immunization. Tr. at 173-74. When asked what caused the event, Dr. Schweller testified,

Well, again, the only thing that we have evidence for that is temporally related with the DPT immunization, in that, the history we have is that he was at least functioning as a normal child, then he had the DPT immunization and within at least 30 minutes, 60 minutes, he had a seizure event that brought him to the hospital where he was hospitalized and that from that point in time, he had some loss, according to the family, of his language ability. And, that he has continued to have problems from that point in time. So he had a linear course that goes back to the DPT immunization.

Tr. at 174.

Dr. Schweller briefly alluded to his own experience, some case reports and articles, a study at UCLA and "the British study" as support for the notion that DPT vaccine can cause neurologic injury in children. Tr. at 175. He believes Michael fits the profile of children who suffer such neurological injury following DPT inoculation in that he suffered a seizure event and a period of regression. Tr. at 176. Dr. Schweller rejected the notion that Michael's first seizure was instead a breath-holding event because of his initial abnormal EEG and associated residual neurologic findings. Tr. at 176.

Dr. Schweller believes that Michael's current condition is a sequela of the initial neuropathic event that

was caused by the DPT vaccine. Tr. at 179. Dr. Schweller bases his opinion on the initial seizure, the dramatic loss of speech skills (a neurologic sign) and the recurrent episodes of seizures. Tr. at 179, 186. He believes the DPT immunization caused Michael's brain to malfunction. Tr. at 180. When asked if he could render his opinion based on the medical records alone, Dr. Schweller testified he depended upon the medical history provided by the family to give a "full opinion." Tr. at 181. Absent that, he could not opine that the DPT vaccination was the cause of Michael's problems. Tr. at 182. Dr. Schweller conceded that there was no inconsolable crying, bulging fontanel, vomiting, focal neurologic signs, continuing seizure activity or loss of consciousness. Tr. at 185-86.

Dr. Albert Spiro

Respondent presented the testimony of Dr. Albert Spiro, a pediatric neurologist.⁽¹⁵⁾ Dr. Spiro believes Michael's DPT immunization had nothing to do with his current condition. In Dr. Spiro's opinion, "there was absolutely not an iota of indication that there was any type of encephalopathic event." If Michael had suffered an encephalopathy, according to Dr. Spiro, one would expect to see a diminished level of consciousness for a prolonged period of time. Tr. at 199. Dr. Spiro acknowledged that Michael had either a crying spell followed by a seizure, a breath-holding attack, or a seizure in temporal association with his DPT vaccination. However, according to Dr. Spiro, Michael's hospital course was "relatively benign." Tr. at 193. Moreover, after reviewing the actual EEG, Dr. Spiro believes it was completely normal.⁽¹⁶⁾ Tr. at 194, 199. Dr. Spiro believes Michael suffered a minor event in temporal relation to the DPT vaccine that is not in any way connected to or responsible for his current language and learning difficulties.⁽¹⁷⁾ Tr. at 195-96.

Dr. Spiro testified that Michael was noted by history to have mastered relatively few words at the time of his initial hospitalization. Dr. Spiro testified, "Regression of speech skills briefly following a seizure and lasting for a relatively short period of time would not be an unusual situation, in my own experience. This is what we were just talking about, in the postictal state. But, return to normal or to pre-existing status occurs after that." Tr. at 205-06. If a regression in speech skills persisted for weeks or months, Dr. Spiro would look for some underlying neurological problem. Tr. at 206.

III.

DISCUSSION

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.⁽¹⁸⁾ The Vaccine Injury Table lists certain injuries and conditions which, if found to have occurred within a prescribed time period following the administration of a

covered vaccine, create a rebuttable presumption that the vaccine caused the injury or condition.⁽¹⁹⁾ Alternatively, petitioners may recover under the Act if the injury they allege is not listed on the Vaccine Injury Table. In that case, however, petitioners must prove that the immunization *actually caused* the alleged injury.⁽²⁰⁾

Administrative changes in the Vaccine Act effective March 10, 1995,⁽²¹⁾ significantly altered the presumptively vaccine-related injuries associated with DPT vaccinations. For that reason, the question in this case is whether petitioners have demonstrated by a preponderance of the evidence that Michael's seizure disorder and learning disabilities were actually caused by the DPT vaccination administered to him on September 29, 1992.

General Discussion of Proof Required in Causation-in-fact Cases

In order to demonstrate entitlement 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 injuries alleged. §§ 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-370 (1990), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991). This requires that petitioner show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); *see also Grant*, 956 F.2d at 1148. Petitioners do not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. Rather, petitioners must explain how and why the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1993), *cert. denied*, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period [following the vaccination] . . . Without more, this proximate temporal relationship will not support a finding of causation"). If petitioners place "singular reliance on the temporal relationship between the administration of the vaccine and the onset of symptoms," the

claim must fail. *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400, 403 (1991). Nor may petitioners meet their burden by eliminating other potential causes of the injury. *Grant*, 956 F.2d at 1149-50.

In addition, petitioners' theory "must be supported by a sound and reliable medical or scientific explanation." *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). "[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for a petitioner seeking to prove causation-in-fact. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 8356. Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993), an expert's testimony based on scientific, technical or other specialized knowledge must be supported by more than "subjective belief or unsupported speculation" and must be "derived by the scientific method." *Daubert*, 113 S.Ct. at 2795. This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993). The overall touchstone is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert*, 43 F.3d at 1316.

In order to answer the single inquiry of whether, based on the record as a whole, petitioners have satisfied their burden of proving an off-Table claim, one must pursue a two-step analysis: (1) *can* DPT vaccine cause the injuries alleged? and (2) *did* the DPT inoculation in question in-fact cause Michael's injuries in this case? See *Guy v. Secretary of HHS*, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994); *Housand v. Secretary of HHS*, No. 94-441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996).

1. Can DPT cause seizure disorders and learning disabilities?

Petitioners' expert, Dr. Gross, was equivocal in his testimony as to whether the DPT inoculation Michael received actually caused his seizure disorder and his current condition. When pressed, Dr. Gross concluded he "probably" believed it did. Tr. at 166. The level of uncertainty expressed by Dr. Gross renders his opinion on causation virtually useless. See, e.g., *Van Epps v. Secretary of HHS*, 26 Cl. Ct. 650 (Cl. Ct. 1992) (expert opinion that causation was "highly possible" not sufficient to establish causation); *Thrall v. Secretary of HHS*, 26 Cl. Ct. 1419 (Cl. Ct. 1992) ("close questions" of causation need not be resolved in petitioner's favor). I also found Dr. Schweller to be singularly unpersuasive in his testimony. His grasp of the scientific literature upon which petitioners' theory rests was not apparent. While he relied on his own limited experience in describing an instance of a purportedly DPT-related neurological injury, he reflected no knowledge of the relevant epidemiological studies except to indicate their existence.⁽²²⁾ See *Gamache v. Secretary of HHS*, No. 90-2545V, 1992 WL 394274 (Fed. Cl. Spec. Mstr. Dec. 16, 1992), *aff'd*, 27 Fed. Cl. 639 (1993), *aff'd*, 5 F.3d 1505 (Fed. Cir. 1993) (medical doctor's failure to describe the medical or scientific basis for his conclusion of actual causation was fatal to petitioner's satisfaction of her burden of proof of causation-in-fact).

The answer to the question of whether DPT can cause seizure disorders and learning disabilities requires an overview of the relevant medical literature. As noted, petitioners' experts did not provide any insightful analysis (or anything but fleeting mention) of the relevant scientific literature linking DPT vaccine with neurological injuries. Petitioners' counsel, however, undertook an analysis of certain scientific evidence which, he argues, would support a causation-in-fact finding in this case. Even though petitioners' counsel is not a qualified medical expert and his analysis of the medical literature as it pertains to this case thus merits questionable weight, I will undertake to review what I believe to be the relevant scientific literature.

Petitioners pursuing a causation-in-fact theory of recovery that the DPT vaccine actually caused the injuries alleged have often relied on epidemiological studies and other pertinent medical reports to substantiate their claims.⁽²³⁾ In his closing brief, petitioners' counsel relies heavily on the National Childhood Encephalopathy Study ("NCES") and the Institute of Medicine ("IOM") reports to demonstrate not only that the vaccine can cause seizure disorders and permanent neurological damage, but that the DPT did cause these injuries in Michael's case. A general overview of the NCES and IOM

reports follows:

National Childhood Encephalopathy Study: The NCES was initiated in 1976 "to assess the risks of certain serious neurological disorders associated with immunization in early childhood." P. Ex. 21 at 80. The researchers set out to confirm their hypothesis that there exists a causal link between pertussis and serious neurological illnesses. P. Ex. 21 at 96. During a three-year period between 1976 and 1979, treating physicians were asked to report all instances in children aged two months to 35 months of:

1. Acute or subacute encephalitis/encephalomyelitis/encephalopathy.
2. Unexplained loss of consciousness.
3. Convulsions:
 - (i) *with a total duration of more than about ½ hour*
 - or (ii) followed by coma lasting two hours or more
 - or (iii) followed by paralysis or other *neurological signs not previously present lasting 24 hours or more.*
4. Infantile spasms (West's syndrome).
5. Reye's syndrome (acute encephalopathy with abnormal liver function tests).

P. Ex. 21, Appendix V.B(a) at 157 (emphasis added).

The NCES researchers acknowledged the biologic plausibility of a causal association between immunization with pertussis and the development of serious neurological disorders. P. Ex. 21 at 142. The researchers stated the results of the NCES

suggest but do not prove that immunization with DTP vaccine does cause the development of serious neurological disorders in a small number of children who were previously apparently neurologically normal as well as in some children who were not neurologically normal and in whom the vaccine is sometimes held to be contraindicated. These disorders occur typically up to seven days after immunization, but most often within seventy-two hours. However, similar cases were also found in association with recent immunization with DT vaccine which underlines the need for caution in attributing a cause in individual cases.

P. Ex. 21 at 143. The authors further admonished, "[i]t seems likely that permanent damage as a result of pertussis immunization is a very rare event and attribution of a cause in individual cases is precarious." P. Ex. 21 at 149.

Institute of Medicine, Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, 1991 Report ("the 1991 IOM Report"): In November 1989, in response to the Vaccine Act's summons for a review of the scientific literature (including the NCES) and other information regarding the possible adverse consequences of pertussis, the IOM created the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines. The committee was charged with several duties, among them to identify and review all available medical and scientific literature on the relationship, if any, between vaccines containing pertussis (including whole cells, extracts, and specific antigens) and certain illnesses and conditions. 1991 IOM Report at vi. The committee published its comprehensive findings in 1991, concluding that the medical evidence was "consistent with a causal relation between DPT vaccine and *acute* encephalopathy." 1991 IOM Report at 118 (emphasis added). The committee also admonished, however, that the evidence was insufficient to indicate such a relationship between DPT immunization and permanent neurologic damage. *Id.*

In 1993, a 10-year follow-up of the NCES study was published. P. Ex. 20. The authors of the follow-up also wrote a brief summary for publication in the British Medical Journal. P. Ex. 26. In the summary, the authors note:

[A]lthough children with severe acute neurological illnesses resulting in death or later dysfunction had a significant excess risk of recent diphtheria, tetanus, and pertussis immunisation when compared with controls, this does not prove that the vaccine was the sole or even the prime cause of either the illnesses or the adverse outcomes in these cases. It remains an open question as to whether or not such illnesses occur related to diphtheria, tetanus, and pertussis vaccine in children whose brains are structurally and functionally normal and in the absence of concomitant factors. Certainly, attribution of a cause in individual cases must be speculative.

P. Ex. 26 at unnumbered p. 5.

Institute of Medicine, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis ("the 1994 IOM Report"): Beginning in December 1993 and prompted by the publication of the NCES ten-year follow-up report, the IOM's Committee to Study New Research on Vaccines revisited the issue of adverse events associated with DPT vaccination, specifically reevaluating the causal relation between the vaccine and *permanent* neurological damage. P. Ex. 19. After examining the follow-up study in conjunction with the 1991 IOM Report, the authors of the 1994 IOM Report concluded that the medical evidence

is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction

described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine. This serious acute neurologic response to DPT is a rare event.

* * *

The *evidence remains insufficient to indicate* the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances.

P. Ex. 19 at 15-16 (emphasis in original).

Based on the above, I conclude that prong one of the inquiry here is answered in the affirmative in instances in which a child would have qualified as a "case child" for purposes of inclusion in the NCES study, suffered a serious acute neurologic illness within seven days after receiving DPT vaccine, and suffered chronic nervous system dysfunction as outlined in the NCES follow-up report. [\(24\)](#)

2. Did the DPT inoculation Michael received cause his seizure disorder and learning disabilities?

Even though I have found that DPT vaccination can cause seizure disorders and learning disabilities, I find that petitioners have not satisfied prong two of the causation-in-fact analysis. My reasoning follows.

The evidence is not persuasive that Michael suffered a serious regression in his speech or motor development following his September 29, 1992, DPT inoculation. Accordingly, I find Michael did not suffer a serious, acute neurological illness within seven days of receiving his September 29, 1992, DPT vaccination.

Michael's initial seizure did not last a half an hour, nor was it followed by coma or paralysis. Accordingly, petitioners' only avenue for proving causation-in-fact is to show that Michael suffered a serious, acute neurological illness within seven days after receiving his DPT vaccine on September 29, 1992. Petitioners have presented testimony that Michael suffered serious regression in his speech and motor abilities as well as behavioral changes following his DPT vaccination. These changes are not noted in any medical records and, indeed, there are contradictions in the evidence which lead me to question the accuracy of petitioners' memories regarding the purported dramatic changes they saw in Michael following his immunization. Mrs. Castillo testified about Michael's speech development prior to the vaccination, noting he was able to speak in short sentences. A medical history taken at the emergency room on September 29, 1992, however, noted that Michael had difficulty expressing himself and "doesn't know many words" at two years of age. P. Ex. 2 at 38.

In her September 26, 1995, affidavit filed in this matter, Mrs. Castillo averred that Michael could not walk for "three or four hours" after his September 29, 1992, seizure. P. Ex. 1 at 2. During the evidentiary hearing, Mrs. Castillo testified that Michael had no strength in his legs following his seizure and could not walk during the four days he was in the hospital. Indeed, Mrs. Castillo testified Michael did not walk for *two weeks* after the seizure. Tr. at 27. Michael's medical records provide a different picture. Michael is described in contemporaneous medical records as walking around his hospital room and as having strong muscle strength. ⁽²⁵⁾ P. Ex. 2 at 74, 78.

Mrs. Castillo testified that Michael was in a stupor after the seizure and slept the entire first day of his hospitalization, not waking until the next day. Tr. at 27. She further testified that Michael was unresponsive and did not recognize her until *three or four days* after the seizure. Tr. at 23. In contrast, Mrs. Castillo provided a declaration filed with the petition in which she noted Michael was not fully responsive until the day following his seizure. P. Ex. 1 at 2. Further, the nurses' notes describe him during the first day of his hospitalization as "alert and responsive" (P. Ex. 2 at 53), "talking with his mother" (P. Ex. 2 at 54), "responding appropriately to questions" (P. Ex. 2 at 56), "eating and drinking" (P. Ex. 2 at 54), "playing [with] mother" (P. Ex. 2 at 53), and "sitting up in bed." (P. Ex. 2 at 54). The following day, on September 30, 1992, Michael was noted to be "playing with balloons." P. Ex. 2 at 59.

As the Federal Circuit has noted, "[O]ral testimony in conflict with contemporaneous documentary evidence deserves little weight." *Cucuras v. Secretary of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993), citing *United States v. United States Gypsum Co.*, 333 U.S. 364 (1947). The Federal Circuit further stated:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras, 993 F.2d at 1528.

In determining how to weigh oral testimony against conflicting medical record evidence, the Claims Court has stated that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 523 (1993) (quoting *Murphy v. Secretary of HHS*, 23 Cl. Ct. 726, 733 (1992), *aff'd* 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 463 (1992)). However, as Special Master Golkiewicz noted in *Stevens v. Secretary of HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990), "discrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent and consistent testimony can overcome such missing or contradictory medical records." *Stevens*, 1990 WL 608693, at *3.

Unfortunately, the testimony in this case is far from clear, cogent and consistent. Indeed, I find, after reviewing all of the medical records, affidavits and testimony at the evidentiary hearings in this matter, that I cannot conclude that Michael suffered the devastating effects from his DPT vaccination that his parents reported, particularly in the areas of a dramatic regression in speech and motor abilities. As noted, although Michael experienced a brief seizure following his DPT inoculation, that alone would not have qualified him for inclusion in the NCES study, because the seizure did not last more than a half hour and was not followed by coma, paralysis or other neurological signs not previously present lasting more than 24 hours. Further, based on all the evidence, I find that Michael did not suffer a serious, acute neurological event within seven days of his DPT immunization that would permit the basis for a finding of causation-in-fact. [\(26\)](#)

Because petitioners' experts based their opinions on facts I do not find to be reliable, their opinions do not support petitioners' contentions.

The conclusions of an expert are only as sound as their factual predicate. *Davis v. Secretary of HHS*, 20 Cl. Ct. 168, 173 (1990); *Loesch v. United States*, 645 F.2d 905, 915 (1981), citing *State of Washington v. United States*, 214 F.2d 33, 43 (9th Cir.), cert denied, 348 U.S. 862 (1954); *Fehrs v. United States*, 620 F.2d 255, 265 (1980). Dr. Gross and Dr. Schweller both relied on the history presented by Mr. and Mrs. Castillo of a dramatic regression in Michael's speech immediately following his DPT immunization which persisted for a lengthy time. They conceded they could not base their opinions on medical records alone. There is no contemporaneous medical record suggesting such a regression. Indeed, medical records during Michael's admission to the hospital indicate that his speech problem actually predated his immunization, in that he was noted to speak few words for a two year old.

Mr. and Mrs. Castillo may have a firm belief that Michael's speech problems began after his vaccination, but I simply do not credit their testimony in that regard. The many contradictions between the testimony, affidavits and medical records lead me to conclude that the passage of time has clouded their memories. Because Dr. Gross and Dr. Schweller based their opinions on a factual predicate I simply do not accept, their opinions do not pass muster. On the other hand, Dr. Spiro was a knowledgeable and persuasive witness. His background and expertise lead me to conclude that he is the more credible witness.

To be sure, I make no suggestion that Mr. and Mrs. Castillo did not testify in good faith. They appear to be devoted parents with a firmly held belief that their son was injured by a DPT vaccination. Congress, however, designed the Program to compensate only those individuals who can demonstrate a causal or temporal link between their injuries and a listed vaccination by a preponderance of the evidence. In this instance, the evidence simply does not demonstrate such a link.

IV.

FINDINGS OF FACT

1. As the parents of their minor son, petitioners have the requisite capacity to bring this action. Section 11(b)(1)(A); P. Ex. 1

2. Petitioners have not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Michael due to the administration of the DPT vaccine in question. Section 11(c)(1)(E); P. Ex. 1.

3. Michael was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(A); P. Ex. 1.

4. Said vaccine was administered in the United States, in Donna, Texas. Section 11(c)(1)(B)(i)(I); P. Ex. 1.

5. There is not a preponderance of the evidence that the vaccination Michael received on September 29, 1992, actually caused him to suffer a seizure disorder and/or learning disabilities.

V.

CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are not entitled to compensation in this case under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Elizabeth E. Wright

Special Master

1. 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 at 42 U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1998)). References shall be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. The evidence in the record consists primarily of exhibits submitted as part of the petition filed in this case ("P. Ex. ____"), respondent's exhibits filed in this matter ("R. Ex. ____"), plus evidence taken at the evidentiary hearings in this matter ("Tr. at ____").

3. As examples of Michael's verbal abilities before his September 29, 1992, DPT vaccination, Mrs. Castillo related Michael was saying the following phrases in Spanish: "Mom, I'm hungry." "I want to eat." "Mom, where are you going?"

4. Medical records indicate Mrs. Castillo informed the doctors that the seizure lasted between three and 45 seconds. P. Ex. 2 at 27.

5. For example, Mrs. Castillo testified that before the seizure Michael could ask for his bottle in Spanish, and afterward he would only point at his bottle. Tr. at 25-26.

6. Jesus Castillo, Michael's father, also testified in this matter, generally corroborating the testimony of Mrs. Castillo. Of note, Mr. Castillo testified that Michael was unconscious following his initial seizure. Tr. at 95. He also testified Michael did not speak in sentences again until approximately three weeks to a month after his seizure. Tr. at 100.

7. According to medical records filed recently, Michael suffered two brief seizures on February 2, 1999, in conjunction with a head injury.

8. A handwritten note contained the following information:

Child had immunization at 9:30 at Donna Clinic - at 10:10 had seizure and was taken to Dr. V. Villarreal office, where child was exam. & ref. to S. Ramirez service for adm - orders with pt. At present child awake no acute distress.

P. Ex. 2 at 23.

9. Because of the EEG findings, Dr. Sy recommended changing Michael's seizure medication from Depakote to Tegretol.

10. Dr. Gross is board certified in general pediatrics and in neurology with special competence in child neurology. P. Ex. 31. He maintains a private practice in pediatric neurology. Tr. at 152-53.

11. Following Mrs. Castillo's testimony regarding regression in Michael's motor functioning, Dr. Spiro,

respondent's expert, suggested an examination would be helpful to assess the level of Michael's deficits. Tr. at 119-21. For that reason, the first hearing was adjourned so that a pediatric neurologist could perform an evaluation on Michael. Dr. Gross performed that evaluation.

12. Dr. Gross conceded that the medical records do not document any decline in Michael's speech or motor development within seven days of his DPT immunization. Tr. at 167.

13. Dr. Gross did not have an explanation for why Michael was kept in the hospital for five days following his initial brief, afebrile seizure. He testified he probably would not have admitted a child who had a brief, afebrile seizure. Tr. at 171.

14. Dr. Schweller is board certified in pediatrics and neurology with special competence in child neurology and also in electroencephalography. P. Ex. 32; Tr. at 109. Dr. Schweller's practice consists of a mixture of evaluations for various state agencies including Social Security and the Department of Rehabilitation. Approximately 50% of his practice involves evaluations for Worker's Compensation. He also testifies in personal injury cases and about 10% percent of his time is spent supervising severely impaired individuals in several facilities in the San Diego area. Tr. at 109.

15. Dr. Spiro is board certified in pediatrics and in neurology with special competence in child neurology. He has been on the faculty of the Albert Einstein College of Medicine since 1966, where is currently a professor of neurology and pediatrics. Until three years ago, Dr. Spiro was the chief of pediatric neurology for approximately 17 or 18 years. Tr. at 191.

16. Dr. Spiro suggested Michael's initial EEG was probably not read by a pediatric neurologist or was read by a pediatric neurologist without extensive experience. The EEG, according to Dr. Spiro, revealed the normal activity one would see in a child who was drowsy. Tr. at 197. Encephalopathic EEGs are typically markedly slow and have high voltage, which was not seen here, according to Dr. Spiro. Tr. at 198.

17. Dr. Spiro was at a loss to explain why Michael was hospitalized for five days following his seizure, and agreed with Dr. Gross that Michael's condition would not have suggested a hospital admission. Tr. at 196. He testified it is not unusual for some postictal changes to last for several days. Tr. at 203. However, he believes the medical records reflect that Michael was active and alert during his hospitalization. Tr. at 204-05.

18. Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "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." *In re Winship*, 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 (Cl. Ct. 1984).

19. Section 14(a).

20. Section 13(a)(1); Section 11(c)(1)(C)(ii). Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine. Section 11(c)(1)(D)(i); (2) that the petitioner incurred in excess of \$1000 in unreimbursable vaccine-related expenses. Section 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States. Section 11(c)(1)(B)(i)(I); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action. Section 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. Section 11(b)(1)(A).

21. See 60 Fed. Reg. 7678 (1995); *O'Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996). It should be noted that the Vaccine Injury Table was revised administratively a second time, applying to petitions filed after March 24, 1997. See 62 Fed. Reg. 7685, 7688 (1997).

22. When asked to describe the injuries of the patients with which he had personal experience, Dr. Schweller testified he was involved in a case involving a young boy who had "recurrent, prolonged encephalopathic conditions," including inconsolable crying and abnormal responsiveness that lasted two to three weeks after his first two immunizations. Tr. at 189. After the third immunization, he began to have seizures and later developed a severe seizure disorder. Tr. at 189.

23. Other special masters have used the NCES studies and 1994 IOM reports as benchmarks for determining whether petitioners have successfully met their burden of proving causation-in-fact. See., e.g., *Terran v. Secretary of HHS*, No. 95-451V, 1998 WL 41330 (Fed. Cl. Spec. Mstr. Jan. 23, 1998); *Lewis v. Secretary of HHS*, No. 95-728V, 1999 WL _____ (Fed. Cl. Spec. Mstr. June 14, 1999).

24. Such chronic neurological dysfunction following a serious acute neurological illness *can* include continuing seizure disorders as well as general (as opposed to specific) depression of educational performance. P. Ex. 20 at 101-02.

25. At the evidentiary hearing, Mrs. Castillo testified Michael continued to have muscle weakness and could not walk for long periods of time. However, no doctor has confirmed any motor difficulties and, in fact, Dr. Gross found Michael to have good muscle strength and coordination.

26. Although Mr. Castillo testified Michael was unconscious after his seizure, this is not corroborated in Dr. Villarreal's office notes or in any other contemporaneous medical record.