

be sustained upon review. Specifically, he determined that credibility concerns I developed regarding Dr. Tornatore's testimony about petitioners' Table Injury claim could not be used to question his opinion on the actual causation claim.² Remand Order at 6-7. Additionally, Senior Judge Merow ruled that, in the absence of testimony by two treating physicians, Dr. Resnick and Dr. Deray, their statements in the medical records reasonably supported Dr. Tornatore's testimony regarding causation. Remand Order at 10, 11-12. Senior Judge Merow ordered:

However, to the extent possible, testimony of Enrique's treating physicians should be obtained. Such evidence with respect to the medical records involved, Enrique's clinical picture with reference to the conflict in the experts' testimony, and the logical sequence of cause and effect with regard to the vaccination and Enrique's seizures would be of assistance in establishing whether it is more likely than not that the seizures were caused by the vaccination, by some other event, or that causation is unknown. Explanation as to efforts to establish causation and potential causes considered and rejected can be detailed. In particular, the testimony of Drs. Resnick and Deray should be most helpful in resolving this issue in a manner to further the administration of justice.

Remand Order at 11-12.

The remand order directed me to reevaluate the evidence to determine if petitioners had established causation by a preponderance of the evidence. *Id.* at 11. Senior Judge Merow indicated that he considered the evidence sufficient to establish the first and third prongs of the *Althen* test.³ However, he ordered me to reevaluate the evidence (less the matters erroneously considered), consider any additional evidence adduced, and then determine whether petitioners had met their burden to demonstrate a logical sequence of cause and effect between vaccination and injury. *Id.* at 10.

Pursuant to the remand order, I held a recorded status conference on March 4, 2008, to discuss what additional evidence should be considered. Petitioner's counsel stated that he opposed taking testimony from Drs. Deray and Resnick, did not intend to offer additional evidence, and intended to seek reconsideration of the remand order. Petitioners filed a motion for reconsideration on March 10, 2008; in the interim, I

² Senior Judge Merow also determined that I erred in finding certain facts based on petitioners' testimony at the onset hearing and in using Dr. Tornatore's reliance on that testimony to question his opinion pertaining to the actual causation claim.

³ *Althen v. Sec'y, HHS*, 418 F.3d 1274 (Fed. Cir. 2005). In the case of an "off-Table" injury, a petitioner must "show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and [the] injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for [the] injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

ordered respondent to subpoena Drs. Resnick and Deray to testify in a hearing on remand. See Order, dated March 10, 2008. Senior Judge Merow denied the request for reconsideration on March 21, 2008.

I heard the testimony of Drs. Deray and Resnick on April 28, 2008. I offered the parties the opportunity to submit any additional matters by May 23, 2008. Respondent filed a post-hearing submission; petitioners did not.

Having carefully considered the additional testimony, I adhere to my earlier opinion that petitioners have failed to prove causation by preponderant evidence. In reaching this decision, I have considered the record as a whole. However, I have not relied upon the matters set forth in the original decision on causation that Senior Judge Merow determined to be error. See Remand Order at 5-6.⁴

I. PROCEDURAL HISTORY

I set forth the procedural history of this case at some length in my original decision and will not repeat that history here. Petitioners filed a timely claim, the resolution of which was delayed for many years at their request.

II. STATUTORY BASIS FOR THE PETITION

During the course of the entitlement hearing, petitioners' counsel conceded that petitioners were proceeding only on an actual causation, or "off-Table" injury, claim. See Tr. At 58. Thus, petitioners must prove that the DPT vaccination administered to

⁴ To the extent that petitioners' testimony conflicted with the contemporaneous medical records, I find the medical records to be more reliable evidence of Enrique's then-existing or recent condition and symptoms, as opposed to testimony offered several years after the events in question. Special masters frequently accord more weight to contemporaneously recorded medical symptoms than those recounted in later medical histories, in affidavits, or in trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991). See also *Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by "clear, cogent, and consistent testimony" explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 U.S. Cl. Ct. LEXIS 510 at *8 (Fed. Cl. Spec. Mstr. Dec. 21, 1990). Although I have not relied upon those findings of Special Master Abell in reaching my decision in this case, I note that special masters often use what are called "onset" or "fact" hearings. In addition to determining when the first symptom or manifestation of onset of a medical condition began for purposes of deciding whether a claim was timely filed or meets the time frame for a "Table" injury, an onset hearing is used to resolve conflicts between affidavits and medical records (or between different sets of medical records) to provide the predicate facts upon which expert witnesses may base their opinions. Because petitioners initially alleged a Vaccine Table injury, determining what symptoms Enrique manifested and when he manifested them were perhaps as important as determining when his seizures began, as a seizure alone does not constitute a Table Injury.

Enrique on October 31, 1995, actually caused the seizure activity Enrique first displayed on November 1, 1995.⁵

III. FACTS

In this remand opinion, I incorporate the facts from Part III of my initial decision, excluding those drawn from Special Master Abell's "findings" at Onset Transcript ["On. Tr."]⁶ at 143-44 and those contained in Part III, C, pertaining to petitioners' credibility.

IV. EVIDENCE DEVELOPED AT THE REMAND HEARING

Doctors Trevor Resnick and Marcel Deray both testified at the remand hearing. Prior to the hearing, both were provided with copies of the medical records pertaining to Enrique's diagnosis and treatment, including Petitioners' Exhibits ["Pet. Ex."] 7, 12, 15, and 22 and Respondent's Exhibit ["Res. Ex."] A. Both physicians are still at Miami Children's Hospital ["MCH"] where Dr. Deray is a pediatric neurologist and sleep specialist and Dr. Resnick is the chair of the Department of Pediatric Neurology.

A. Testimony of Dr. Resnick.

It was clear from Dr. Resnick's testimony that he had carefully reviewed Enrique's medical records prior to testifying, particularly those that reflected his own observations and treatment.

Doctor Resnick was the admitting neurologist at the time of Enrique's first hospitalization in November 1995. R. Tr. at 40. He was the attending physician throughout this hospitalization. *Id.*; Res. Ex A, pp. 11-12. Additionally, he saw Enrique after his hospitalization, in December 1995, and again in May 1996. R. Tr. at 47, 49, 54; Pet. Ex. 7, p. 27.

During Enrique's hospitalization, Dr. Resnick wrote several notes on Enrique's chart concerning his observations. Specifically, on November 12, 1995, he wrote that Enrique had "no change in consciousness...normal neurodevelopmental exam. CT scan was normal." Res. Ex A, p. 13. He also noted several days later, on November 15, that Enrique had no further seizures once he was on a twice daily dose of phenobarbital. Res. Ex. A, p. 17; R. Tr. at 51-52. Neither fever nor excessive

⁵ The petition asserts that Enrique's first seizure occurred on November 3, 1995. Special Master Abell adopted the testimony of Enrique's great-grandfather, Mr. Gutierrez, in finding that onset of the seizure disorder occurred on November 1, 1995.

⁶ There are several transcripts in this case. The abbreviation "Tr." will refer to the transcript from the causation hearing. The abbreviation "On. Tr." will be used for the onset hearing transcript. The abbreviation "R. Tr." will be used for the transcript of the remand hearing.

sleepiness was noted during the hospitalization.⁷ The lack of these factors were cited by Dr. Resnick during his testimony as significant to his contemporaneous conclusion that the DPT vaccine did not cause the seizures. R. Tr. at 48-49, 65. He characterized Enrique's initial seizures as afebrile, and noted later in his testimony that there was no mention of fever in the histories provided. R. Tr. at 44, 62-64.

The imaging studies, including the SPECT scan and the MRI, did not suggest any cause for Enrique's seizures, although they did aid in pinpointing the location for his seizures. R. Tr. at 59-61.

Doctor Resnick also explained that the recommendation to withhold future pertussis vaccinations was partially based on the parents' concern that the pertussis vaccine had caused the seizures, but also that it was a standard recommendation made by some physicians at that time. R. Tr. at 46, 52-53. He was "just being conservative." R. Tr. at 53.

According to Dr. Resnick, seizures "in the absence of encephalopathy and other findings as I mentioned earlier" had not been linked to pertussis. R. Tr. at 53. He explained that a "provoked seizure" which could be caused by pertussis occurred in the context of a child who is sick, irritable, has a fever, and then has seizures. A provoked seizure is not connected with recurrent epilepsy. R. Tr. at 63. The history he received of Enrique's condition did not fit into the pattern of a provoked seizure. R. Tr. at 65-66. In essence, Dr. Resnick testified that at the time Enrique was hospitalized, he was looking for specific symptoms that would link the DPT vaccination to the seizures but that he did not find such evidence.

B. Testimony of Dr. Deray.

Doctor Deray was not one of Enrique's treating physicians at the time of his initial hospitalization. The first medical record reflecting his treatment of Enrique is dated November 22, 1996.⁸ As that record indicates a followup visit, it was possible that Dr. Deray saw Enrique before November 1996, but he was unable to say when that might have been. It was also possible that the prior visit was with another doctor. R. Tr. at 7. Doctor Deray is currently Enrique's treating specialist.

At the time of his testimony, he did not know whether Enrique's initial seizures were febrile or afebrile or whether they were focal or general. R. Tr. at 22. See also R.

⁷ Respondent's Exhibit A includes the nursing notes, which recorded Enrique's condition at frequent intervals throughout the hospitalization. With the exception of Enrique's seizure activity, those notes contain no evidence of encephalopathy, altered consciousness, or indifference to his environment. *Id.*, pp. 4, 8, 49-81.

⁸ He read a sleep study on August 8, 1996, (Pet. Ex. 7, p. 12), but Dr. Deray indicated that he did not examine Enrique at that time. R. Tr. at 5-6.

Tr. at 23-25. I thus conclude that he had not reviewed the medical records supplied to him before the remand hearing.

He did not recall whether he had reviewed the records of Enrique's initial hospitalization in 2001 when he wrote Pet. Ex. 22, the "To Whom It May Concern" letter. When asked what he had reviewed before drafting Pet. Ex. 22, he was uncertain, given the passage of time. R. Tr. at 26-28. He explained this letter was intended to state his opinion that the DPT vaccination caused Enrique's initial seizures. When asked why he did not explicitly say that in the letter, he responded that he "thought that was the best way to express" his opinion. He stated a belief that DPT could cause afebrile seizures and although he believed the medical literature supported this, he would have to research that matter. R. Tr. at 35-36.

In contrast to Dr. Tornatore's testimony, Dr. Deray did not find anything in the SPECT scan or MRI, performed during Enrique's November 1995 hospitalization, to be helpful in pinpointing a cause for Enrique's seizures. R. Tr. at 38.

Doctor Deray conveyed, in tone and demeanor, his antipathy at being called as a witness. The presence of Enrique and his parents at the remand hearing may have contributed to his discomfort or reluctance in testifying in this case.

C. Analysis of the Testimony.

Taken as a whole, Dr. Resnick's testimony supported Dr. Herskowitz's expert opinion and contradicted Dr. Tornatore's. Doctor Resnick agreed with Dr. Herskowitz that the medical literature and epidemiologic studies do not demonstrate an association between DPT and afebrile seizures. He testified that DPT is not associated with the symptoms Enrique displayed and the sequelae that he experienced. R. Tr. at 65-66. Doctor Resnick explained, as did Dr. Herskowitz, that the recommendation to withhold further pertussis vaccinations was a practice in accordance with a conservative approach. This comports with the medical literature indicating that pertussis vaccines can cause fever, which can provoke febrile seizures, giving a medical basis for withholding further pertussis vaccinations unrelated to causation of the initial afebrile seizures.⁹ Doctor Resnick's testimony effectively refutes Dr. Tornatore's conclusion that the recommendation to withhold further pertussis vaccinations meant Dr. Resnick believed the vaccine to be causal.

Doctor Resnick's note at Pet. Ex. 7, pp. 31-32, reflects the appropriate process

⁹ The decision in *Kelley v. Sec'y, HHS*, 68 Fed. Cl. 84 (2005), construing a "no pertussis instruction" as supporting a causation finding, thus has a factual predicate distinct from this case in that this treating physician explained the basis for his recommendation to withhold further pertussis vaccinations. I also note that the testimony of both Drs. Herskowitz and Resnick on this point is buttressed by the treatise, *VACCINES* ["VACCINES"], Chapter 14, p. 305, authored by S. Plotkin and W. Orenstein (filed as a court exhibit).

of differential diagnosis discussed in *Hocraffer v. Sec’y, HHS*, 63 Fed. Cl. 765, 777, n. 15 (2005). He considered the vaccine as a possible cause of Enrique’s seizures, but eliminated it based on the lack of fever or irritability. Doctor Deray, years later, may have included the vaccine in his differential diagnosis, but failed to eliminate it, based on his belief that medical literature supported pertussis causation of afebrile seizures. If such medical support exists, it was not filed as evidence in this case. The articles actually filed and the 1991 IOM report¹⁰ rejected such an association.

V. APPLICABLE LAW.

As the remand order stated that I had used the correct legal standard in my initial opinion, I adopt by reference Part V of that decision in this case. Remand Order at 11, n. 2 (“the successor special master correctly sets forth the applicable standards to be applied in resolving this issue”).

VI. APPLYING THE LAW TO THE FACTS.

The remand order reflected Senior Judge Merow’s conclusion that the evidence was sufficient to establish prongs one and three of the causation test established in *Althen*. Remand Order at 10. Therefore, I set forth my analysis of the evidence which leads me to conclude that petitioners have failed to demonstrate a logical sequence of cause and effect *Althen*’s second prong. Because I conclude that petitioners have failed to show a logical sequence between the theory and the injury, the burden never passes to respondent to establish an alternate cause. *Bradley v. Sec’y, HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed).

I base my conclusion that petitioners failed to meet their burden to show a logical sequence of cause and effect on: (A) conflicts between Enrique’s clinical presentation and Dr. Tornatore’s theory; (B) the weight of the medical research showing no connection between DPT and afebrile seizures; and (C) my assessment of witness credibility (without considering Dr. Tornatore’s testimony on the abandoned Table Injury claim). In accord with the Federal Circuit decision in *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), I have given great weight to Dr. Resnick’s assessment made at the time of Enrique’s initial hospitalization, that there was no connection between his seizures and the DPT vaccination. I have also placed considerable weight on the relative qualifications of the two testifying experts, concluding that Dr. Herskowitz’s training and experience as both a pediatrician and a pediatric neurologist enhance the reliability of his conclusions over those of Dr. Tornatore, an adult neurologist who rarely sees or treats children. Finally, I have considered the decisions of my colleagues in similar cases for guidance, while recognizing that their decisions do

¹⁰ A subsequent IOM report was published in 1994, but it came to the same conclusion regarding afebrile seizures and DPT.

not constitute binding precedent.

A. The Reliability of the Theories Advanced and their Relationship to the Clinical Presentation.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court charged trial judges to consider whether proffered testimony constitutes “scientific knowledge” such that it is “more than subjective belief or unsupported speculation”, and whether such testimony is consistent with the facts of the case, before admitting it. *Daubert*, 509 U.S. at 589-590. *Daubert* provides a useful framework for evaluating scientific evidence in Vaccine Act cases. *Terran v. Sec’y, HHS*, 41 Fed. Cl. 330, 336 (1998), *aff’d* 195 F.3d 1302, 1316 (Fed. Cir. 1999), *cert. denied*, *Terran v. Shalala*, 531 U.S. 812 (2000). See also *Ryman v. Sec’y, HHS*, 65 Fed. Cl. 35, 40 (special master performs gatekeeping function when he “determines whether expert testimony may be admitted or credited or otherwise relied upon”). In *Terran*, the Federal Circuit held that *Daubert*’s framework for determining admissibility could be applied by special masters in order to determine what, if any, weight to accord testimony of experts in Vaccine Act cases.

Doctor Tornatore’s opinions on causation in this case fail *Daubert*’s reliability requirement. They are contravened by the medical literature filed as evidence and are unsupported by Enrique’s clinical presentation.

Doctor Tornatore’s logical sequence of cause and effect is quite a large and precipitous leap. He jump from the “excitotoxic effect” of pertussis toxin when injected directly into solutions of animal brain cells to a causal connection between intramuscular injection into human infants and subsequent focal seizures.

Doctor Tornatore could not confirm that the pertussis toxin used in his references came from the formulations or strengths similar to those found in DPT vaccines, but he said it was “probably...pretty close” to the whole cell pertussis found in the DPT vaccine. Tr. at 95-96. He acknowledged that the researchers and the cited studies did not draw any specific conclusions about the role of pertussis vaccine and seizures or the effects of pertussis toxin on humans. Tr. at 98-99. In fact, none of the references he supplied involved research into seizure activity. He was not aware if any of the studies had been cited in other literature for the conclusion that DPT vaccine causes brain injury. Tr. at 102.

In vitro studies may be considered in Vaccine Act cases.¹¹ However, these

¹¹ *Kelley v. Sec’y, HHS*, 02-223V, 68 Fed. Cl. 84 at *91 (Fed. Cl. 2005) (“indirect evidence of factual causation may take the form of: epidemiology (evidencing a relative risk greater than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles, institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive, but inferential clinical

studies were so dissimilar to the administration of a vaccine to a human infant that they were of limited evidentiary weight. Extrapolation from the *in vitro* studies filed in this case requires significant evidentiary leaps. These studies do not even purport to demonstrate that direct administration of pertussis toxin to the brain of animals can cause seizures in those animals, much less that pertussis does so when given by injection into the thigh muscles of human infants. I note that courts have overwhelmingly found both *in vitro* and *in vivo* studies to be unreliable in the absence of testing on closely related species, comparable doses, and supporting epidemiologic studies. See, e.g., *Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997) and cases cited therein. Although *Raynor* involved testimony on teratogenicity rather than seizures, the same principles of scientific methodology are involved.

Doctor Tornatore testified that when nerves are sufficiently injured by chemical action, they may die or form scars. The scars are what cause ongoing seizure disorders. Tr. at 78. He theorized that in Enrique's case, a cytotoxic effect of the vaccination injured or killed some nerves which caused scarring in his brain. Tr. at 78-79. As support, he noted that the SPECT scan showed hypoperfusion in the left temporal area. This would be indicative of cell injury in that area. Tr. at 79. However, with regard to cell damage, he could not explain a toxin's affinity for a specific (or focal) region of the brain, rather than causing global insult.

In contrast, both Dr. Resnick and Dr. Deray testified that the SPECT scan offered no insight into causation. Doctor Herskowitz testified that Dr. Tornatore's theory (a toxin affecting Enrique's brain) did not account for Enrique's clinical presentation, particularly the lack of identifiable brain injury or atrophy. However, such a toxin would be highly unlikely to cause dysfunction in a small, localized area of the brain, rather than affecting the brain in general. Tr. at 218-19. A toxin affecting the brain would likely manifest with significant changes in mental status that would be inconsistent with Enrique's behavior during the time period of the first seizures. Tr. at 185-87. A metabolic insult would normally present with multifocal seizures. Because Enrique was on an EEG for a few days during this initial hospitalization, there is a record of how his brain was functioning, and that record contains no evidence of a serious or severe toxin affecting his brain. Tr. at 187. There was no evidence of dying brain cells, such as brain atrophy, a fall-off in head circumference, or a change in personality or behavior. Tr. at 184, 187-88.

and laboratory studies"). See also *General Electric Company, et. al. v. Robert K. Joiner Et Ux*, 522 U.S. 136 , 146 (1997) (with regard to animal studies informing expert opinions, "Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinions proffered." [citation omitted]). See also *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir.), *cert denied*, 506 U.S. 826 (1992) ("We do not mean to intimate that animal studies lack scientific merit or power when it comes to predicting outcomes in humans. Animal studies often comprise the backbone of evidence indicating biological hazards, and their legal value has been recognized by federal courts and agencies").

Doctor Herskowitz noted that the EEG taken during the initial hospitalization demonstrated a localized seizure discharge that was not correlated to observable seizure activity. This suggested a very subtle brain dysfunction. Tr. at 170-71.

According to Dr. Herskowitz, subsequent MRIs cast additional doubt upon Dr. Tornatore's hypothesis of pertussis injury to brain cells or their supporting cells. He explained that nerve cells are gray matter. Tr. at 181-182. Glia, which are among the supporting cells, make up the myelin that sheathes the nerves. *Id.* The later MRIs demonstrate that the myelination of Enrique's brain was age-appropriate, indicating that the supporting cells had not been damaged. *Id.*

Dead brain tissue results in fluid collection in the brain's ventricles. Because the MRIs never revealed any ventricular enlargement, there was no evidence to support there was death of brain matter. Tr. at 174-175, 181-82. Thus, there is no evidence for a serious multi-focal or global insult at the time of his first hospitalization for seizures. Tr. at 185-188.

In the final analysis, Dr. Tornatore's opinion is little more than "subjective belief or unsupported speculation...". *Daubert* at 590. Therefore, I adhere to my earlier conclusion that Enrique's clinical picture and test results are not consistent with a toxic insult to his brain.

B. DPT and Afebrile Seizures.

If petitioners are relying on the theory that Enrique's initial seizures were febrile, it is their burden to show fever as a condition precedent. They have not done so. While there was some speculation that Enrique may have had a slight fever at or around the time of his initial seizure activity, there was no evidence adduced that he did. Petitioners did not report or record any fever. Mr. Gutierrez did not mention any fever at the time he observed the initial seizure. During Enrique's initial hospitalization, Dr. Resnick noted that no fever was reported or present.

The testimony that DPT causes afebrile seizures was undermined, not only by the opinions of Dr. Resnick and Dr. Herskowitz, but also by the medical literature filed as evidence. Initially, Dr. Tornatore asserted that a medical journal article, filed as Pet. Ex. 27, supported his position that DPT vaccine was associated with afebrile seizures. Tr. at 111-15. The article actually compared the incidence of febrile seizures associated with DPT vaccine versus the rate of febrile seizures associated with the DTaP vaccine.¹² When questioned more closely on this assertion, he admitted that the article appeared to be comparing the incidence of febrile, rather than afebrile, seizures between the two

¹² DTaP vaccine contains the same diphtheria and tetanus toxins as the DPT vaccine. The difference between the two vaccines is that the more recent DTaP vaccine contains acellular pertussis as opposed to whole-cell pertussis. VACCINES at 311.

vaccines. Tr. at 115. Doctor Tornatore was unable to cite to any other article that supported an association between DPT vaccine and afebrile seizures. Petitioners' counsel was invited to file representative articles in support of the proposition that DPT vaccine causes afebrile seizures (Tr. at 116-17; 229).¹³ None were filed.

The weight of the evidence is that DPT does not cause afebrile seizures. The New England Journal of Medicine article, filed as Res. Ex. F¹⁴, illustrated this point. The article described a study of over half a million children that found no increased risk of afebrile seizures after vaccination with DPT. It found an increased risk of febrile seizures only on the day of vaccination. The article also referred to earlier studies that had likewise failed to find any increased risk of afebrile seizures. Tr. at 189; Res. Ex. F, pp. 656, 659.

A second article, filed as Res. Ex. E¹⁵, was a 1994 population-based case-control study.¹⁶ The study matched confirmed cases of neurological illness during a 12-month period with two other children with similar birth dates, gender, and birth location. Immunization records were used to determine whether the illness occurred within one week of DPT vaccination. Febrile seizures, afebrile seizures, infantile spasms, and acute encephalopathies were all examined. While the study was not designed to provide a definitive answer regarding causality of the pertussis component of the DPT vaccination and neurological illness, its findings were consistent with other studies that had found no association between afebrile seizures and DPT vaccination. Res. Ex. E, pp. 37, 39, 41; Tr. at 190.

¹³ Petitioners' counsel asserted that the issue of DPT vaccine causing afebrile seizures had "been debated for years" and was one of the reasons the Vaccine Act existed. Tr. at 116. I noted that I had not found any references supporting an association between DPT vaccine and afebrile seizures. Tr. at 117. I invited petitioners to file such references. The only arguably responsive filing was Pet. Ex. 34, an excerpt from a textbook on child neurology. The excerpted section is entitled "Encephalopathy after Pertussis Vaccination." It does not include the footnotes/endnotes containing the articles referenced. The exhibit refers to "afebrile seizures, which are generalized" within 72 hours of vaccination. Pet. Ex. 34, p. 3. As Enrique did not have either generalized seizures or an encephalopathy after his DPT vaccination, I placed little weight on this excerpt. Doctor Deray also mentioned, without citing specifically to, medical literature supporting DPT causation of afebrile seizures. R. Tr. at 38. Doctor Resnick echoed Dr. Herskowitz's testimony that DPT does not cause afebrile seizures. Tr. at 188-189 and R. Tr. at 63.

¹⁴ William E. Barlow, *et al.*, "The Risk of Seizures after Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine," *N. ENGL. J. MED.*, Vol. 345, No. 9 (Aug. 30, 2001).

¹⁵ James L. Gale, *et al.*, "Risk of Serious Acute Neurological Illness after Immunization with Diphtheria-Tetanus-Pertussis Vaccine: A Population-Based Case-Control Study," *Journal of the American Medical Association*, Vol. 271, No. 1, pp. 37-41, sometimes referred to as "SONIC" ["Study of Neurological Illness in Children"] (1994).

¹⁶ A case control study compares a group of individuals with a particular disease or condition to another group of similar individuals without the disease or condition. Federal Judicial Center, *REFERENCE MANUAL ON SCIENTIFIC EVIDENCE*, (2d ed. 2000), p. 342.

Doctor Tornatore's theory of injury was outweighed by the numerous medical studies that failed to find a relationship between afebrile seizures and DPT vaccination, supporting the opinion of Dr. Herskowitz and his critique of Dr. Tornatore's connection between vaccine and injury.

C. Credibility and Relative Qualifications of the Experts.

Having heard and seen all four medical doctors (two treating physicians and two expert witnesses), I find the testimony of Drs. Resnick and Herskowitz to be more credible and reliable than that of Drs. Deray and Tornatore.

Doctor Resnick clearly spent a considerable amount of time reviewing the medical records from his involvement in Enrique's care and treatment over 12 years. He was equally candid, careful, and deliberate in his testimony regarding what he saw and did, and why he wrote what he did in the medical records. This attention to detail and position as Enrique's treating physician at the time of the initial seizure activity lead me to credit Dr. Resnick's opinion against causation over Dr. Tornatore's hypothesis to the opposite. *Holbrook v. Lykes Bros. - Co.*, 80 F.3d 777 (3d Cir. 1995) (treating doctor's testimony given greater weight than those who had not examined petitioner). As he is no longer treating Enrique and has no history of testifying in the Vaccine Program that I could discover, he cannot be said to favor one side or another.

In contrast, Dr. Deray conveyed his reluctance to testify in both body language and tone.¹⁷ He was unfamiliar with the records. He was uncertain what he had relied upon in writing Pet. Ex. 22. R. Tr. at 21-27. Although he testified that he believed the vaccine had caused Enrique's seizures, he first wrote two more ambiguous statements in the medical records, one in November 1998 (Pet. Ex. 15, p. 40), and one in December 2001 (Pet. Ex. 22). R. Tr. at 28. In neither document did he state that the vaccine was the probable cause of the seizures, in spite of his testimony that this is what he meant. This lack of consistency causes me some concern.

Doctor Deray gave three reasons for his opinion: the temporal connection, the lack of any other identified cause, and medical literature. A temporal connection, standing alone, is insufficient to demonstrate causation. See *Fricano v. U.S.*, 22 Cl. Ct. 796, 800 (1991). A vaccination is not the cause of every ill that follows it. *Hasler v. U.S.*, 718 F.2d 202, 205 (6th Cir. 1993), *cert. denied*, 469 U.S. 817 (1994). Many causes

¹⁷ Some of what I perceived as Dr. Deray's reluctance may have been related to the presence of Mr. and Mrs. Andreu and Enrique at the remand hearing. Doctor Deray continues to treat Enrique. Doctor Resnick testified that Enrique's treatment was probably transferred to Dr. Deray, because Dr. Deray is a sleep specialist and Enrique suffers from apnea. R. Tr. at 58.

for seizures can be identified, but frequently a cause cannot be identified.¹⁸ Additionally, the medical literature filed was not supportive of his opinion.

Although Dr. Deray testified as a “treating doctor,” he was not treating Enrique at the time the seizure disorder initially began, and thus his opinion is not informed by observations of Enrique at the critical period. He did not have the same opportunity to observe Enrique and search for a cause that Dr. Resnick had as the attending physician.

As Senior Judge Merow noted, both Drs. Tornatore and Herskowitz have testified many times in Vaccine Act cases, with Dr. Tornatore always testifying on behalf of petitioners and Dr. Herskowitz always testifying on behalf of respondent. An expert witness always associated with only one side in a particular type of litigation has some inherent credibility issues. In a recent Vaccine Act case, Chief Special Master Golkiewicz cited the testimony of a witness who helps attorneys locate expert witnesses. That witness indicated that he would not recommend employment of an expert who appears on behalf of only plaintiffs or only defendants because of these credibility concerns. *Simon v. Sec’y, HHS*, 05-941V, 2008 U.S. Claims LEXIS 67, *8-9 (Fed.CL. Spec. Mstr. Feb. 21, 2008).

As both of the testifying experts have this same credibility problem, I evaluated their testimony on other objective criteria, as well as my subjective assessments of their demeanor, tone, approach to questions, and quality and comprehensiveness of their answers. Objectively, I considered the extent to which their opinions were buttressed or undercut by the medical literature filed into the record of this cases, and whether their opinions fit the facts of the case. I also considered the relative qualifications of the two expert witnesses in determining how to resolve the conflict between their opinions on causation.

In summary, Dr. Tornatore has excellent qualifications, particularly in the field of multiple sclerosis treatment. However, he is an adult, not a pediatric, neurologist. He does not routinely see children with seizure disorders, and has not done so since his residency. His areas of research and publication are not focused on pediatric neurology. He is not board certified in pediatric neurology.

In contrast, Dr. Herskowitz is board certified in pediatrics and in pediatric neurology. Tr. at 165. While he currently refers his seizure patients to other physicians, he had an active clinical pediatric neurology practice, including seizure patients, in the past. Tr. at 165-166. His academic training and clinical experience make his opinions on the issue of the diagnosis and treatment of infants and children with seizures generally more reliable than those of a physician without his background, training, and

¹⁸ Respondent’s Exhibit A, p. 89, a patient handout given with Enrique’s discharge instructions, indicates that a cause is not identified in over 50% of seizure cases. Doctor Deray testified that a cause is identified in about 75% of cases.

experience.

I also note that Dr. Herskowitz was much more conversant with the medical research into the relationship between DPT vaccine and seizure disorders. His testimony was well-grounded in the objective medical records, was supported by medical literature, and was in accord with the weight of scientific opinion on the lack of connection between DPT vaccination and afebrile seizures. The general acceptance of a theory within the scientific community may affect an assessment of the theory's reliability. *Daubert*, 509 U.S. at 594.

In contrast, Dr. Tornatore misread evidence (Pet. Ex. 27), overstated the risk of CNS complications from whooping cough (pertussis) "wild-type" infections, and cited studies in neurotoxicity of pertussis toxin as support for his medical theory, when the authors of those studies drew no conclusions regarding the role of pertussis toxin in causing seizures.

Although petitioners advanced an hypothesis regarding vaccine causation as the source of Enrique's injury that was theoretically possible, it was not persuasive. The postulated "excitotoxic" effect of pertussis vaccine on the brain did not square with the other evidence in this case. The clear failure in petitioners' case was their inability to draw the logical connection, required by *Althen*, between the postulated mechanism of injury and the clinical evidence in this case.

Whatever theoretical allure the excitotoxin theory regarding the cause of seizures may have, the weight of the scientific and clinical evidence adduced here does not support pertussis toxin as the cause of Enrique's afebrile seizures.

D. Decisions in Similar Vaccine Act Cases.

The decisions of the Court of Appeals for the Federal Circuit are binding on special masters. *Guillory v. Sec'y, HHS*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, *Guillory v. Sec'y, HHS*, 104 Fed. Appx. 712 (Fed. Cir. 2004). Decisions issued by special masters and judges of the Court of Federal Claims constitute persuasive, but not binding, authority. *Hanlon v. Sec'y, HHS*, 40 Fed. Cl. 625, 630 (1998). Differences in the medical presentation of the injured individual, as well as differences in the expert opinions and other evidence, sometimes lead to what may appear to be anomalous results when the various special masters consider cases involving the same vaccines and similar injuries. Medical science continues to evolve, and evidence sufficient for causation in one case might be superseded by additional research and evidence in a subsequent case.

I emphasize that I have decided this case based upon the evidence presented to me, including the court exhibits and those articles filed by petitioners in response thereto. However, I note that, prior to the replacement of the DPT vaccine Enrique received with the acellular DTaP, numerous cases alleging seizure injuries were filed in

the Vaccine Program. Virtually every special master who has heard and considered a claim that DPT vaccine caused afebrile seizures has ruled against causation. See, e.g., *Borin v. Sec’y, HHS*, No. 99-491V, 2003 U.S. Claims LEXIS 159 (Fed. Cl. Spec. Mstr. May 29, 2008) (focal seizure without fever, irritability, or a decrease in oral feeding does not establish entitlement to compensation, citing to the National Childhood Encephalopathy Study [“NCES”]); *Grady v. Sec’y, HHS*, No. 95-0173V, 2000 U.S. Claims LEXIS 247, (Fed. Cl. Spec. Mstr. Nov. 16, 2000) (case decided without hearing on the basis that DPT causation for afebrile seizures could not be established); *Salmond v. Sec’y, HHS*, No. 91-123V, 1999 U.S. Claims LEXIS 230, (Fed. Cl. Spec. Mstr. Sept. 16, 1999) (relying on the Institute of Medicine’s [“IOM”] 1991 report and other similar cases, the special master concluded that the evidence was insufficient to support DPT causation of afebrile seizures); and *Castillo v. Sec’y, HHS*, No. 95-0652V, 1999 U.S. Claims LEXIS 197 (Fed. Cl. Spec. Mstr. July 19, 1999).¹⁹

In my initial decision, I discussed the thoughtful and well-reasoned opinions of two of my colleagues on the relationship between DPT vaccination and seizure disorders. In *Liable v. Sec’y, HHS*, No. 98-120V, 2000 U.S. Claims LEXIS 209 at *15 (Fed. Cl. Spec. Mstr. Sept. 7, 2000) and *Moberly v. Sec’y, HHS*, No. 98-0910V, 2005 U.S. Claims LEXIS 220 (Fed. Cl. Spec. Mstr. June 30, 2005), Special Masters Hastings and Edwards, respectively, engaged in a comprehensive review of the medical literature concerning DPT vaccine and neurologic injuries. I adhere to my earlier analysis. Enrique did not have a serious acute neurologic illness in the month following his vaccination. His focal seizures within 24 hours of his vaccination, followed by repeated focal seizures in the next two weeks, would not have qualified him as an NCES case child.

The 1991 IOM Report rejected a causal relationship between the DPT vaccine and afebrile seizures. While the review committee focused on the NCES, it also specifically considered the relationship between the DPT vaccine and different types of seizures, including febrile and afebrile seizures. The committee concluded that “the available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccinations” and, consequently, “the evidence does not indicate a causal relation between DPT vaccine and afebrile seizures.” The IOM relied on the results of a meta-analysis performed controlled studies which considered cases of afebrile seizures. IOM Report, pp. 115, 118.

VI. CONCLUSION

¹⁹ In one case, *Almeida v. Sec’y, HHS*, No. 96-412V, 1999 U.S. Claims LEXIS 294 (Fed. Cl. Spec. Mstr. December 20, 1999), Special Master French found that an afebrile seizure of 45 minutes duration was caused by the DPT vaccination. Special Master French relied upon the NCES for her decision, noting that the seizure duration would have qualified the petitioner as an NCES “case child.” However, brief focal seizures of the type Enrique initially experienced would not have qualified him as an NCES “case child.” As I indicated in my initial opinion, petitioners did not argue the NCES supported causation in this case, likely for this very reason.

Petitioners must present adequate evidence of each of *Althen's* three causation factors. 418 F.3d at 1278. I conclude that they have failed to demonstrate the logical connection between vaccine and injury in this case, and thus adhere to my initial opinion that the petition for compensation must be denied.

In the absence of a timely-filed motion for review filed pursuant to Appendix B of the Rules of the U.S. Court of Federal Claims, the clerk of the court shall enter judgment in accordance herewith.²⁰

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell
Special Master

²⁰ Entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review. See Vaccine Rule 11(a).