OFFICE OF SPECIAL MASTERS

No. 97-125V

Filed: May 28, 1999

(Reissued for Publication June 22, 1999)[(1)]

ELIZABETH CORDER, as Legal Representative of DILLON N. CORDER, a minor,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew W. Dodd, Torrance, California, for petitioner.

Glenn A. MacLeod, Washington, D.C., for respondent.

ENTITLEMENT DECISION

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("the Act")[(2)] on February 27, 1997 on behalf of her son, Dillon N. Corder. Petitioner alleges that Dillon suffered an "encephalopathy, a residual seizure disorder, a shock collapse, a hyporesponsive/hypotensive event and Acute Disseminated Encephalomyelitis" as a result of DPT and OPV vaccinations administered

on December 15, 1994. Petition at 2-3.

Respondent filed her Report pursuant to Vaccine Rule 4 on May 28, 1997, contesting petitioner's right to compensation. Respondent challenged the sufficiency of evidence on two counts: first, that petitioner did not establish a Table injury (stating that "[r]esidual seizure disorder is not a Table injury for DTP or OPV vaccine") and that "there is no evidence that Dillon suffered an acute encephalopathy or ADEM in association with his December 15, 1994 vaccinations." Respondent's Report at 1-2. Petitioner did not include a medical opinion at the time the petition was filed.

Thereafter, petitioner filed expert reports on August 11, 1997 (Dr. Uchiyama), February 27, 1998 (Dr. Arrieta), and June 17, 1998 (supplemental report from Dr. Arrieta and report from Dr. Prentice). Respondent filed expert reports on August 21, 1997 (Dr. Wientzen) and March 18, 1998 (Dr. Sriram).

The court conducted an evidentiary hearing in Orange County, California on September 30, 1998 to resolve the causation issues presented. The court took testimony from the parties' respective medical experts, Drs. Prentice and Arrieta for petitioner and Drs. Wientzen and Sriram for respondent. Petitioner filed an article by respondent's expert, Dr. Sriram, on October 6, 1998. Petitioner filed Submission of Additional, New Authority on December 11, 1998.

On March 8, 1999, the Federal Circuit issued a decision in Shyface v. Secretary of HHS, -- F.3d --, setting forth a "substantial factor" test for determining whether a vaccine is the legal cause of petitioner's harm. My office contacted the parties on February 23, 1999 and asked whether they wanted to file briefs addressing the possible application of the Federal Circuit's decision in Shyface to the case at hand. Petitioner's counsel expressed an interest in addressing the applicability of Shyface to this case. Petitioner filed her brief on February 26, 1999, and respondent filed her responsive brief on March 26, 1999. After considering the parties' briefs, the court finds that Shyface had no impact on the outcome of this case. See note 12, infra.

BACKGROUND FACTS

The facts in this case are not in dispute. The experts relied upon the medical records for the foundation of their opinions. Dillon Corder was born on August 10, 1994 by repeat cesarean section. P. Ex. 1. He was seen for well baby care and immunizations at the Bristol Park Medical Group. P. Ex. 6. On November 3, 1994, Dillon was diagnosed by Dr. Greenspan with "viral cold syndrome." Id. at 351-356. On December 15, 1994, Dillon received DTP and OPV immunizations. P. Ex. 6 at 50. On December 16, 1994, petitioner reported to Dillon's pediatrician that Dillon was irritable and had a low temperature following his immunization. Petition at 2. On January 3, 1995, Dillon was taken to the Emergency Room at Samaritan Medical Center for "left arm shaking, fever, glassy eyed appearance, . . . intermittent irritability and decreased activity." P. Ex. 5 at 167. He was transferred and admitted to Mission Hospital

Regional Center, where he was diagnosed as having acute disseminated encephalomyelitis ("ADEM"). P. Ex. 5 at 321. During the night of January 3, 1995, Dillon experienced multiple seizures and went on to have a well-expressed, obvious seizure disorder. P. Ex. 5 at 169. On January 27, 1995, Dillon's pediatrician filed a VAERS (Vaccine Adverse Event Reporting System) Report with the Food and Drug Administration. P. Ex. 6 at 372.

II. ISSUES

A. Did Dillon suffer a Table[(3)] injury?

After considering the entire record, and for the reasons discussed below, the court finds that petitioner has not demonstrated that Dillon suffered a Table injury as a result of the DTP vaccination administered to him on December 15, 1994.

B. If Dillon did not suffer a Table injury, was the vaccination the cause of his injury?

1) ***Can*** the DTP[(4)] vaccination cause ADEM?

2) If the DTP vaccination can cause ADEM, did the DPT vaccination result in ADEM ***in this case***?

After considering the entire record, and for the reasons discussed below, the court finds that petitioner has not demonstrated that Dillon's December 15, 1994 DTP vaccination caused his ADEM.

III. PETITIONER'S MEDICAL EXPERTS

Dr. Uchiyama

Petitioner submitted a report by Dr. Naomi Uchiyama in support of her position.[(5)] Dr. Uchiyama provided a one paragraph letter, in which she opined that Dillon's ADEM "was more likely than not to

have been the result of immunization given to him on 12/15/94." However, Dr. Uchiyama's report contained no support for her opinion other than a statement that "ICD 9CM coding of 323.5 refers to encephalomyelitis post immunization or post vaccine." P. Ex. 25. Dr. Uchiyama did not testify at the hearing; thus, her opinion was unhelpful.

Dr. Prentice

In support of her case, petitioner presented the report and testimony of Dr. Georgia Prentice, Dillon's treating pediatric neurologist.(6) Dr. Prentice was asked to consult on Dillon when he was admitted to Mission Community Hospital. P. Ex. 29. She opined that Dillon's ADEM was caused by his DPT vaccination. Dr. Prentice proved an unconvincing witness, providing little or no basis or support for her opinions.

When asked, repeatedly, by respondent's counsel to provide support for her opinion, she could not:

Q [MacLeod]: Have there been any controlled observational studies of laboratory animals involving the association between DPT vaccination and ADEM?

A [Dr. Prentice]: I'm sure that there have.

Q: Do you know of any?

A: No.

Transcript at 42.

Q [MacLeod]: Can you point to anything else other than the fact that he got a DPT shot and he had ADEM that lead [sic] you to conclude that it's most likely DPT as opposed to idiopathic, other than the fact he had [a] DPT [shot]? Is there anything in his clinical presentation which says, "Oh, this is most likely --"

A: No. There's no way that you can have a clinical presentation that says one way or the other unless you have an exanthem from say, chicken pox.

Transcript at 55-56.

The court then attempted to elicit support from Dr. Prentice, without success:

THE COURT: [W]hy then would you tip the scales in this particular case in favor of the vaccination as opposed to the virus? Is there a factor, or is there something that you saw in the presentation in this case that leads you to believe that it's the vaccination over the virus?

THE WITNESS: Just in that I have, on doing the research, it seems to me like it's a very, very good possibility [that the vaccine caused the injury], greater than 50 percent.

* * *

THE COURT: And what I'm not hearing is, on what basis are you applying one as opposed to the other? What is it that you point to in this case, that when you apply that literature, you say it's the vaccination not the virus?

THE WITNESS: [I]t just seemed like it was more likely [that the vaccination caused the injury] than that it was just [caused by] a cold.

* * *

THE COURT: [B]ut in concluding, there's nothing that you can point to in this case, a factor that's in this record that points to the vaccination, as opposed to the virus?

THE WITNESS: There's not anything scientifically that we can say the value of this is whatever, that says that it has to be that.

* * *

THE WITNESS: There's been a controversy all along as to whether or not the vaccination causes the problem. How are we supposed to prove it?

THE COURT: Well, that's what I'm asking you. That's why we're here.

THE WITNESS: Well, in other words, there is no way that we can ever prove that it was the vaccination.

Transcript at 63-66.

In short, although Dr. Prentice was passionate in her belief that Dillon's injuries were caused by his DPT vaccination, she provided the court with almost no medical or scientific support for her opinion. Dr. Prentice, when asked by respondent to support her opinion, would answer that she "was sure" there were studies or incident rates to support her opinion, yet she could not provide any cites to any of these studies or rates. See Transcript at 42, 43. When asked by the court, several times, whether she could point to medical literature supporting her opinion, Dr. Prentice could not. On balance, the court found Dr. Prentice's testimony to be unhelpful.

Dr. Arrieta

Petitioner also provided the report and testimony of Dr. Antonio Arrieta, a pediatric infectious disease specialist.[(7)] Dr. Arrieta appeared very knowledgeable and convincing at the hearing. He, too, however, was unable to provide persuasive support for causally linking the DPT shot to the onset of Dillon's ADEM.

Dr. Arrieta's opinion appeared to be primarily based on the time-relatedness of the vaccine to the injury. Dr. Arrieta testified that "if I would have to be put in that position in which this child had not received vaccination in the recent past before this incident [the onset of ADEM], I would have to say this was an idiopathic case[.]" Transcript at 85. This point was driven home a few questions later:

Q [Dodd]: Doctor, let's talk about the scientific link between vaccination and ADEM. How does this occur?

A: I don't think it's scientific. I think it is the most far away you can go from science. I think it is correlative stories that basically say patient x, was exposed to this and had this event. So, ***it's basically a time-related function***[.]"

Transcript at 88 (emphasis added).

In responding to respondent's counsel's questions asking the doctor what led him to conclude that Dillon's injury was vaccine-induced, the doctor answered:

I think the ***only thing*** that conduces me to believe this, is the fact that the child was presented with antigenic assimilation ***within a period of time that would be reasonable*** for him to have developed the antibodies that promoted the degeneration and developed the appropriate antibodies against the myelin.

Transcript at 92 (emphasis added). Mr. MacLeod continued this line of questioning a little later in his cross-examination, evoking a similar response:

Q: How do you know it's more likely than not the DPT shot, as opposed to a viral antigen then, Doctor?

A: The timeframe.

Transcript at 101.

Dr. Arrieta's opinion that the vaccination caused Dillon's injury was also one of exclusion, having been unable to pinpoint another cause: "I have reached the conclusion, reluctantly, to say that I ***could not rule out*** the vaccine involvement. And ***in the absence of any other event***, I would have to say that most likely than not, that this was related to an antigen preceding that vaccine." Transcript at 88 (emphasis added). Dr. Arrieta also testified that respondent's theory, that Dillon's ADEM was caused by a viral infection not caused by the vaccination, was possible. Transcript at 99.

IV. RESPONDENT'S MEDICAL EXPERTS

Dr. Wientzen

Respondent provided the report and testimony of Dr. Raoul Wientzen in support of her position.[(8)] Dr. Wientzen's testimony was based on his review of Dillon's medical records and the medical literature supplied by the parties. Dr. Wientzen testified that he did not believe Dillon's DPT vaccination caused his ADEM. Transcript at 136.

Dr. Wientzen testified that his opinion was based on: 1) his belief that the medical community does not yet accept a causal relationship between DPT vaccination and ADEM, and 2) biostatistics. Transcript at 136.

In his expert report, Dr. Wientzen stated his opinion that "ADEM is not a known complication of DTP or OPV vaccination." R. Ex. B. Dr. Wientzen further stated that "it is inconceiveable [sic] to me that a relationship between DTP and OPV vaccination and ADEM could have gone undescribed during the last ten years when these vaccines have been the subject of such intense scrutiny, and MRI a readily available tool to study cases of ADEM." Id.

Dr. Wientzen addressed the temporal relationship between the vaccination and Dillon's diagnosis of ADEM:

Q [MacLeod]: If you assume that DPT can cause ADEM and we move on to the next phase which is, you know, did it cause the ADEM in this case, what is there that we can point to that would lead one to believe it was the DPT immunization?

A: Well, I think the only thing that would be consistent with ADEM and DPT being linked is the time sequence here.

* * *

Q: Other than the temporal relationship between the onset of ADEM and the DPT shot is there [anything] in Dillon's clinical presentation that would implicate his immunization?

A: I see nothing besides the temporal sequence that would implicate DPT and his ADEM.

Transcript at 145.

Dr. Wientzen testified that he believed Dillon's ADEM was most likely caused by a preceding viral illness. Transcript at 138. Dr. Wientzen based this belief in part on the fact that most cases of ADEM are linked to a preceding viral illness, 80 percent according to an article submitted by petitioner.[(9)] According to the medical records, Dillon's mother had cold sores in the weeks preceding his illness; additionally, his sister had a cold and his father had a stomach flu around the time Dillon was diagnosed with ADEM. P. Ex. 5 at 169, 172, 316; P Ex. 9 at 206, 448. Dillon's mother adamantly contested the information in the medical records that Dillon's father had a stomach virus and that his sister had a fever. Transcript at 128-130. Dr. Wientzen testified that just looking at the medical records, he believed that Dillon's white count at the time of his hospitalization and subsequent diagnosis of ADEM was indicative of a viral infection preceding Dillon's illness. Transcript at 139.

Dr. Wientzen agreed with Dr. Arrieta that if DPT could cause ADEM, the only link in this case between Dillon's DPT vaccination and his injury would be the time frame. Transcript at 145. Additionally, Dr. Wientzen expressed his opinion that if there were enough case reports linking DT to ADEM, a large study would have been done. Dr. Wientzen testified that, instead, there is a noticeable absence of information linking vaccinations and ADEM.[(10)]

Dr. Sriram

Respondent also presented the testimony of Dr. Subramaniam Sriram at the hearing.[(11)] In his report, Dr. Sriram stated that none of the vaccines Dillon received "are known to cause CNS demyelinating disease." Respondent Ex. D. Dr. Sriram reiterated Dr. Weinzten's point that "all we have here is a temporal association." Transcript at 167. Dr. Sriram also addressed the fact that although multiple tests were performed to discover a possible viral origin for Dillon's ADEM, none were found. While Dr. Arrieta concluded that Dillon's ADEM did not have a viral origin because no viruses were isolated through testing, Dr. Sriram stated that "when the individual develops the autoimmune response to the virus, it is often difficult to find the virus. It's often done and -- gone and over with." Id. at 172. In other words, a viral origin for ADEM is often not isolated because the virus is out of the system before a diagnosis of ADEM is made. In addition, the lack of studies concerning a possible connection between the DTP vaccine and ADEM also poses a concern. According to Dr. Sriram, there are currently no tests that can be performed "to show a direct immunological correlation . . . between DPT and ADEM." Id. at 176.

V. STATUTORY REQUIREMENTS

A petitioner may establish causation in Vaccine Act cases in one of two ways: either through the statutorily prescribed presumption of causation (a "Table" injury) or by proving that the vaccine was the cause-in-fact of the injury. A petitioner must prove one or the other in order to recover under the Act.[(12)] The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed period of time, create a rebuttable presumption that the vaccine caused the injury or condition.[(13)] To overcome this presumption, respondent must show that a factor unrelated to the vaccine was the actual cause of the injury. 13(a)(1)(B). If a petitioner's evidence cannot support the finding of a Table injury, petitioner may still be entitled to compensation if petitioner provides sufficient proof that the vaccination was the cause-in-fact of the injury.

In order to establish entitlement to compensation in a causation-in-fact case, a petitioner must

demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the alleged injury.[14] This requires petitioner to prove that the vaccine was not only a but-for cause but also a substantial factor in bringing about the injury. See Shyface v. Secretary of HHS, 165 F.3d 1344, 1999 WL 11564, at *9-10 (Fed. Cir. 1999).[15] The Federal Circuit in Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992), summarized the legal criteria required: "Causation-in-fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Id. at 1148 (citations omitted).[16]

DISCUSSION

A. Table Issue

The petition alleged that Dillon suffered an "encephalopathy, a residual seizure disorder, a shock collapse, a hyporesponsive/hypotensive event and Acute Disseminated Encephalomyelitis" as a result administration of DPT and OPV vaccinations administered on December 15, 1994. Petition at 2-3. Although the medical records filed with the petition indicate that Dillon's mother reported to his physician that Dillon experienced a low grade fever and irritability for one day following his vaccination,[17] this alone is insufficient to support petitioner's allegation that Dillon suffered a Table injury. Petitioner provided no evidence that Dillon suffered an acute encephalopathy within seventy-two (72) hours of the immunization, as required by the revised Vaccine Injury Table. Further "hyporesponsive/hypotensive event," "shock collapse," and "residual seizure disorder" are not Table injuries for the DTP or OPV vaccines.[18] Thus, petitioner's claim fails

to qualify for compensation as a Table injury.

B. Causation-in-Fact Issue

Dillon suffers from acute disseminated encephalomyelitis ("ADEM"), and petitioner claims the DTP vaccination caused this injury. Because ADEM is not a Table Injury, petitioner must show "a medical theory causally connecting the immunization to the injury. There must be a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). The parties relied on the reports and testimony submitted by their experts in this case.

1. *Can* the DTP vaccination cause ADEM?

Petitioner's experts failed to provide sufficient evidence linking the DTP vaccination as a cause of ADEM. Dillon's treating physician, Dr. Uchiyama, submitted a report, in which she referred to "ICD 9CM coding of 323.5." This code simply refers to "post-immunizat[ion] encephalit[is.]" R. Ex. E. Dr. Uchiyama neither elaborated on this code nor did she state why she cited this as support for her theory that Dillon's DTP vaccination caused his ADEM.

Petitioner also presented the testimony of Dr. Georgia Prentice in support of her position. As previously stated, the court found Dr. Prentice an unconvincing witness who was unable to provide any support for her position.

In contrast, the court found petitioner's third expert, Dr. Arrieta, a very knowledgeable and convincing witness. In his testimony, Dr. Arrieta admitted that there is scant evidence connecting the DTP vaccine and acute neurologic disorders. See Transcript at 88. Dr. Arrieta did refer to published studies, albeit very few, discussing a possible correlation between DTP vaccine and ADEM. Dr. Arrieta referred to the Mancini Article, P. Ex. 27 at 20, as support for his position. The article, entitled *Relapsing Acute Encephalopathy: a Complication of Diphtheria-Tetanus-Poliomyelitis Immunization in a Young Boy*, concluded that "relapsing acute encephalitis . . . may occur as a very rare complication of diphtheria-tetanus-poliomyelitis vaccination." Id.

Respondent argued that the article addressed DT and poliomyelitis, whereas Dr. Arrieta claimed the pertussis component of a DTP vaccination was the most likely cause of Dillon's ADEM. Transcript at 114-118. Dr. Arrieta, upon questioning from the court, stated that his focus on the pertussis component of the vaccine was "probably unnecessary" and that instead of zeroing in on that component, the court should just be looking at the DPT vaccination itself. Id. at 117-18. In addition, the court pointed out that the Institute of Medicine (IOM) does in fact support the plausibility "that

injection of an inactivated virus, bacterium, or live attenuated virus might induce an autoimmune response in the susceptible host." R. Ex. G at 84. The same report also indicates that there have been case reports where "ADEM in association with tetanus toxoid have been described." Id. at 83. Additionally, another article submitted by respondent stated that "the diagnosis of PIE or postvaccinal encephalomyelitis should be considered when neurologic signs develop **4 to 21** days following . . . vaccination." R. Ex. Q at 163 (emphasis added). In this article, the term "postvaccinal encephalomyelitis" is used when describing acute disseminated encephalomyelitis. See id. at 161. Based upon these conclusions, the court finds that it is possible that DPT vaccination ***can*** cause ADEM. However, it remains for petitioners to prove that the DPT was the cause in this case of Dillon's ADEM. Petitioners failed in this proof.

2. Assuming the DTP vaccination *can* cause ADEM, did the DTP vaccination result in ADEM *in this case*?

Upon questioning by both petitioner's counsel and respondent's counsel, Dr. Arrieta admitted that his

opinion was based primarily on the time relation between Dillon's vaccination and the onset of his ADEM. See supra pp. 5- 6. As previously stated, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. Section 11(c)(1)(C)(ii)(I) and (II). A petitioner does not meet this affirmative obligation by merely showing a temporal association with the vaccination, see Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation"). Dr. Arrieta also based his opinion on the "absence of any other event." Transcript at 99. Like temporal relationships, a petitioner does not meet her obligation by simply eliminating other potential causes of the injury. Grant v. Secretary of HHS, 956 F.2d 1144, 1149-50 (Fed. Cir. 1992).

Dr. Arrieta also stated that he relied on the Mancini article[(19)] for support of his position. This one article, however, did not causally connect the vaccination with the injury. At most, the article discusses a case report lending support to a possible connection between ADEM and another vaccine with the DT component. Further, in and of itself, this single article is insufficient to support petitioner's theory.

Although a causal connection between the DPT vaccination and ADEM may be biologically plausible, petitioner in this case has failed to provide sufficient evidence that Dillon's ADEM was caused by his DTP vaccination. Respondent's experts, Drs. Wientzen and Sriram, stated in their reports and their testimony that a causal relationship has not yet been accepted between DPT vaccination and ADEM. See supra pp. 7-8. Additionally, it is clear from Dr. Arrieta's testimony that the requisite cause and effect relationship between the DPT and ADEM is missing. In its place, Dr. Arrieta presumes that absent another identified cause, the DPT is causative.[(20)] Such testimony amounts to a speculative assumption, not a supportive theory or test, as required by Daubert.

The essence of Daubert is a practical requirement for objective substantiation of the expert's testimonial support to eliminate baseless hypotheses. While Daubert's requirements were designed to protect juries from exposure to complex scientific testimony, which they, for the most part, have neither the educational background nor experience to understand and weigh, the same can be said of judges. Requiring the same validation in testimony before a judge ensures a dispute over legitimate professional differences of opinion, rather than the most glib presentation. Thus, the expert's analysis is measured against the scientific standards of his peers. In this case, Dr. Arrieta readily conceded that his testimony was anything but scientific:

I think it is correlative stories that basically say patient x, was exposed to this and had this event. So, it's basically a time-related function.

Transcript at 88. This quotation is representative of Dr. Arrieta's testimony. As testified to by respondent's experts, the scientific support for a causal relationship between the DTP and ADEM is, at this time, non-existent. Thus, Dr. Arrieta was forced to rely upon the only available element of proof -- the temporal relationship. Precedent and logic teaches that such proof alone is insufficient.[(21)]

Although the IOM acknowledged that it is biologically plausible for a DTP vaccination to lead to ADEM, it concluded that "the evidence is inadequate to accept or reject a causal relation between tetanus toxoid, DT, or Td and demyelinating disease of the CNS [central nervous system] (ADEM, transverse myelitis, and optic neuritis)." R. Ex. G at 86. In this case, petitioners did not provide adequate evidence to accept a causal relation between DTP and the onset of Dillon's ADEM.

CONCLUSION

The outcome of this case was dependent on the court's weighing of the expert testimony. The court found Dr. Prentice's testimony little more than mere speculation. Although the court found Dr. Arrieta's testimony credible, his medical opinion causally connecting the DPT vaccination and ADEM remains, at this point in time, unsubstantiated by literature and the medical community. In contrast, the court found the opinions of Drs. Wientzen and Sriram, that Dillon's DTP vaccination did not cause his ADEM, credible and consistent with the medical literature submitted in this case.

Dillon's story is a tragic one. However, Congress designed the Vaccine Program to compensate only those petitioners who could substantiate their claims either through a presumption of causation (Table case) or prove a causal link between their injuries and a vaccination. In this case, petitioner has not demonstrated, by a preponderance of the evidence, that it is more likely than not that Dillon's ADEM was actually caused by the DPT vaccination he received. Therefore, petitioner is not entitled to compensation under the Program. Accordingly, the Clerk shall enter judgment dismissing this claim.

Gary J. Golkiewicz

Chief Special Master

1. This Decision was originally entered by the court on May 28, 1999, as an unpublished decision. This reissuance as a published decision follows in response to respondent's Motion to Publish, filed June 3, 1999. Respondent's motion is hereby granted.

2. The National Childhood Injury Compensation Program comprises Part 2 of the National Childhood

Injury Act of 1986, *amended by* 42 U.S.C.A. § 300aa-1 et seq. (West 1991 & Supp. 1999). For convenience, individual sections of the Act will be cited without reference to 42 U.S.C.A. § 300aa

3. Section 14 of the Vaccine Act, entitled "Vaccine Injury Table," identifies certain vaccines and specifies illnesses, disabilities, injuries, and conditions that have been associated with those vaccines. However, since this case was filed after March 10, 1995, it is governed by the revised Vaccine Injury Table found at 42 C.F.R. § 100.3 (1995).

4. The abbreviations "DTP" and "DPT" are used interchangeably throughout this decision in reference to the diphtheria, tetanus, pertussis vaccination.

5. Dr. Uchiyama's report was filed as P. Ex. 25. Petitioner's filed a short biography of Dr. Uchiyama as P. Ex. 26. Dr. Uchiyama is board certified in Pediatrics.

6. Dr. Prentice's report and Curriculum Vitae were filed on June 17, 1998 as P. Ex. 29 and 30. Dr. Prentice is board eligible in Pediatrics and "Psychiatry and Neurology." P. Ex. 30.

7. Dr. Arrieta's report was filed as P. Ex. 27, his supplemental report as P. Ex. 27a, and his Curriculum Vitae as P. Ex. 28. Dr. Arrieta is Board certified in Pediatrics and Pediatric Infectious Diseases.

8. Dr. Wientzen's report was submitted as R. Ex. A and his Curriculum Vitae as R. Ex. B. Dr. Wientzen is Board certified in Pediatrics and Pediatric Infectious Diseases.

9. See P. Ex. 16.

10. Dr. Wienzten stated that "right now in this country, there probably are 30 million cases of DPT given every year, thirty million cases every year just in the last decade. Three hundred million cases of DPT, and we don't have a series of children who are proven by MRI and by their clinical presentation to have developed ADEM within this timeframe."

11. Dr. Sriram's report was submitted as R. Ex. D and his Curriculum Vitae as R. Ex. E. Dr. Sriram is Board certified in Internal Medicine and "Psychiatry and Neurology."

12. 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, 372-373 (1970) (Harlon, J., concurring) (quoting F. James, Civil Procedure, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

13. See Section 14(a).

14. See Section 11(c)(1)(C)(ii)(I) and (II)

15. Petitioners in this case did not produce convincing evidence which demonstrates that the DTP vaccination can be *any* factor in causing ADEM, much less a "substantial factor." Therefore, the court finds that the "substantial factor" test set forth in Shyface has no effect on the case at hand.

16. A reputable medical or scientific explanation does not simply mean, however, any theory that a medical expert is willing to espouse. In construing the Federal Rules of Evidence, the Supreme Court

held that it is the trial judge's responsibility to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2795 (1993). The Court added that an expert's "knowledge . . . connotes more than subjective belief or unsupported speculation . . . [and must have been] derived by the scientific method." Id. 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). Factors relevant to that determination may include, but are not limited to:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert, 43 F.3d at 1316; see also Daubert, 113 S.Ct. at 2796-97: 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.

Respondent's counsel argued in a July 15, 1998 motion for summary judgment that petitioner failed to present reliable expert medical testimony in accordance with Daubert. On March 25, 1999, respondent filed Notice of Supplemental Authority, arguing that the Supreme Court's recent decision in Kumho Tire Company Ltd. v. Carmichael, -- U.S. -- (March 23, 1999), reveals that petitioner's expert medical testimony in this case "falls far short of establishing causation-in-fact by a preponderance of the evidence." In Daubert, the issue was whether the Federal Rules of Evidence required the court to exclude the expert testimony and Kumho expanded the Daubert ruling to include non-scientific experts; however, while the Federal Rules of Evidence are looked to for guidance, they are not strictly applied in vaccine cases. Although petitioner must support her causation-in-fact theory by a reputable medical or scientific theory, 956 Grant v. Secretary of HHS F.2d 1144, 1148 (Fed. Cir. 1992), the Act specifies that Vaccine Program case proceedings are to "include flexible and informal standards of admissibility of evidence." 12(d)(2)(B). The special master must "articulate a satisfactory explanation for [his] action including a 'rational connection between the facts found and the choice made.'" Hines v. Secretary of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (citation omitted). The court will not, therefore, grant respondent's motions for summary judgment; using the teachings in Daubert and Kumho for analyzing and weighing the expert testimony, the court has decided this case on its merits.

17. Petition at 2.

18. 42 C.F.R. § 100.3 (1995). These injuries were listed on the original Table, but they were removed from the Table in the 1995 revision. However, even if these injuries were still listed on the Vaccine Injury Table, petitioner failed to provide any evidence that Dillon suffered any of these injuries as a result of his DTP or OPV vaccinations. In fact, the first manifestation of any injury did not occur until January 3, 1995, nineteen (19) days post-immunization. See P. Ex. 29 (stating Dillon "reportedly had no problems until January 3, 1995"). Thus, Dillon could only be eligible for compensation if he could prove the vaccine was the cause-in-fact of his injuries.

19. See discussion supra p. 12.

20. See Grant v. HHS, 956 F.2d 1144 (Fed. Cir. 1992) (showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation).

21. See, e.g., Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period. . . [w]ithout more, this proximate temporal relationship will not support a finding of causation"); Strother v. HHS, 18 Cl. Ct. (1989), subsequent decision, 21 Cl. Ct. 365 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991) (temporal relationship alone is insufficient to establish causation in fact).