

United States Court of Federal Claims
March 23, 1998
No. 90-1334 V

JOHN HANLON AND RUTH ANN)	Vaccine case; tuberous
HANLON, as parents and next)	sclerosis as existing
friends of Michael Hanlon,)	condition at time of
)	administration of DPT
Petitioners,)	vaccine; significant
)	aggravation; Vaccine
versus)	Injury Table, 42 U.S.C.
)	§ 300aa-14.
SECRETARY OF HEALTH AND)	
HUMAN SERVICES,)	
)	
Respondent.)	

Robert T. Moxley, Cheyenne, WY, for petitioners.

Mary Hampton Mason, with whom were Assistant Attorney General Frank W. Hunger, Helene M. Goldberg, John Lodge Euler and Gerard W. Fischer, Washington, DC, for respondent.

OPINION and ORDER

TURNER, Judge.

Petitioners seek relief under the National Vaccine Injury Compensation Program (established pursuant to 42 U.S.C. § 300aa-10) for injuries suffered by their son, Michael Hanlon. Applications for and determinations of eligibility for Program compensation are controlled by 42 U.S.C. § 300aa-11 to -16 and -33(2)&(4) (Vaccine Act). (For convenience, we sometimes hereafter shorten references to sections of the Vaccine Act to the portion following the hyphen.)

Petitioners allege that Michael suffered compensable injuries as a result of diphtheria-pertussis-tetanus (DPT) vaccinations. On September 15, 1997, Special Master Laura Millman issued a decision denying relief. The case stands on petitioners' motion filed October 20, 1997 to review that adverse decision. We conclude that the special master did not abuse her discretion, that she was not arbitrary or capricious, and that she acted in accordance with applicable law. Thus, we further conclude that the master's decision should be affirmed.

I

Michael was born on March 30, 1978 and received his first DPT vaccination on June 1, 1978. Decision (5/31/94) at 2. The next day, Michael suffered his first seizure. *Id.* at 3, App. at 142. Michael received three more DPT vaccinations on July 28 and October 3, 1978 and on October 1, 1979. *Id.* at 3-4. After the initial seizure, Michael suffered other seizures continuing at least through 1990. *Id.* Michael's seizures were afebrile "complex partial (focal) seizures." Decision (9/15/97) at 45. Michael was eventually diagnosed with a seizure disorder. Decision (5/31/94) at 3-4. Michael was also diagnosed as having tuberous sclerosis (TS), a genetic disease of the brain known to cause seizures and mental retardation.

On September 25, 1990, petitioners filed a petition for compensation under the Vaccine Act. On May 31, 1994, Special Master Millman filed a decision in favor of compensation. The special master found that Michael's injuries conformed in type and timing to the injuries described in the Vaccine Injury Table (Table), § 14. Decision (5/31/94), App. at 141-42. The special master next concluded that petitioners proved Table significant aggravation of Michael's TS condition. *Id.*, App. at 142. Finally, she concluded that two then-recent cases, *Suel v. Secretary of the Dep't of Health and Human Servs.*, 31 Fed.Cl. 1 (Fed.Cl. 1993), and *Costa v. Secretary of Dep't of Health and Human Servs.*, 26 Cl.Ct. 866 (Cl.Ct. 1992), mandated that she find in favor of petitioners on the issue of entitlement to compensation. *Id.*, App. at 142. The special master then initiated the damages phase of the case. Prior to a ruling on damages, and thus before any final decision by the special master, respondent sought reconsideration of the liability determination.

Thereafter, the special master received more evidence on the issue of liability and ultimately held omnibus hearings in October 1996 and June 1997 "to facilitate the disposition of over twenty [TS] cases (even those in which entitlement had already been decided but which were awaiting disposition of damages)." Decision (9/15/97) at 5. The special master determined that petitioners had demonstrated a prima facie Table significant aggravation under the Vaccine Act. *Id.* at 64. The special master concluded that petitioners were entitled to a "presumption" that the vaccine significantly aggravated Michael's TS. *Id.* However, the special master also concluded that respondent had met its rebuttal burden by proving that a factor unrelated to the vaccine, TS, caused Michael's seizures as well as his "current condition." *Id.* For this reason, the special master denied compensation, *id.* at 67, and vacated her prior decision, Order (9/18/97).

On October 20, 1997, petitioners filed their motion for review of the special master's final decision.

II

The petition in a vaccine case must allege the occurrence of one or more of the following events: (1) the vaccine caused an injury listed in the Vaccine Injury Table, (2) the vaccine caused an injury not listed in the Table, (3) the vaccine aggravated an injury or "pre-existing condition" listed in the Table, or (4) the vaccine aggravated an injury or pre-existing condition not listed in the Table. § 11(c)(1)(C). Thus, a threshold question is whether the injury complained of or the pre-existing condition allegedly aggravated is listed in the Table.

In this case, petitioner alleges that DPT vaccine caused Michael to suffer residual seizure disorder (RSD). (1) The injury complained of, RSD, is listed in the Table. § 14(a). For this reason petitioners may proceed with the theory that the vaccine caused Michael to suffer a Table injury, keeping in mind that they must show that the *first* seizure Michael suffered, "the first symptom or manifestation of the onset" of an illness listed in the Table, "occurred within the time period after vaccine administration set forth in the Vaccine Injury Table," in this case, within three days. (2) § 11(c)(1)(C)(i), 14(a).

In the alternative, petitioners allege that, "within the time frame set forth in the Vaccine Injury Table," the DPT vaccinations "significantly aggravated [Michael's] existing Tuberos Sclerosis condition." Pet. ¶ 12. The pre-existing condition allegedly aggravated, TS, is *not* listed in the Table and cannot be considered a condition listed in the Table. (3)

Because TS is not listed in the Table and cannot be considered a condition listed in the Table, petitioners must prove causation in fact with respect to the significant aggravation portion of the case. Despite this, the special master evaluated the case as a significant aggravation case under the Vaccine Injury Table. Decision (9/15/97) at 64. Indeed, the special master found that petitioners made out a significant aggravation case under the Table. Id.

Based on our discussion of the law above, we conclude that the special master erred in so ruling. However, because petitioners were entitled to proceed under the Table by alleging that DPT caused Michael's RSD, this error is harmless. By finding that petitioners had proved Table significant aggravation, in effect, the special master found that petitioners proved Table onset: (1) Michael suffers from a condition listed in the Table, RSD, (2) the first seizure Michael suffered occurred within three days and (3) Michael suffered "2 or more seizures ... within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by fever of less than 102 degrees." See Decision (9/15/97) at 64; Decision (5/31/94) at 5.

Because petitioners meet the requirements for proof of a Table injury (RSD), they are entitled to a presumption that the vaccine injured Michael. The presumption shifts the burden to respondent to show by a "preponderance of the evidence" that the injury was actually caused by "factors unrelated" to the vaccine. § 13(a)(1)(B). In this case, the special master decided that respondent had proved that a factor unrelated to the vaccine, TS, caused the initial seizure, the residual seizure disorder and any seizure-related problems from which Michael currently suffers. Decision (9/15/97) at 64. Petitioners seek review of the special master's decision. Specific objections follow. A

Petitioners argue that the special master abused her discretion when she reconsidered, prior to her final decision, her initial finding that Michael suffered a compensable injury. Pet. Memo. of Obj. at 55. Whether or not to reconsider, prior to issuance of a final decision, an announced finding of entitlement in a vaccine case is left to the discretion of the special master. Vant Erve v. Secretary of Health and Human Servs., 39 Fed.Cl. 607, 611-12 (Fed.Cl. 1997); McGowan v. Secretary of the Dep't of Health and Human Servs., 31 Fed.Cl. 734, 737 (Fed.Cl. 1994). Therefore, we review under the abuse of discretion standard. § 12(e)(2)(B); Saunders v. Secretary of Dep't of Health and Human Servs., 25 F.3d 1031, 1033 (Fed.Cir. 1994).

Petitioners claim that in order for a party to prevail on a motion to reconsider a settled entitlement issue the party must show that there is newly discovered evidence, that the evidence could not have been submitted for timely consideration, and "that the evidence would probably change the outcome of the previously adjudicated case." Pet. Memo. of Obj. at 56. We disagree. To determine whether or not the special master's decision to reopen the finding of entitlement was an abuse of discretion we simply look at the facts and circumstances surrounding her decision. But cf. Vant Erve, 39 Fed.Cl. at 612 (setting out a four-prong test for reconsideration of an entitlement decision in a vaccine case).

The special master reconsidered her finding because respondent alleged that there was new and relevant medical evidence which proved that in severe TS cases seizures are inevitable. Decision (9/15/97) at 4. This evidence would have been significant because, if respondent could prove that Michael had a severe case of TS, the evidence would suggest that TS, and not DPT, caused his seizures. For this reason, we conclude that the special master's decision to reconsider entitlement was not an abuse of discretion.

B

Petitioners also argue that the government should have been precluded from presenting a defense in its case which contradicts a defense presented in prior TS vaccine cases:

The government has on many occasions in Tuberos Sclerosis litigation sponsored witnesses who agreed that DPT 'unmasked' seizures in TS. In order to put on its omnibus defense herein, the government had to get witnesses who would sponsor a contrary position. This is a violation of the principle of estoppel by oath

Pet. Memo. of Obj. at 57. Petitioners' position is without merit.

While it may be true that the government has called witnesses who have testified that DPT "unmasks" TS, it does not follow that the government is not allowed to call other witnesses or the same witnesses who, based on new or different medical research or on further reflection upon the same evidence, believe and testify to the contrary. Petitioners argument has no basis in law.

In a similar vein, petitioners argue that the government should have been collaterally estopped from presenting its defense. Pet. Memo. of Obj. at 57-58. In order for respondent to be collaterally estopped on any issue, petitioners must first show that the issue is identical to an issue litigated in a prior action. See, e.g., Arkla, Inc. v. United States, 37 F.3d 621, 623-24 (Fed.Cir. 1994).

Petitioners' rationale for estoppel is unclear. However, they seem to be arguing that the determination that DPT significantly aggravates TS has been decided and cannot be relitigated. The conclusion that DPT significantly aggravates TS depends upon the constantly evolving state of medical research and its application to the facts of each particular case. Under these circumstances, there is no identity of issues. We conclude that respondent cannot be estopped from presenting its "unrelated factor" defense in this case.

C Throughout their brief, petitioners argue that the special master committed reversible error by failing to follow the "precedent" announced by judges and special masters of this court in other cases, such as Bernard v. Secretary of Health and Human Servs., No. 90-2720 V, slip op. (Fed.Cl. Jan. 30, 1997), Costa v. Secretary, 1992 WL 365421 (Fed.Cl. Office of Special Masters) and Suel v. Secretary of the Dep't of Health and Human Servs., 31 Fed.Cl. 1 (Fed.Cl. 1993). Pet. Memo. of Obj. at 46, 58-60.

In making their argument petitioners assume that the special master is bound by her prior opinions and by the opinions of the Court of Federal Claims in other cases. This assumption is mistaken. Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand. Moreover, Bernard is an unpublished opinion and, as such, "shall not be employed as authority by [the Court of Federal Claims] and may not be cited by counsel as authority." RCFC 52.1(a).

D

Petitioners argue that TS is not a "factor[] unrelated to the administration of the vaccine" for purposes of the Vaccine Act. See § 13(a)(1)(B). In order for respondent to rebut petitioners' prima facie case, it must prove that a "factor[] unrelated to the administration of the vaccine" caused the purported significant aggravation. See id. Petitioners set forth three reasons why the special master erred in treating TS as a "factor unrelated."

First, petitioners argue that TS is a "cutting-edge medical uncertaint[y]" and therefore cannot meet the requirements of § 13(a)(2)(A) of the Vaccine Act which provides that a "factor[] unrelated to the administration of the vaccine" cannot be "idiopathic, unexplained, unknown, hypothetical, or undocumentable" Pet. Memo. of Obj. at 47. Petitioner also cites Koston v. Secretary, Dep't of Health and Human Servs., 974 F.2d 157 (Fed.Cir. 1992) for the proposition that an idiopathic condition (condition of unknown cause or origin) does not meet the requirements of § 13(a)(2)(A).⁽⁴⁾ Pet. Memo. of Obj. at 51.

Whether or not TS is idiopathic is a question of fact and we review questions of fact under the arbitrary and capricious standard. § 12(e)(2)(B). There is ample evidence that TS is not idiopathic. An expert for respondent, Dr. Gomez, testified that TS is a "genetic disorder which is either inherited or results from a mutation." Decision (9/15/97) at 6. An expert for petitioners, Dr. Osborne, also testified that TS is genetic and identified the gene sites for the condition. Id. at 36. Dr. Osborne specifically stated that TS is not idiopathic. Id. The special master concluded that Drs. Gomez and Osborne were credible. Id. at 61. We therefore conclude that petitioners' argument that TS is idiopathic has no merit.

Second, petitioners argue that TS cannot be a factor unrelated because, to be a factor unrelated, TS must be, but is not, an "infection, toxin[], trauma ... or metabolic disturbance" with "no known relation to the vaccine involved." Pet. Memo. of Obj. at 46. See § 13(a)(2)(B). Petitioners assume that a factor unrelated must be an "infection, toxin[], trauma ... or metabolic disturbance[]" -- that a "'Table Case' only allows the **listed** factors to be raised."⁽⁵⁾ Pet. Memo. of Obj. at 46. The Vaccine Act provides:

[T]he term "factors unrelated to the administration of the vaccine" ... may ... include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the ... [vaccinee's] illness, disability, injury, condition, or death.

§ 13(a)(2)(B) (emphasis added). Upon reading the statute, we conclude that the § 13(a)(2)(B) list is not all-inclusive. Factors unrelated may include certain conditions listed, but also may include some other condition which is not listed, so long as that other condition has "no known relation to the vaccine involved, but which in the particular case [is] shown to have been the agent ... principally responsible for causing" the vaccinee's injury. For this reason, we conclude that respondent may introduce evidence that TS is a factor unrelated.

Third, petitioners argue that "seizures, the injury in TS, cannot possibly be demonstrated as a condition with 'no known relation' to [DPT]" as required by § 13(a)(2)(B) of the Vaccine Act. Pet. Memo. of Obj. at 47. Petitioners argue that "where the statute itself **codifies** the 'relationship' between DPT and seizures ... the Secretary [of Health and Human Services] cannot prevail in TS cases." *Id.* Petitioners misconstrue the provision in question. The Vaccine Act requires that the "factor unrelated," in this case, TS, be unrelated to the vaccine. See § 13(a). Petitioners seem to suggest that because DPT can cause seizures and TS can cause seizures that DPT and TS are related. This point is fallacious.

For the reasons above, we conclude that the special master properly evaluated TS as a "factor[] unrelated to the administration of the vaccine."

E

Petitioners argue that the special master held them to a causation-in-fact standard after they had proved their Table case. Pet. Memo. of Obj. at 43. Petitioners cite the portion of the special master decision stating: "where a child receives DPT and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure in three days, TS, not DPT, is the cause in fact of that seizure." Pet. Memo. of Obj. at 41-42 (citing Decision (9/15/97) at 63-64). Petitioners continue: "[t]he 'new' rule ... is that a TS petitioner will recover for a Table injury **only** if a 'real vaccine reaction' is demonstrated. The perfect fit of a TS residual seizure disorder is no longer good enough." Pet. Memo. of Obj. at 39.

Petitioners are confusing two different stages of their case. The special master held that petitioners had proved a prima facie Table case. Decision (9/15/97) at 64. If respondent had not rebutted, the prima facie showing would be "good enough." However, respondent offered evidence to rebut petitioners' case. After reviewing all the evidence the special master found a preponderance of evidence supporting respondent's argument that TS caused the seizures. The special master then offered a scenario under which petitioners might have prevailed. Specifically, the special master opined that respondent's case would not have been as convincing if the vaccinee had had a more severe "vaccine" reaction. See *id.* at 62-64. Petitioners thereby were not held to a causation-in-fact standard. Respondent simply put on a strong rebuttal which itself "required" petitioners to do more than rest on their prima facie showing if they wished to prevail. We conclude that petitioners were not required to prove that DPT caused in fact Michael's seizures in order to prove a Table injury.

III

Petitioners argue that the special master erred in finding that respondent had carried its rebuttal burden because it did not prove by a preponderance of the evidence that TS caused Michael's seizures. On review, we must determine whether the special master's findings are arbitrary and capricious. See § 12 (e)(2)(B); Saunders, 25 F.3d at 1033.

A

In order to evaluate the special master's findings we must first decide whether any evidence she relied on was irrelevant or improperly admitted.

Petitioners assert that respondent acted unethically when it retained Manuel Gomez, a pediatric neurologist, as an expert for its omnibus defense. For this reason, petitioners argue the special master erred in allowing Gomez to testify in the case. On October 21, 1991, Dr. Gomez testified at a deposition in other cases on the relationship among TS, DPT and seizures. Decision (5/31/94) at 4. Petitioners allege that Dr. Gomez was their retained expert witness at that time. Pet. Memo. of Obj. at 65. Petitioners state that "Dr. Gomez was 'retained' when he learned of the petitioners' litigation strategy and rendered opinions." Id. at 66. Respondent disputes that Dr. Gomez was ever petitioners' retained expert. Response (11/20/97) at 43. In any case, it is undisputed that respondent ultimately retained Dr. Gomez as its expert.

As a preliminary matter we address whether Dr. Gomez was retained by petitioners as an expert witness, a fact witness, or neither. We conclude that Gomez was not any type of witness for petitioners. Petitioners have submitted no evidence that Dr. Gomez was ever a witness in their case. The only connection between Gomez and petitioners is that Gomez testified in the 1991 deposition at the request of petitioners' counsel and that Gomez's 1991 testimony was cited by the special master in her initial and omnibus decisions in this case. However, the fact that petitioners' counsel had dealings with Gomez in other cases does not mean that Gomez was a witness in this case. Additionally, the fact that the special master cited Gomez's deposition from another case to summarize what she considered to be accepted medical conclusions does not mean that Gomez was a witness in this case.

Gomez's 1991 deposition in other cases generally favored petitioners and was cited as evidence of accepted conclusions about TS and seizures in the special master's first decision in this case. Later, Gomez informed respondent that he had changed his opinion so that his prior testimony was flawed and/or incomplete. Respondent called this to the attention of the special master and doing so was entirely proper. Subsequently, respondent retained Gomez as its expert. Because the special master had relied on Gomez's first opinion, it was important to the ultimate resolution of the case to know how and why his opinion had changed.

Additionally, we firmly believe that if petitioners' counsel realized that the special master was going to rely on Gomez's past testimony, which favored petitioners, and knew that Gomez's opinion had changed materially based on newer studies or a change in the prevailing medical opinion, petitioners' counsel would have had an ethical duty to bring this to the special master's attention.

Courts are engaged in a search for truth no matter who calls the witness.

Because petitioners have made no showing that Gomez was ever their witness, we conclude that respondent properly contacted and retained him as an expert. For this reason and because Gomez's new testimony was pivotal, we further conclude that it was not erroneous for the special master to allow Gomez to testify.

B

Petitioners argue that the special master improperly relied on evidence that tends to undermine the

Vaccine Injury Table. Pet. Memo. of Obj. at 43-45. One example is the special master's reliance on expert testimony that febrile, generalized seizures are more closely associated with DPT, while afebrile, focal seizures are more closely associated with TS. Decision (9/15/97) at 45, 61-62. This type of evidence contradicts apparent Table assumptions because the Table specifically includes focal seizures as a valid vaccine-related seizure and, in the case of RSD, the Table requires afebrile seizures. See § 14(a), (b)(2), (b)(4). Another example is expert testimony that in TS cases a seizure with additional vaccine-related symptoms is more suggestive of a vaccine reaction than a seizure alone. Id. at 61-62. This type of evidence, petitioners say, contradicts the Table because the Table does not require that the seizure be accompanied other symptoms. (6) See § 14(a).

In evaluating petitioners' objection, it makes a difference whether the conflicting testimony is used to undermine directly a Table presumption or to prove causation in fact due to an unrelated factor. Proof of causation in fact is entirely independent of the Table. Once a Table injury or aggravation is demonstrated, plaintiff has established a prima facie case and the burden of going forward with the evidence shifts to the respondent who may, using any available evidence, attempt to prove alternative causation. Actual causation evidence would then be offered as if respondent were the party with the burden of persuasion in a separate tort case. Similarly, if petitioners had elected to assert and had attempted to prove causation in fact of an injury or an aggravation of a pre-existing condition, respondent would then have to present other evidence, independent of the Table, to rebut petitioners' showing.

*Thus, we are not troubled by the special master's consideration of this evidence, nor are we surprised that modern medical research may conflict with the Vaccine Injury Table. However, it is important to note that this evidence alone would be insufficient to prove that a factor unrelated to the vaccine caused the injury. See Quinn v. Secretary of Health and Human Servs., 1992 WL 183197, at *3-4, 6-7 (Cl.Ct. Office of Special Masters) (holding proof that measles vaccine does not cause stroke is not sufficient to prove that a factor unrelated caused vaccinee's stroke).*

We conclude that it was not improper for the special master to rely on causation-in-fact evidence which may have contradicted the Table.

C

Petitioners assert that the special master's finding is error to the extent that she relies on a "unity theory," rejected by Knudsen v. Secretary of the Dep't of Health and Human Servs., 35 F.3d 543 (Fed.Cir. 1994). Pet. Memo. of Obj. at 48. In Knudsen, the vaccinee had some symptoms which were consistent with the vaccine and a virus and some symptoms that were consistent with only the virus. There, respondent's medical expert theorized that "the only single thing that could explain all of [the vaccinee's] symptoms ... was a systemic viral infection." Id. This is the "unity theory." The Federal Circuit rejected this logic because it was possible that the vaccinee had both a reaction to the DPT and a viral infection. However, Knudsen is not on point. In this case, there are no extraneous symptoms. The symptoms at issue are seizures and they are presumed to conform to a vaccine reaction unless respondent proves otherwise. The logic in this case is that the type of seizure Michael suffered is consistent with TS and inconsistent with a DPT reaction. We cannot say that such logic is arbitrary or capricious.

*D*We now consider whether the special master's decision that "TS caused in fact [Michael's] initial seizure as well as [his] current condition," Decision (9/15/97) at 64, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." § 12(e)(2)(B).

The special master made the following relevant findings. She found, based on the testimony of two experts, Gomez and Osborne, that "TS is the overwhelming cause of seizures in a child afflicted with the disease, unless he develops a fever or some other well-recognized reaction to a vaccination." Id. at 61-62. She found that studies "strongly indicate that there is a programmed aspect [i.e., natural, genetic

timetable in children with TS] to seizure onset." *Id.* at 62. She found "that the presence of tubers ... the hallmark of TS, leads to seizures in the majority of TS patients." *Id.* at 64. And she found that "DPT does not initiate seizures in TS patients." *Id.* at 65.

The preceding paragraph includes all the findings relevant to TS vaccinees who, like Michael Hanlon, do not suffer from infantile spasms.⁽⁷⁾ Based on these findings, the special master came to a general conclusion:

When faced with the choice of whether TS caused in fact an individual's seizure disorder so as to rebut the presumption that DPT vaccination is the cause, the court must choose the former over the latter in every case in which the vaccinee has no symptom other than the seizure.

Id. at 62. Then the special master applied her general conclusion to Michael Hanlon's case:

[W]here a TS child receives DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect, and activity) but has a seizure within three days, TS, not DPT, is the cause in fact of that seizure. This is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as Michael Hanlon ... had.

Id. at 63-64. She later made a few additional findings for Michael Hanlon's case and reiterated her decision:

Michael Hanlon had repetitive eye blinking occasionally between the ages of two and four months. Between the ages of four and six months, he had recurrent blinking of the eyes associated with some jerking of the head to the right. These episodes were unaccompanied by fever. He received DPT vaccinations when he was two, four, and six months of age. Petitioners alleged that onset occurred one day after the first DPT. In light of this court's above holdings, the onset of Michael's seizures was coincidental to his first DPT vaccination. By looking at the course of his seizures, one can see that they were happening without any reaction to an antigenic insult.

Id. at 65-66.

There is other evidence in the record which supports the special master's decision. Perhaps the most significant example of such evidence is case-specific testimony by two pediatric neurologists, Drs. Gomez and Lee, that Michael's TS, not DPT, caused his seizures. *Id.* at 42, 55. Other evidence includes Gomez's testimony that TS causes seizures, seizures are the most common manifestation of TS and children with TS most often suffer seizures during the first year of life. *Id.* at 6-7. There is also evidence that (1) Michael had ten detectable tubers and there is a significant correlation between a high number of tubers, such as ten, and seizures and (2) DPT does not cause focal or afebrile seizures, the type of seizures Michael suffered. *Id.* at 7, 12, 17, 25, 45, 54.

Petitioners assert that the findings are not sufficient, in part, because of the Federal Circuit's holding in *Knudsen v. Secretary of the Dep't of Health and Human Servs.*, 35 F.3d 543 (Fed.Cir. 1994). *Pet.'s Memo of Obj.* at 48-50. In *Knudsen*, a special master found that petitioners had made out a prima facie case and were entitled to a presumption that DPT caused Debra Ann Knudsen to suffer an encephalopathy. *Id.* at 546. However, the special master also found that "at the time Debra suffered the encephalopathy, she was also suffering from a systemic viral infection, and that the viral infection in fact caused the encephalopathy and the DTP vaccine did not." *Id.* In *Knudsen*, the special master had based the decision, in part, on a finding that "encephalopathies caused by DTP vaccine occur less frequently than encephalopathies caused by viral infection." *Id.* The Court of Federal Claims upheld the findings. *Id.* The Federal Circuit reversed. The Circuit stated, "[a]lternative causation is not automatically proved simply

by the mere fact that a child is infected with a virus ... at the time of vaccination or injury." Id. 549. The court continued:

[E]vidence that there are more occurrences of encephalopathies caused by viral infections than there are encephalopathies caused by DTP vaccines ... is not evidence that in a particular case an encephalopathy following a DPT vaccination was in fact caused by a viral infection present in the child and not caused by the DPT vaccine.

Id. at 550.

We find Knudsen distinguishable from the master's decision in the instant case. The rationale of the portion of Knudsen we now address was that the "mere" fact that a child had a viral condition which could explain alternative causation, or the "bare statistical fact" that there are more reported cases supporting a non-vaccine cause for a Table condition than reported cases supporting a vaccine cause, does not, standing alone, prove alternative causation. Id. at 549, 550.

In contrast, the special master's decision under review found that in a TS child exhibiting the kind of seizures that Michael had and having the absence of all other symptoms typical in a child suffering DPT-induced seizures, "TS is the overwhelming cause of seizures" and that "DPT does not initiate seizures in TS patients." Decision (9/15/95) at 61-62, 65. In support of these conclusions, the master recited, inter alia, evidence that DPT simply does not cause the kind of seizures that Michael suffered and that two pediatric neurologists, including one the master regarded as the world's leading expert on TS, opined that TS, not DPT, caused Michael's seizures. Id. at 42, 54-55. We find this combination of conclusions and evidentiary support different from "the bare statistical fact" focused upon in Knudsen.

We conclude that the special master's decision, that respondent had proved by a preponderance of the evidence that a factor unrelated to Michael Hanlon's DPT vaccinations was the actual cause of his residual seizure disorder, is neither arbitrary, capricious, an abuse of discretion or contrary to law.

IV

Based on the foregoing, the special master's decision filed September 15, 1997 is AFFIRMED. Accordingly, it is ORDERED that judgment shall be entered in favor of respondent. Each party shall bear its own costs.

James T. Turner

Judge

- 1. Petitioners allege that "the onset of a residual afebrile seizure disorder ... is to be presumed caused by his DPT vaccinations under the provisions of the Vaccine Injury Table." Pet. ¶ 21.*
- 2. In accordance with the Table, petitioners must also show that the vaccinee suffered "2 or more seizures ... within 1 year after the administration of the vaccine which were unaccompanied by fever or*

accompanied by fever of less than 102 degrees." § 14(b)(2).

3. The illnesses, disabilities, injuries and conditions "covered" for the DPT vaccine include, inter alia, encephalopathy and residual seizure disorder. § 14(a). We are mindful that TS has been treated as an encephalopathy or a latent seizure disorder in other cases. See, e.g., Suel v. Secretary of the Dep't of Health and Human Servs., 31 Fed.Cl. 1, 7-8 (Fed.Cl. 1993) (treating TS as a condition listed in the Table); Costa v. Secretary of the Dep't of Health and Human Servs., 26 Cl.Ct. 866, 869-871 (Cl.Ct. 1992) (holding that TS is an encephalopathy or a latent seizure disorder).

However, respondent's expert (Gomez), "the world's expert in TS," has given uncontroverted testimony that "TS is not an encephalopathy." Decision (9/15/97) at 5-6. Moreover, there is no evidence that TS is a residual seizure disorder.

4. In Koston, the Federal Circuit held that Rett Syndrome was not a factor unrelated to the administration of the vaccine because experts did not know what caused the condition. Id. at 160-61. The Federal Circuit rejected respondent's argument that because Rett Syndrome "is present from birth ... [it] must be a factor unrelated to the vaccine." Id. at 160. See also Whitecotton v. Secretary of Dep't of Health and Human Servs., 17 F.3d 374 (Fed.Cir. 1994) (holding that micro-encephalopathy was idiopathic), rev'd sub nom. on other grounds, Shalala v. Whitecotton, 514 U.S. 268 (1995).

5. Petitioners also suggest that Knudsen v. Secretary of the Dep't of Health and Human Servs., 35 F.3d 543 (Fed.Cir. 1994), addresses this issue. Pet. Memo. of Obj. at 46, 53. It does not. Knudsen interprets § 13(a)(2)(A), not § 13(a)(2)(B).

6. Petitioners also argue that the portion of the special master's decision where she opines that DT does not cause seizures illustrates her attempt to "repeal" the Vaccine Injury Table. Pet. Memo. of Obj. at 44. Because petitioners do not allege that Michael suffered any injury from DT, we will not address this argument.

7. The special master made numerous other findings pertaining to TS children who suffer from infantile spasms. Decision (9/15/97) at 58-60.