

No. 91-1555 V

(FILED: March 19, 1998)

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**MARC PLAVIN and TONI REISS, Parents  
and Next Friends of RACHEL LEAH  
REISS-PLAVIN,**

*Petitioners,*

v.

**SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,**

*Respondent.*

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**National Childhood Vaccine  
Injury Act, 42 U.S.C. §  
300aa-1 - 34; Standard of  
Review; Review of Dismissal  
Order; Diphtheria-Pertussis-  
Tetanus Vaccine; Tubercous  
Sclerosis; Reopening Entitlement;  
Witnesses.**

*Robert T. Moxley and Richard Gage, Cheyenne, Wyoming, for petitioners.*

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

**ORDER**

**TIDWELL, Judge:**

This case is before the court on petitioners' motion for review<sup>(1)</sup> of the September 18, 1997 decision of Special Master Millman denying compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-1 - 34 (1994). *See Plavin v. Secretary of HHS*, No. 91-1555V (Fed. Cl. Sp. Mstr. Sept. 18, 1997) (dismissal order). In denying the petition for compensation, the special master adopted the reasoning of her "TS Omnibus Decision," captioned in 22 cases, including this case. *Id.* (adopting *Barnes, et al. v. Secretary of HHS*, slip op. (Fed. Cl. Sp. Mstr. Sept. 15, 1997, as amended Sept. 18, 1997) (hereinafter "TS Omnibus Decision")<sup>(2)</sup>). For the reasons set forth below, the court grants in part and denies in part petitioners' motion for review. In doing so, the court reverses in part, affirms in part, and remands the special master's denial of entitlement to compensation in *Plavin*.

**BACKGROUND**

On behalf of Rachel Leah Reiss-Plavin ("Rachel"), petitioners filed a petition on October 30, 1991 for compensation under the Vaccine Act. Rachel was born on June 8, 1989, in Lexington Kentucky. Rachel received her first Diphtheria-Pertussis-Tetanus ("DPT") vaccination on August 4, 1989 at the age of two months. She received her second DPT vaccination on September 15, 1989, when she was three and a half months old. Rachel's parents allege that later that day, Rachel was staring, her left arm shook and she drew her legs up.

On September 26, 1989, Rachel was brought to Humana Hospital. Dr. Jacqueline Campbell noted that Rachel had been healthy until her mother noticed occasional trembling of her left hand while she nursed, along with one blank stare. Dr. Campbell concluded that Rachel was suffering from a seizure disorder, and in her summary mentioned Rachel's second DPT vaccination, given 10 days before admission to the hospital, and that Rachel had had "no reaction" to it.

In November 1989, Rachel was diagnosed with Tuberous Sclerosis ("TS"), a neurocutaneous genetic disorder affecting the skin and nervous system. TS causes lesions to appear on some organs, including the brain. One type of lesion, located on the cortex of the brain and called a "cortical tuber," is responsible for seizures, although not all TS patients with tubers have seizures. Other symptoms of TS include mental retardation.

Also in November, 1989, Dr. Robert J. Baumann, a pediatric neurologist at the University of Kentucky Chandler Medical Center, indicated in his records that at two months of age, Rachel's mother noticed that Rachel had begun to have episodes where her left arm would shake, and by two and a half months of age it was apparent that these were seizures.

On December 12, 1989, Rachel was seen by Dr. Bryan C. Hall, the chief of the Division of Genetics and Dysmorphology and Professor of Pediatrics at the University of Kentucky. Dr. Hall recorded that Rachel had her first seizure on September 15, 1989, following a DPT vaccination. Dr. Hall stated that while Rachel was nursing, she pulled away from the nipple, and her left arm vibrated for a short period. She also began shaking and staring. A history given at the University of Kentucky Medical Center on November 1, 1990 records an onset of seizures at three and a half months.

Finally, on March 15, 1991, Dr. Campbell documented in a letter the sequence of events leading up to the diagnosis of Rachel's seizure disorder and TS. Dr. Campbell wrote that on September 15, 1989, Rachel's mother called her to discuss Rachel's fussiness, apparent abdominal cramping, and occasional brief arm tremor.

Presently, Rachel continues to suffer seizures and developmental delay, and she is approximately two years behind in gross and fine motor skills.

### **PROCEDURAL HISTORY**

In their original petition, petitioners alleged that as a result of her second DPT vaccination, Rachel suffered significant aggravation of her pre-existing TS in the form of a residual seizure disorder ("RSD") within the Table time limits of the Vaccine Act. *See* 42 U.S.C. § 300aa-14(a)(I)(D) and (E). Respondent asserted that the onset of Rachel's seizure disorder occurred outside the Table time limits. In the alternative, respondent claimed that Rachel's seizure disorder was caused by a factor unrelated, Rachel's TS. No hearings were held, as the special master found that the records were sufficient to make a

determination. On December 29, 1994, the special master issued her decision granting compensation to petitioners on the grounds that Rachel had suffered an on-Table significant aggravation of her TS. *Plavin v. Secretary of HHS*, No. 91-1555V (Fed. Cl. Sp. Mstr. Dec. 29, 1994) (original entitlement order). In so deciding, the special master took into account prior TS/DPT decisions and the testimony elicited from them. *Id.*

Prior to the grant of entitlement to compensation in *Plavin*, two cases and the testimony of the world's acknowledged expert on TS, Dr. Manuel Gomez, had established a *per se* rule whereby when an on-Table significant aggravation was demonstrated in TS cases, entitlement to compensation was virtually automatic. This theory was premised on the testimony of Dr. Gomez, taken at the Mayo Clinic on October 21, 1991. Dr. Gomez's testimony was interpreted as stating that medically, DPT could be a "trigger" of seizures in TS children, and that based on that possibility he advised that his patients with TS should not receive the DPT vaccine. Dr. Gomez's fear was that the earlier onset of seizures in TS children resulted in an outcome worse than if the seizures, if they ever started, started later. At that time, Dr. Gomez did not discount the theory

that the presence of cortical lesions on the brain of a TS child was also a factor involved in any resulting seizures and/or mental retardation.

The first case to apply that testimony was *Costa v. Secretary of HHS*, No. 90-1476V, 1992 WL 47334 (Cl. Ct. Sp. Mstr. Feb. 26, 1992) ("*Costa I*"), *vacated and remanded*, 26 Cl. Ct. 866 (1992) ("*Costa II*"), *on remand*, 1992 WL 365421 (Fed. Cl. Sp. Mstr. Nov. 5, 1992). In *Costa I*, the special master held that petitioners were entitled to an award of damages based on their proof of an on-Table RSD. On appeal to the Court of Federal Claims in *Costa II*, the court agreed that petitioners were entitled to compensation, but reversed the special master's basis for compensation of the vaccine injury as an on-Table RSD as a result of its finding that the case must be analyzed under the theory that the DPT vaccination had "significantly aggravated" the vaccinee's TS. *See Costa*, 26 Cl. Ct. at 870-71. The court held that because TS is a pre-existing condition, analysis under the "significant aggravation" prong was necessary. *Id.* In addition, the court adopted the "triggering" theory advanced by Dr. Gomez in ordering entitlement for petitioners. *Id.* at 871. As a result of *Costa*, the remaining TS cases were analyzed solely under a theory of significant aggravation.

In addition, in *Suel v. Secretary of HHS*, No. 90-935V, 1993 WL 241430 (Fed. Cl. Sp. Mstr. June 18, 1993) ("*Suel I*"), *rev'd and remanded*, 31 Fed. Cl. 1 (1993) ("*Suel II*"), *on remand*, 1997 WL 617034 (Fed. Cl. Sp. Mstr. Sept. 22, 1997), the special master initially denied compensation based upon her finding that David Suel's eyes rolling back two days after his DPT vaccination, although a seizure, was not of sufficient severity to constitute a "substantial deterioration" under the Act's definition of "significant aggravation." Therefore, the special master held that although DPT was a trigger for David Suel's first seizure, it did not significantly aggravate his TS. The decision was appealed to the Court of Federal Claims, which reversed and remanded, holding that a *single* seizure in a previously asymptomatic TS child was *per se* significant aggravation of TS as a result of the vaccine "triggering" the TS. *Suel*, 31 Fed. Cl. at 11-12. In *Suel II*, as in *Costa II*, Dr. Gomez's "triggering" theory was explicitly adopted. *Id.* at 4-5, 9, 11-12.

Therefore, based upon *Costa* and *Suel*, and Dr. Gomez's testimony, the special master initially granted entitlement to compensation in *Plavin* on the grounds that Rachel's DPT vaccination had significantly aggravated her TS in the form of an on-Table partial focal afebrile seizure. *Plavin v. Secretary of HHS*, 91-1555V (Fed. Cl. Sp. Mstr. Dec. 29, 1994). On March 24, 1995, however, respondent filed a motion for reconsideration in light of a letter from Dr. Gomez, dated February 2, 1995 and sent to respondent, that indicated that Dr. Gomez was troubled with his initial testimony as recorded in the transcript and that there is actually no concrete evidence that supports the "triggering" theory. In addition, respondent

alleged that additional new evidence in a January, 1995 article highlighted that cerebral dysfunction in TS children, resulting in seizures and mental retardation, is primarily caused by the extent of the cortical tubers in a TS child's brain. Therefore, respondent requested that the special master reconsider her decision of whether it is more likely than not that the child's current condition is due to the significant aggravation of TS resulting from the vaccination or whether the condition is primarily due to TS alone.

Several TS cases had been decided prior to the apparent availability of the "new evidence." Subsequently, all of the TS cases were transferred to Special Master Millman, and on April 11, 1996, the special master issued an "Omnibus TS Order." The order stated that "[i]n order to resolve most efficiently all of [the TS] cases, the special master has undertaken an inquiry into the general medical and scientific issues surrounding TS and immunization, with the hope that knowledge and conclusions developed from this inquiry will apply to each individual case." *Barnes et al. v. Secretary of HHS*, 92-0032V (Fed. Cl. Sp. Mstr. Apr. 11, 1996). The special master held an Omnibus Hearing in two parts -- on October 8-11, 1996 and June 3-4, 1997 -- and particularly applied the testimony elicited from such hearings to *Plavin*, and also to *Hanlon v. Secretary of HHS*, 90-1334V (another case involving TS/DPT).<sup>(3)</sup> On September 15, 1997, the special master issued her TS Omnibus Decision, issued with the caption of *Barnes v. Secretary of HHS*. While the TS Omnibus Decision discussed Rachel's case and determined that she was not entitled to compensation based upon the findings therein, on September 18, 1997, the special master issued a separate order formally denying entitlement to compensation in *Plavin* based upon the TS Omnibus Decision. *Plavin v. Secretary of HHS*, No. 91-1555V (Fed. Cl. Sp. Mstr. Sept. 18, 1997). In the same order, the December 29, 1994 order finding petitioners entitled to compensation was vacated. *Id.*

On October 20, 1997, petitioners filed a motion for review of the special master's denial of compensation in *Plavin* after the Omnibus hearing. On November 20, 1997, respondent filed its response. In their motion for review and accompanying memorandum of objections, petitioners advanced three primary arguments. First, petitioners argue that the special master's "creation" of a "coincidence" theory of "factors unrelated" was arbitrary, capricious, contrary to the case law of TS vaccine compensation claims, and contrary to the terms of the Vaccine Act. Second, petitioners argue that the special master's reopening of the entitlement issues in the absence of newly discovered evidence was arbitrary, capricious and contrary to law. Finally, the petitioners state that the special master further abused her discretion and acted in a manner contrary to law by permitting the government, over petitioners' objection, to illegally contact, hire and co-opt the testimony of the petitioners' expert, Dr. Gomez. As the requested remedy, petitioners ask the court to reinstate the rule of *Suel* for Omnibus application in TS cases that fall under the Vaccine Injury Table. Therefore, petitioners request that the court reverse and remand this case to resume fact-finding and damages. In addition, petitioners request that the court order sanctions, "in the form of damages for delay caused by improper conduct contrary to the interests of justice."

In its memorandum in response to petitioners' motion for review, respondent asserts that the special master correctly applied the factors unrelated standard in her review of the Omnibus evidence, and that the special master's conclusion that Rachel's seizure onset and current condition is due to her TS is well supported by the record. Respondent also argues that the special master's reopening of the TS entitlement proceedings was not an abuse of discretion, and that petitioners' contentions about Dr. Gomez are specious.

## DISCUSSION

As a result of the Omnibus approach utilized by the special master for this and several other TS/DPT cases, two separate records, both relevant to the outcome in *Plavin*, have been created. There is a record relevant only to *Plavin*, and a record created during the Omnibus proceeding, which considered medical issues surrounding the general causal relationship, if any, between DPT, seizures, and TS. This court has been asked to review the September 18, 1997 denial of entitlement to compensation for Rachel Plavin. It

is important to note that while this September 18, 1997 order adopted the reasoning of the TS Omnibus Decision, which specifically addressed Rachel's case, review of the factual and legal findings in the TS Omnibus Decision by this court will only be to the extent it applies to Rachel Plavin. This distinction is important in light of the parties' briefs, which largely addressed only the general findings in the TS Omnibus Decision that were intended to apply to all 22 cases captioned on that order.

The discussion below addresses the three arguments presented in petitioners' motion for review and accompanying memorandum of objections.

## **I. Standard of Review**

In reviewing the special master's decision, findings, and conclusions, the court may (1) uphold the findings of fact and conclusions of law and sustain the decision, (2) set aside any findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law," or (3) remand the petition to the special master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e) (2); see *McCarren v. Secretary of HHS*, 1997 WL 801447 at 1-3 (1997) (clarifying that the standard of review is not *de novo*, but is the narrow "arbitrary and capricious" standard for both facts and law). The scope of review for this standard is exceedingly narrow; a court "may not substitute its own judgment for that of the special master if the special master has considered all relevant factors, and has made no clear error of judgment." *Costa*, 26 Cl. Ct. at 868 (quoting *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 432 (1991)).

## **II. The Special Master's Denial of Entitlement to Compensation in *Plavin***

### **A. Statutory Requirements and Burden of Proof**

The Vaccine Act provides two principal avenues for a petitioner to seek compensation for injuries arising from the administration of a DPT vaccine. First, if a claimant suffers the first symptom or manifestation of an injury set forth on the Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14(a), or if a claimant suffers the first symptom or manifestation of a significant aggravation of a pre-existing condition, within the time period designated on the Table, then causation is presumed. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Significant aggravation is defined as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). The Act requires petitioner to demonstrate only that the symptoms, including a residual seizure disorder<sup>(4)</sup> or encephalopathy,<sup>(5)</sup> were suffered within three days of the administration of the DPT vaccination. See 42 U.S.C. § 300aa-14(a)(I)(B), 300aa-14(a)(I)(D). In addition, even after it is determined that petitioner is entitled to a Table presumption, petitioner still must prove that any damage for which compensation is sought is in fact a sequela<sup>(6)</sup> of the Table injury. 42 U.S.C. § 300aa-14(a)(I)(E); see also *Song v. Secretary of HHS*, 31 Fed. Cl. 61, 65 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 1994).

As stated above, since *Costa*, TS cases have been analyzed under the "significant aggravation" theory. In *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), the Federal Circuit clarified the appropriate test to apply to determine if petitioners have met their burden of "significant aggravation" entitling them to the presumption of causation under the Act. *Whitecotton* articulated a four-part test to: (1) assess the person's condition prior to the administration of the vaccine; (2) assess the person's current condition; (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute; and, if so, (4) determine whether the first symptom or manifestation of the significant aggravation occurred within Table-time. *Id.*

The second avenue for compensation under the Act is more difficult. If manifestation or significant aggravation of an injury not listed on the Table occurs, or if a Table injury manifested itself outside the time period prescribed in the Table, then causation is not presumed and petitioner must prove *by a preponderance of the evidence* that the vaccine *actually caused* the injury. 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (emphasis added); 42 U.S.C. § 300aa-13(a)(1)(A) (emphasis added).

Once petitioners satisfy their burden of proving presumptive or actual causation, the burden shifts to respondent to demonstrate by "*a preponderance of the evidence* that the illness, disability, injury, condition, or death described in the petition [was] due to *factors unrelated* to the administration of the vaccine." 42 U.S.C. § 300aa-13(a)(1)(B) (emphasis added). The phrase "factors unrelated to the administration of the vaccine:"

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioners' evidence or other material in the record, 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 petitioners' illness, disability, injury, condition, or death.

42 U.S.C. § 300aa-13(a)(2). Therefore, in significant aggravation cases, once the petitioner has made a prima facie case, and therefore benefits from the statute's presumption of causation, the burden shifts to the government to show, by a preponderance of the evidence, that the pre-existing condition, was, in fact, the cause of the individual's post-vaccination significant aggravation. *Whitcotton*, 81 F.3d at 1107.

Respondent's proof of alternate causation in fact, that a "factor unrelated" caused the injury at issue, is subject to the same standards that apply to a petitioners' proof of actual causation in fact in off-Table cases. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). To satisfy the burden of proving the existence of the factor unrelated, and that this alleged condition actually caused the injury, respondent must prove a "logical sequence of cause and effect." *Id.* at 548 (citations omitted). This sequence "must be supported by a sound and reliable medical or scientific explanation." *Id.* (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 2795-97 (1993)). In addition, "[t]he determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49 (citations omitted). As stated in *Knudsen*,

The Court of Federal Claims is . . . not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury or that the child's injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury.

*Id.* at 549 (citing 42 U.S.C. § 300aa-13(a)(1), (b)(1)). Therefore, "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549 (citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)).

## **B. Review of the Special Master's Omnibus Findings and Her Dismissal of *Plavin***

With the above standards and burdens as a backdrop, the special master in the Omnibus case undertook the colossal task of evaluating the evidence provided by the parties on the relationship, if any, between DPT, seizures and TS. As described above, the purpose of the Omnibus proceedings was to consider the defenses presented by respondent in support of its "factor unrelated" defense. Respondent asserted, and attempted to prove through testimony and numerous written materials, that DPT does not cause infantile spasms or any afebrile seizures. Respondent also attempted to demonstrate that TS, and not DPT, is responsible for any seizures (including infantile spasms and other afebrile seizures) in a TS child if the child has eight or more cortical tubers.

Before issuing her TS Omnibus Decision, the special master heard testimony elicited through two hearings, as stated above, and reviewed countless articles submitted by the parties.

The special master found in the TS Omnibus Decision that under the principles of *Whitecotton*, petitioners in Rachel's case "initially satisfied their burden of showing Table onset" under the significant aggravation theory as the court had previously found that "onset of seizures occurred within Table time and their current condition is obviously worse than their pre-vaccination status." TS Omnibus Decision at 64. The special master also held, however, that "respondent has successfully rebutted that presumption by showing that TS [as a "factor unrelated"] caused in fact the initial seizure as well as the current condition." *Id.* The special master based this conclusion on two general findings: (1) that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel Plavin experienced; and (2) that absent other symptoms of a vaccine reaction, infantile spasms or afebrile seizures of the type that Rachel Plavin suffered is caused by a "factor unrelated," TS. In so holding, the special master determined that DPT does not "trigger" seizures in TS children. While the special master specifically discussed Rachel's case in the TS Omnibus Decision, she also subsequently issued an order on September 18, 1997 vacating the prior grant of entitlement to compensation in *Plavin* and denying entitlement based upon the findings in the TS Omnibus Decision. Therefore, a review of the denial of entitlement requires a review of the findings in the TS Omnibus Decision as those findings affect Rachel.

In their motion for review, petitioners ask the court to reinstate the *per se* rule of *Suel*, based upon their view that the special master's new rule articulated in the TS Omnibus Decision was arbitrary, capricious, an abuse of discretion and contrary to law. Petitioners advance numerous arguments in support of their contention that the TS Omnibus Decision should be reversed in its entirety.<sup>(7)</sup> Notably, petitioners argue that the TS Omnibus rule that requires proof of a "real vaccine reaction" imposes an improper causation in fact burden on petitioners. They state that an on-Table RSD, under the "pre-change" Table, is supposed to allow petitioners a presumption of causation. In addition, petitioners contend that in her ruling, the special master failed to hold the government to its burden of demonstrating actual alternative causation with its "factor unrelated" defense. Petitioners therefore contend that the grant of entitlement to Rachel Plavin prior to the TS Omnibus Decision should be reinstated. Respondent, on the other hand, stated that the "new" rule in TS/DPT cases is well-supported by the record created in the TS Omnibus Proceedings and should be upheld, and therefore that the denial of compensation to Rachel Plavin should be upheld.

### **1. TS Omnibus Finding That DPT Does Not Cause Afebrile Seizures**

In the TS Omnibus Decision, the special master stated that the evidence presented during the Omnibus hearings supported respondent's assertion that DPT does not cause infantile spasms or any other afebrile seizures. The special master relied, among other evidence, on the opinions of Drs. Osborne and Gomez who doubted that DPT causes infantile spasms or partial afebrile seizures of the type Rachel suffered.

The court does not question that significant evidence exists to support this theory, as presented during the Omnibus Proceedings and in other forums.<sup>(8)</sup> The court does question, however, the propriety of applying this evidence to petitioners' case that falls under the pre-change Table that presumes that DPT is the cause of the RSD if the first seizure occurs within 72 hours of the DPT vaccination. *See* 42 U.S.C. § 300aa-14 (a)(I)(D) (1994) (containing the pre-change Vaccine Injury Table listing as a "Table injury" "[r]esidual seizure disorder[s]"). In their motion for review and at oral argument, petitioners argued that the special master's decision effectively repealed the relevant portions of the Vaccine Act granting a presumption of entitlement to compensation in TS cases when an on-Table RSD is demonstrated. Petitioners argue that in its general finding that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel experienced, the special master imposed an improper actual causation burden on petitioner. Respondent argues that, to the contrary, the special master repeatedly stated that petitioners were entitled to the presumption of significant aggravation when an on-Table seizure was demonstrated. Respondent argues that *Knudsen* held that once a "factor unrelated" defense is asserted, evidence of whether immunization is in fact a possible cause of a petitioners' symptoms is relevant.

The court is concerned, as were petitioners, that in making the finding that DPT does not cause infantile spasms or the type of afebrile seizure that Rachel experienced on-Table, that petitioners' presumption of causation was diminished. The court does not disagree with respondent that after reviewing *all* of the facts and evidence in a particular case, a "factor unrelated" such as TS may be shown to be the cause of the seizures rather than the DPT reaction. This finding, however, cannot be based solely on the special master's assertion that a type of seizure cannot be caused by DPT when the Act presumes that the opposite is so. Accordingly, because the court finds that the special master committed legal error in so finding, this narrow finding is reversed in *Plavin*.

## **2. TS Omnibus Finding That a Factor Unrelated, TS, Caused Rachel's Seizure**

In support of their "factor unrelated" defense, respondent attempted to prove, in the Omnibus proceedings, that if a vaccinee has eight or more cortical tubers, seizures will inevitably develop and mental retardation will occur. Respondent presented evidence in support of this theory, including, among other evidence, an epidemiological "meta-analysis" by Dr. Steven H. Lamm, pediatrician and epidemiologist, of studies on the relationship between cortical tubers and the presence of seizures in TS children. The special master, however, refused to draw the line at eight tubers, noting in her Omnibus Opinion that "there is no clear-cut correlation between number of tubers and developmental delay" among the TS children presently in the Vaccine Program. She stated:

While a large number of tubers is indeed a factor (one that Dr. Gomez mentioned in his 1991 testimony and to which all the witnesses agreed at the hearing), it is not the sole factor. As Dr. Osborne and Dr. Roach (in his editorial to the published cortical tuber count paper) as well as Drs. Shepherd, House, and Gomez in their 1995 paper, stated, other factors decisive in outcome are the tubers' size and location. We do not have all the answers yet. But, as Dr. Gomez said, biology is more than statistics. The court cannot make a statistical determination based solely on tuber count that a child would more likely than not have his current condition.

By looking at the TS children whose cases are before me, the court sees a child with 13 tubers who is vegetative, while one with 17 tubers is planning to attend college. And both have seizure disorders.

TS Omnibus Decision at 63.

Instead of focusing on the number of tubers, the special master instead focused on the presence of the tubers and found that:

Respondent has proven by a logical sequence of cause and effect that the presence of tubers in the cerebral cortex, which is the hallmark of TS, leads to seizures in the majority of TS patients. Moreover, most of those who have seizure disorders are also mentally retarded. The effect of numerous tubers, as well as their location and size, is a given. Not one witness disputes their importance.

*Id.* at 65. The special master cited, among other evidence, the studies on monozygotic twins that suggest that there is a programmed aspect to seizure onset, as well as the testimony that "surgical resection of cortical lesions results in the alleviation permanently or for a time of seizures in afflicted individuals" to show that seizures are linked to brain lesions. *Id.* In addition, the special master stated that "it makes sense ("a logical sequence of cause and effect") that brain cells that are disordered and form lesions play a role in abnormal firing of those cells, or in the cells that lie between the lesions and the normal cortex." *Id.*

As a result of the substantial evidence presented during the Omnibus proceeding, the special master, in her ruling, explicitly stated that in certain TS cases, TS rather than DPT, is the factor unrelated that causes on-Table seizures. The special master held:

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*. It begs credulity to link DPT to a seizure in a child who is not anorexic, insomniac, feverish, crying, moody, irritable, depressed, vegetative, or behaves in any other abnormal way that would lead a parent as well as a physician to assume the child was unwell. The child need not manifest all these symptoms, but in a case in which he does not manifest any of them, one could hardly be reasonable, not arbitrary, and not capricious to hold that TS, a disease known to produce seizures, and consequent mental retardation, autism, and developmental delay, is not the cause and that respondent has failed to rebut the presumption that DPT is the cause.

*Id.* at 62 (emphasis added). Later in the opinion, the special master again stated that TS, and not DPT, is the cause in fact of a seizure "when a TS child receives a DPT vaccine and remains perfectly normal (in temperature, eating, sleeping, affect and activity)." *Id.* at 63. She went on to say that "[t]his is so whether or not the initial seizure takes the form of an infantile spasm or some other type of afebrile seizure such as . . . Rachel Plavin had." *Id.* at 63-64.

In the Omnibus Decision, the special master applied her holding to Rachel's case, by referring to Rachel's parents' account of the initial seizure allegedly on the day of Rachel's second DPT shot, that Rachel was "staring, her left arm shook, and she drew her legs up." *Id.* at 66. In addition, the special master cited the hospital's account of Rachel's mother's history of Rachel's condition following the second DPT vaccination, in which she stated that "Rachel had been healthy until she noticed occasional trembling of her left hand while she nursed and one blank stare." *Id.* In addition, Rachel's mother did not give an onset date, but stated that Rachel did not have a reaction to her DPT vaccination ten days earlier. *Id.* The special master stated that subsequent histories of Rachel's condition characterized the first seizure as occurring on the day of the DPT vaccination while nursing when "Rachel's left arm vibrated and she began shaking and staring." *Id.* The special master then held that "Rachel's symptoms seem to be totally unrelated to the DPT vaccination and purely coincidental." *Id.* The special master stated that "[i]n her mother's mind, she was not having a DPT reaction. These symptoms are typical of a TS child's initial seizures." *Id.* Then the special master added that "[o]ne should also note that Rachel has 43 or more cortical tubers, making up a substantial percentage of her cortex." *Id.* Finally, the special master stated that "[b]ased on the court's above holdings, the onset of Rachel's seizures was coincidental to her second DPT vaccine." *Id.*

To support her conclusion on Rachel, the special master relied on the testimony of Dr. Charles R. Fitz, a pediatric neurologist, who after studying Rachel's MRI stated that Rachel has at least 43 tubers, and that based on her 1990 MRI, between 20-30% of her cortex and subcortex are tubers. *Id.* at 56. In addition, the special master heavily relied upon the testimony of Dr. Gomez, who reviewed Rachel's medical records to come to the conclusion that "the cause of Rachel Plavin's seizures is her cortical lesions." *Id.* at 42, 61. In addition, the special master relied on the testimony of Dr. Mary Ann Guggenheim, a pediatric neurologist, to confirm that "Rachel Plavin's course was due to TS." *Id.* at 57. In addition, the special master relied upon the record submitted in support of Rachel's petition.

In their motion for review, petitioners argue that the special master failed to hold respondent to proving that TS is indeed a "factor unrelated" and that it not only existed in Rachel's case, but that TS caused her on-Table seizure. The court finds both arguments to be invalid. First, the evidence more than adequately supports the special master's finding that TS fits the "factor unrelated" definition. TS is a well-established and explained disease with a known genetic origin unrelated to the administration of any vaccine. Although petitioner argues that TS does not fit the two-prong test enunciated in *Bernard v. HHS*, No. 90-2720V, slip op. (Fed. Cl. Jan. 30 1997), to determine whether a disease can be a "factor unrelated," unlike Aicardi Syndrome, which was found in *Bernard* to be idiopathic, the two-prong test with respect to TS is satisfied in this case as the TS causing gene has been identified and evidence of the actual syndrome has been established. Even petitioners' expert, Dr. John Osborne, affirmed the special master's opinion that TS is a well-explained and non-idiopathic disease. As a result of all of the evidence elicited during the Omnibus proceedings, the special master's finding that TS can properly be a "factor unrelated" was not arbitrary, capricious or contrary to law.

Petitioners also argue that pursuant to the "factor unrelated" analysis in *Knudsen*, while respondent may have identified TS as a "factor unrelated," it did not actually prove that TS caused the injury. *See Knudsen*, 35 F.3d at 549 (requiring the government to prove that the factor unrelated not only exists but actually caused the Table injury complained of). This argument is also specious in light of the special master's more than adequate analysis of how the cortical tubers in TS patients cause seizures. *Knudsen* requires that the government prove that the factor unrelated was "principally responsible for causing the injury." *See Knudsen*, 35 F.3d at 550. The court is impressed with the weight of the evidence supporting the special master's finding that TS is, more likely than not, the cause, or the "factor unrelated" to the administration of the vaccine, of seizures in Rachel's case, absent some other symptom or reaction to DPT. Respondents presented substantial evidence on how the lesions on a TS child's brain contribute to the child's seizure disorder. As described above, the special master's general analysis of the Omnibus testimony and evidence submitted is sound. In addition, both her Omnibus opinion and the record indicates that the special master went to great lengths to carefully apply the appropriate legal standards and burdens in this case.

However, while the weight of the evidence supports the special master's TS Omnibus Decision, the court remains concerned that in making her finding that Rachel's TS, as a factor unrelated, caused Rachel's on-Table seizure, the special master relied upon her finding above that DPT does not generally cause infantile spasms or the type of afebrile seizures that Rachel suffered. Nowhere in her analysis is it clear whether the finding, that TS is the "factor unrelated" in *Plavin*, where allegedly no other vaccine reaction presented itself, can stand on its own absent the finding that DPT does not generally cause Rachel's type of afebrile seizure. Therefore, the court remands this part of the special master's decision in order for the special master to clarify whether her finding that TS is the "factor unrelated" that caused Rachel's on-Table seizure still stands absent the finding that DPT does not cause the type of afebrile seizure that Rachel experienced.

### **3. Whether "Other Symptoms" May Have Accompanied Rachel's Seizure**

As stated above, the special master articulated a standard in TS cases whereby in instances in which a TS child suffers afebrile seizures within Table time allegedly as a result of a DPT vaccination, that TS, rather than the DPT vaccination, is the factor unrelated that actually caused the seizure *absent any other symptoms of a vaccine reaction*. Notably absent, however, from the record in the Omnibus proceedings is any indication that the special master considered evidence on the role of other *symptoms of a vaccine reaction* in TS/DPT cases, such as what those symptoms may be and how they may relate to either DPT vaccines or possibly to TS. And, of particular interest to this court, is whether Rachel Plavin actually had any other such symptoms, and if so, whether those symptoms can be causally related to the DPT vaccination from which petitioners alleged Rachel suffered a reaction. While the special master, in her TS Omnibus Decision, stated that "Rachel's symptoms seem to be totally unrelated to the DPT vaccination and purely coincidental," and that "these symptoms are typical of a TS child's initial seizures," absent from the record, the TS Omnibus Decision, and the subsequent order vacating the prior grant of entitlement to Rachel and dismissing the petition, is any evidence or discussion of whether Rachel's Table time injury included any "symptoms" outside of the seizures that allegedly are "caused" by Rachel's TS. See TS Omnibus Decision at 66.

In support of its concerns, the court points the special master to a portion of Rachel's medical records encompassing a letter written on March 15, 1991, from Rachel's pediatrician, Dr. Jacqueline Campbell, documenting the events that led up to the diagnosis of seizure disorder and subsequently TS in Rachel. On the day of the second DPT vaccination, Dr. Campbell noted that Rachel's mother telephoned her to discuss:

Rachels [sic] fussiness and apparent abdominal cramping. She also mentioned observing an occasional brief arm tremor without other symptoms.

*Plavin v. Secretary of HHS*, No. 91-1555V, Pet. for Vaccine Compensation, Medical R. at 289. While the court makes no findings as to whether the symptoms described above and in other portions of Rachel's medical records are indicative of an afebrile seizure or another type of vaccine reaction, it questions, for example, whether *fussiness* could be interpreted as a symptom of vaccine injury outside of the seizure allegedly caused by Rachel's TS. Therefore, the court remands to the special master in order to consider specifically whether Rachel Plavin had a "vaccine reaction" outside of her afebrile seizure. The court notes that petitioner mentioned during oral argument in this phase, and the record supports, that petitioners were not afforded a hearing as to Rachel's particular situation. While petitioners indicated they did not think such a hearing was necessary based on their arguments that the entire Omnibus opinion should be reversed, the court surmises that in the absence of such reversal, such a hearing would allow petitioners their opportunity to present any evidence, if available, that Rachel experienced any symptoms of a vaccine reaction outside of her seizure.

### **III. The Special Master Did Not Commit Reversible Error in Reopening the Proceedings on Entitlement**

In their motion for review, the petitioners fault the special master's decision to reopen entitlement proceedings in *Plavin* and in other TS cases in order to hear allegedly new evidence on the possibility that TS is the "factor unrelated" which caused the Table injury in TS cases. As stated above, on December 29, 1994, the special master issued her initial decision granting entitlement to petitioners in *Plavin*, as petitioners had satisfied their burden of showing Rachel having an on-Table onset of seizures which constituted a significant aggravation of her TS. The special master based her decision on Dr. Gomez's October 21, 1991 testimony that DPT may "trigger" the onset of seizures in TS children. *Plavin v. Secretary of HHS*, No. 91-1555V (Ct. Fed. Cl. Sp. Mstr. Dec. 29, 1994). Further support for her decision was based on the record submitted by petitioners, and on the report petitioners' expert, Dr. Kinsbourne, that Rachel's onset of seizures was on the same day of her second DPT vaccination. *Id.*

On March 24, 1995, respondent filed a motion for reconsideration of the December 29, 1994 grant of entitlement to compensation to petitioners in *Plavin* and in other TS cases. Respondent alleged that new evidence had surfaced which discounted the original testimony of Dr. Gomez on the "triggering" effect of DPT on TS children. Notably, respondent filed a letter from Dr. Gomez, dated February 2, 1995, that indicated that Dr. Gomez was troubled with his initial testimony and that there is actually no concrete evidence that supports this "triggering" theory. In addition, respondent cited an article published in January, 1995 that highlighted cerebral dysfunction, resulting in seizures and mental retardation, is primarily caused by the extent of the cortical tubers in a TS child's brain. Therefore, based on this evidence, respondent requested that the special master reopen the entitlement proceedings in all TS cases in which entitlement to compensation had been decided, in order to determine whether the original "triggering" theory was indeed accurate.

Petitioners objected to the reopening of entitlement. The special master, however, was interested in the new evidence and reasonably decided to reopen entitlement in all TS cases under the Vaccine Program, in an "Omnibus" fashion, in order to provide an efficient forum to address the complex medical and scientific issues involved in all of the TS cases. The discussion above describes the nature and outcome of those proceedings.

In their motion for review, petitioners revisit this issue of reopening the proceedings in order to consider the new, and additional, evidence, supporting a "factor unrelated" case. Petitioners allege that at the time the entitlement proceedings were reopened, the evidence respondent proffered in support of the reopening was not "newly discovered," that the reopening itself was arbitrary, capricious and contrary to law, and that the reopening frustrated Congressional intent for the Vaccine Act to provide a "no-fault" remedy in a quick and inexpensive forum. Respondent argues that the special master in no way abused her discretion in hearing the Omnibus evidence in this case, because the reopening of the entitlement proceedings before a final judgment was entered was clearly within her discretion, particularly in the context of the flexible evidentiary rules of the Vaccine Program. Furthermore, respondent states the reopening was a result of the special master's correct interpretation of the situation as necessary to ensure fundamental fairness to both parties.

The court reviews the special master's rulings on evidence for abuse of discretion. *See Munn v. Secretary of HHS*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992). Under the abuse of discretion standard, this court can only reverse for an error in interpreting law, or exercise of judgment on clearly erroneous findings of material fact, or irrational judgment in weighing relevant factors. *See, e.g., Chiu v. United States*, 948 F.2d 711, 713 (Fed. Cir. 1991) (citations omitted). Under the authority granted by 28 U.S.C. § 2071 (1994), and 42 U.S.C. § 300aa-12(d)(2), the Court of Federal Claims has promulgated rules of procedure for use by special masters.<sup>(9)</sup> These rules are governed by principles of fundamental fairness to both parties. *See Dickerson v. Secretary of HHS*, 35 Fed. Cl. 593, 598 (1996). Overall, the Vaccine Rules accord the special master extensive discretion in conducting proceedings.

The record reveals that the special master acted well within her discretion in reopening the TS entitlement proceedings. The grant of entitlement in *Plavin* and in TS cases decided prior to it gave great weight to the 1991 testimony of Dr. Gomez that DPT could "trigger" the onset of seizures in children with TS. *See Costa*, 26 Cl. Ct. at 871; *see also Suel*, 31 Fed. Cl. at 4-5, 9, 11-12. In fact, that testimony led to the establishment of a per se grant of entitlement for TS children after it was established that the "significant aggravation" occurred within Table time. In light of the importance of Dr. Gomez's opinion on this matter, it was hardly an abuse of discretion for the special master to express interest in this new evidence. In addition, the article presented by respondents on the relationship between cortical tubers and seizures provided additional evidence that perhaps TS was the cause of the seizures. Accordingly, the court finds that the special master acted properly and did not abuse her discretion in reopening the proceedings based on this evidence.

In addition, the court agrees with the test promulgated by *Vant Erve v. Secretary of HHS*, 39 Fed. Cl. 607 (1997), which reversed a decision by a special master denying respondent's motion to reopen the issue of entitlement when new evidence had surfaced on the condition of the petitioner following a DPT vaccination.<sup>(10)</sup> While *Vant Erve* considered whether to reopen the entitlement proceedings in light of new medical information specific to the petitioner, and in *Plavin* the issue whether to reopen centered around general information on whether DPT "triggered" the onset of seizures in TS children, both cases where in the same procedural posture, namely that the liability phase had ended, the special master had issued a ruling on entitlement, but a final judgment had not yet been entered. *See id.* at 612 (stating further that the standards of Federal Rule of Civil Procedure 60(b)(2) for relief from judgment did not directly apply at that procedural posture). Therefore, application of the *Vant Erve* test here is appropriate.

In *Vant Erve*, the court adopted a four-factor test to judge whether reopening the record is appropriate: "(1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay." *Id.* While the special master in this case may not have applied this test verbatim, the record indicates that she took the relevant aspects of the test into consideration. As stated in *Vant Erve*, the first factor, the nature of the new evidence, is "paramount," and if the new evidence is "both relevant and affective of outcome," the other factors' importance diminishes. *Id.* As stated above, the relevance of the new evidence in *Plavin* was substantial. If Dr. Gomez had in fact changed his mind or disagreed with the way his prior evidence had been analyzed, the outcome of at least some of the TS cases would likely change. In addition, while evidence that the extent of the cortical tubers influenced greatly the severity of a child's seizures or mental retardation had been present when the initial entitlement decision was made, respondent in submitting the new article stated that the article provided updated and probative evidence that this was so. In light of the potential effect of these two pieces of evidence, the special master did not abuse her discretion in reopening the proceedings.

Second, while petitioners asserted the delay and expense of continuing with the TS entitlement proceedings to show prejudice in reopening the proceedings, as the court stated in *Vant Erve*, such considerations are not of primary importance. *Id.* at 613-14. Rather, the record of Rachel's condition had been adequately preserved, and the same witnesses in the prior proceeding were coming forward with their new thoughts on TS. *See id.* at 614. Therefore, petitioners were not unduly prejudiced. Third, the length of the delay was "of diminished importance" as the final judgment had not yet been entered, and the new evidence was highly probative of whether the initial grant of compensation was proper. *See id.* at 614-15. Finally, the reason for the delay, as described above, more than adequately overrode any prejudice to the parties. The special master's decision to reopen the entitlement proceedings in the TS cases was entirely proper in light of the new evidence proffered by respondent. For these reasons, the court firmly denies this portion of petitioners' motion for review.

#### **IV. The Special Master Did Not Commit Reversible Error in Permitting Respondent to Contact Dr. Gomez, to Contract With Him, and to Present Him as a Witness**

In their motion for review, petitioners further argue that "by permitting the government over objection to illegally contact the petitioners' expert Dr. Gomez, hire him away from petitioners, hide him from discovery, and ultimately to co-opt his testimony, the special master

abused her discretion and acted in a manner contrary to law." Pet'r's Mem. of Objections at 64. Petitioners allege that:

The special master **grossly** abused her discretion by allowing the government to steal away and co-opt Dr. Gomez, re-open the cases based on his equivocal and cryptic statements, and shield him from

participation in trial proceedings (where he would have supported petitioners' theory of recovery), only then to allow him to present his opinion testimony, which he was induced to change **subsequent to the trial**, to favor the government's case on a peripheral and legally irrelevant point.

*Id.* at 67-68 (emphasis in original). Therefore, they allege that Dr. Gomez was originally their "expert" witness, and that the special master later allowed the "theft" of Dr. Gomez by respondent, resulting in "a miscarriage and mockery of justice."<sup>(11)</sup> *Id.* at 68. Accordingly, petitioners request a remedy of sanctions, "in the form of damages for delay caused by improper conduct contrary to the interests of justice." *Id.*

The record reveals that petitioners' irresponsible and intemperate attacks upon the special master are wholly without merit. The Special Master's decision on allowing respondent to contact Dr. Gomez, and ultimately present him as a witness, was proper and not an abuse of discretion. The Vaccine Act contemplates evidentiary flexibility and informality in proceedings. The Vaccine Rules state that "[t]he special master shall determine the nature of the proceedings, with the goal of making the proceedings flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case . . ." Vaccine Rule 3(b). Indeed, the Vaccine Act itself mandates a "less-adversarial, expeditious, and informal proceeding" which "include[s] flexible and informal standards of admissibility." 42 U.S.C. § 300aa-12(d)(2). As both parties stated in their briefs, the special master is entitled to direct discovery as she sees fit and that "there shall be no discovery as a matter of right." Vaccine Rule 7. In addition, "[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b). In addition, "[i]n conducting a proceeding on a petition a special master . . . may require the testimony of any person . . . as may be reasonable and necessary." 42 U.S.C. 300aa-12(d)(3)(B)(iii). The special master is allowed to, and frequently did in the Omnibus proceedings, ask her own questions of a witness. *See* Vaccine Rule 8 (e).

Overriding the analysis of whether it was improper for the special master to allow respondent to contract with Dr. Gomez as an expert witness after petitioners had allegedly presented him as a witness at the October, 1991 hearing, is the fact that it is undisputed that Dr. Gomez is *the world's expert on Tuberculous Sclerosis*. Throughout the record, he is consistently referred to as the world's expert by petitioners, respondent and the special master. For the special master to be interested in his testimony is indeed valid. The special master indicated on more than one occasion that she was not so concerned about who brought Dr. Gomez to her, she was more concerned with simply hearing his opinion on whether he had changed his mind. In fact, at one point she advised the parties on the subject of Dr. Gomez that "where someone is unique, because the area is limited in the number of people who could truly be considered experts, his testimony does not belong to anybody." *Barnes*, 92-0032V, Omnibus TS Proceedings, Tr. of Status Conf., May 30, 1997, at 15. In addition, the special master stated that "where someone has the expertise of Dr. Gomez, the fact that one side or another calls him, I frankly do not believe influences him that much." *Id.* In another status conference, the special master responded to petitioners' concerns on Dr. Gomez that:

I've asked for Dr. Gomez forever to be here, the Government is providing him in this hearing because I asked for him. I want him because he's the world's expert, everybody defers to him in the issue of tuberculous sclerosis. If he has changed his opinion about things he has said before, I want to know the basis of that. You might jump up and down and say, that's wonderful, he's not believable because he's reversed himself. Well, maybe that's true. I have to decide that.

*Barnes*, 92-0032V, Omnibus TS Proceedings, Tr. of Status Conf., April 11, 1997, at 22-23. Finally, in response again to the petitioners concerns that Dr. Gomez was no longer petitioners' witness, the special master stated, "Mr. Moxley, consider [Dr. Gomez] my witness, except for the fact that I'm not paying

him. I want to know certain answers to questions that I have, and he's the only one that could answer them, because he is the world's premier expert in tuberous sclerosis." *Id.* at 37.

By approving of the government's contracting with Dr. Gomez and stating that no ethical violations had occurred, the special master was focusing on her role of determining whether DPT actually had any role in "triggering" seizures in TS children. The special master was not concerned with who brought Dr. Gomez to her, she was simply concerned that he testify. In addition, the record indicates that she took into account petitioners concerns of impropriety, and was determined to make her own credibility determination of Dr. Gomez. She ultimately gave the testimony of Dr. Gomez great weight in her findings in the TS Omnibus Decision, only after hearing petitioners' cross-examination of Dr. Gomez and by questioning Dr. Gomez herself. The court has reviewed the extensive record documenting petitioners' objections to respondent's contracting with and presenting Dr. Gomez in the Omnibus proceedings. The special master was well within the bounds of reason and in no way abused her discretion in allowing respondent to present Dr. Gomez as their witness and in discounting petitioners concerns. The record indicates and the court finds that petitioners argument is specious. Accordingly, petitioners' motion for review on this issue is denied. The court also wholly denies petitioners' request for sanctions.

### CONCLUSION

The court has carefully investigated all of petitioners arguments and allegations, of which there are many, in petitioners motion for review. Among other things, the court has carefully reviewed all of the legal and factual conclusions of the special master in *Plavin*, which in her decision on entitlement adopted the reasoning and findings of the TS Omnibus Decision. In addition, the court has carefully reviewed the record with respect to petitioners' arguments on the propriety of the special master's reopening the *Plavin* entitlement proceedings and with respect to Dr. Gomez as respondent's witness in the Omnibus proceedings. For the foregoing reasons, the court directs the following:

(1) petitioners' motion for review is granted with respect to the special master's finding that DPT does not generally cause infantile spasms or afebrile seizures such as the one Rachel Plavin suffered, and accordingly the court reverses the special master on this finding;

(2) the special master's finding that TS is the "factor unrelated" which causes afebrile seizures absent other symptoms of a vaccine injury is remanded for further findings with respect to;

(a) whether the special master would uphold this finding without the benefit of her finding reversed above that DPT does not generally cause infantile spasms or afebrile seizures of the type that Rachel Plavin experienced; and

(b) whether Rachel Plavin actually experienced any symptoms of an on-Table vaccine injury outside of her seizure;

(3) petitioners' motion for review is denied as to its contentions that the special master was arbitrary, capricious, or that she did not act in accordance with law in reopening the proceedings on entitlement; and

(4) petitioners' motion for review, including its request for sanctions, is denied as to its allegations that the special master allowed certain improprieties on the part of the government with respect to Dr. Gomez.

In accordance with 42 U.S.C. § 300aa-12(e)(2), the court orders that the special master issue her decision on remand within 90 days of this order.

**IT IS SO ORDERED.**

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**MOODY R. TIDWELL**

*Judge*

1. In referring to petitioners' motion for review, the court is also referring to the accompanying memorandum of objections.
  2. The court's page references to the TS Omnibus Decision will refer to the version issued by the special master on September 15, 1997, as amended September 18, 1997.
  3. While the TS Omnibus Decision only applied the evidence elicited from the TS Omnibus Proceedings to the *Plavin* and *Hanlon* cases, the special master is subsequently applying such evidence to each TS case in the Vaccine Program.
    4. An RSD occurs if:  
the petitioner did not suffer seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if-- . . . (B) [in the case of a DPT vaccine], the first seizure or convulsions occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsion occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.  
42 U.S.C. § 300aa-14(b)(2).
- While RSD was removed from the Table effective March 10, 1995, *see* 42 C.F.R. § 100.1-100.3, Rachel's petition was brought in 1991 when RSD was still a "Table injury." *See* 42 U.S.C. § 300aa-14(a)(I)(D). Accordingly, Rachel's petition is considered under the "pre-change" Table. *See* 42 U.S.C. § 300aa-14(c)(4) ("[a]ny modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.").
5. "Encephalopathy" means "any significant acquired abnormality of, or injury to, or impairment of a function of the brain." 42 U.S.C. § 300aa-14(b)(3)(A).
  6. "Sequela" is defined as "an abnormal condition resulting from a previous disease." Random House College Dictionary 1201 (1<sup>st</sup> ed. 1982).
  7. As noted above, complicating the analysis is the omnibus approach taken in this case. Petitioners, in their motion for review, argued almost exclusively in general terms as to why the TS Omnibus Decision is faulty. As the court stated above, its review is limited to the affect of the TS Omnibus Decision on *Plavin*. Therefore, petitioners' arguments, while general, are interpreted solely in that light.
  8. In fact, the court recognizes that the United States Department of Health and Human Services changed the Table, effective March 10, 1995, to remove RSD as a Table injury following DPT vaccination. *See supra*, note 3.
  9. The Vaccine Rules of the Office of Special Masters are found in Appendix J of the Rules of the Court of Federal Claims (hereinafter "Vaccine Rules").
  10. As noted by respondent in its Notice of Supplemental Authority, filed January 14, 1998, petitioners' reliance in its Motion for Review on Special Master Hastings' denial of respondent's motion to reopen the issue of entitlement was flouted by the Court of Federal Claims' reversal of that decision on November

21, 1997. *See Vant Erve*, 39 Fed. Cl. at 607, 616.

11. The record indicates that Dr. Gomez's "status" at the Mayo Clinic precluded him from contracting with any litigant, including petitioners, prior to his attaining Emeritus Status. His testimony in October, 1991 was presented through petitioners as a result of his being the attending physician for some of the TS children (other than Rachel Plavin) in the Vaccine Program. Subsequent to his attaining Emeritus status, respondent did formally contract with Dr. Gomez to be a retained expert witness in the Omnibus proceedings.