# OFFICE OF SPECIAL MASTERS

## No. 90-1335V

## (Filed: February 20, 2001)

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JOHN C. HULBERT and WILMA A. HULBERT,	*
Parents and Next Friends of	*
TREVOR KENNETH HULBERT,	*
	*
	*
Petitioners,	* <b>TO BE PUBLISHED</b>
	*
V.	*
	*
SECRETARY OF HEALTH AND	*
HUMAN SERVICES,	*
	*
Respondent.	*
	*
* * * * * * * * * * * * * * * * * * * *	*

<u>Robert Moxley</u>, Cheyenne, WY, for petitioners. <u>Mark W. Rogers</u>, Washington, DC, for respondent.

## **DECISION**

## MILLMAN, Special Master

#### Statement of the Case

On behalf of Trevor Hulbert (hereinafter, "Trevor"), petitioners filed a petition on September

25, 1990 for compensation under the National Childhood Vaccine Injury Act of 1986<sup>1</sup> (hereinafter,

the "Vaccine Act" or the "Act"). Petitioners satisfied the prerequisites required in Section 300aa-

<sup>&</sup>lt;sup>1</sup> The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

11(c) of the Act by showing that Trevor has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, and that DPT vaccine was administered to Trevor in the United States.

Petitioners allege that Trevor suffered significant aggravation of his pre-existing tuberous sclerosis (TS) within the Table time limits of the Act. 42 U.S.C. § 300aa-14(a). Respondent defends that Trevor's seizure disorder was caused by a known factor unrelated: TS. 42 U.S.C. § 300aa-13(a)(1)(B).

Initially, two hearings were held: October 21, 1991 (at the Mayo Clinic) and November 16, 1994. Testifying for petitioners were Dr. Manuel Gomez at the Mayo Clinic (1991), and Dr. Wilma Alice Hulbert (1994). The November 16, 1994 hearing was restricted to the issue of the onset of Trevor's seizures.

In an unpublished decision, dated December 28, 1994, the court held that the onset of Trevor's seizures was on-Table after his DPT vaccination. During that hearing, the undersigned did not hear any expert testimony.

This case became part of the TS Omnibus hearing that included six days of expert medical testimony on October 8-11, 1996, and June 3-4, 1997. The undersigned issued a lengthy opinion on the TS cases on September 15, 1997. <u>Barnes, et al. v. Secretary, HHS</u>, No. 92-0032V, et al., 1997 WL 620115 (Fed. Cl. 1997), <u>aff'd sub nom.</u>, <u>Hanlon v. Secretary, HHS</u>, 40 Fed. Cl. 625 (March 20, 1998), <u>aff'd</u>, 191 F.3d 1344 (Fed. Cir. Sept. 8, 1999), <u>reh'g denied</u> (Oct. 20, 1999), <u>cert. denied</u>, <u>\_\_\_\_</u>U.S. \_\_\_\_, 120 S.Ct. 2212, 147 L.Ed.2d 245 (May 30, 2000); and <u>Plavin v. Secretary, HHS</u>, 41 Fed. Cl. 671 (Aug. 25, 1998), <u>aff'd</u>, 184 F.3d 1380 (Fed. Cir. Sept. 8, 1999), <u>reh'g denied</u> (Oct. 20, 1999).

The Federal Circuit affirmed the undersigned's holding that respondent had satisfied her burden of proving that TS is the known factor unrelated to the vaccine that caused in fact the vaccinees's worsened symptoms and that DPT does not cause afebrile seizures in a vaccinee with TS. Therefore, DPT did not significantly aggravate the vaccinees's TS. Infantile spasms are a type of afebrile seizure.

On September 24, 1997, the undersigned issued an Order in the instant action stating the court needed expert testimony to determine if Trevor experienced significant aggravation of his TS. Trevor experienced more than afebrile seizures within three days of his DPT vaccination, i.e., swelling, redness, and heat at the vaccine site, low fever, and a little fussiness. The issue before the court was whether Trevor's swelling at the vaccine site, low fever, and fussiness were merely a transient reaction to DPT or part of a more involved reaction including his twitching, grunting, and lifting his hand while feeding.

On January 28, 2000, the undersigned held a hearing in this case as well as in two other cases.<sup>2</sup>

#### WRITTEN SUBMISSIONS

Respondent filed a report from Dr. Robert A. Zimmerman, a neuroradiologist, who reviewed Trevor's MRI dated June 17, 1998. He noted prior surgery on the left posterior front, anterior parietal portion of the skull. He saw two areas of abnormalities, both subcortical, which could be subcortical tubers. One is high on the left in the posterior frontal region, and the other is lower on

<sup>&</sup>lt;sup>2</sup> <u>Milo E. Decker and Karla K. Decker, Parents and Next Friends of Destry Decker v.</u> <u>Secretary, HHS</u>, No. 90-1115V, and <u>Milo E. Decker and Karla K. Decker, Parents and Next</u> <u>Friends of Damien Decker v. Secretary, HHS</u>, No. 90-1116V.

the left in the posterior frontal, anterior parietal region. Dr. Zimmerman thought it possible that Trevor has a forme fruste<sup>3</sup> of TS with a very limited intracranial expression. R. Ex. S.

Petitioners filed a report from Dr. Roy D. Strand, a pediatric neuroradiologist, dated April 7, 1999, stating that he reviewed Trevor's MRI dated June 17, 1998 and found a single, left high hemispheric expansion or mass that altered the brain surface configuration which was nonspecific as to a particular condition. P. Ex. 14.

#### TESTIMONY

Because petitioners benefit from the statutory presumption at that time that DPT caused Trevor's seizures since they occurred within three days, respondent's witness testified first. Tr. at 221. Respondent put on Dr. Max Wiznitzer, a clinical pediatric neurologist. *Id.* He did a pediatric residency for three years and a fellowship in developmental disorders. Tr. at 17. He is also an examiner for the American Board of Psychiatry and Neurology and teaches at the Case Western School of Medicine. Tr. at 18. One of his areas of expertise is behavioral neurology, specifically autism. Tr. at 19. He sees 60 to 70 patients a week. Tr. at 20. He has both a hospital clinic and two private offices. Tr. at 20-21. At least fifteen of his current patients have TS. Tr. at 22. Over the years, he has seen 40 to 50 children with TS. *Id.* He has seen at least 1,200 patients with autism. Tr. at 23. Dr. Wiznitzer has been a reviewer for peer-reviewed journals such as *Neurology, Annals of Neurology*, and *Lancet. Id.* 

Dr. Wiznitzer's opinion is that TS is the cause of Trevor's condition. Tr. at 223. Trevor had spells, drawing up of his legs, 10 to 15 of these episodes in a row, seizures involving his right side,

<sup>&</sup>lt;sup>3</sup> "Forme fruste" is "an atypical, especially a mild or incomplete, form, as of a disease or anomaly." <u>Dorland's Illustrated Medical Dictionary</u> 27<sup>th</sup> ed. (1988), p. 653.

flexor spasms, and spasms with a focal component. Tr. at 225. His seizures were persistent. *Id.* Phenobarbital did not stop them and he improved on Depakene only for a time. *Id.* Trevor's seizures clearly evolved to infantile spasms. *Id.* He received ACTH in February 1986. *Id.* Trevor's seizures stopped prior to surgery, although some records say that he had some seizures. *Id.* On May 16, 1986, Trevor had brain surgery to resect a mass in his left frontal lobe (a cortical tuber). Tr. at 226. The records all agree that his seizures stopped at that time. *Id.* After surgery, Trevor showed delayed developmental progress. Tr. at 227.

After Trevor was weaned from ACTH, he improved. *Id.* He never had any deterioration or loss of developmental function. *Id.* When he was on Phenobarbital, Trevor was sedated. *Id.* When he was on ACTH, he was irritable and had hypertension. *Id.* 

Today, Trevor is mentally retarded and significantly delayed with autistic features. Tr. at 228. He has had recurrence of partial seizures, five episodes a day, due to two remaining tubers. *Id.* According to Dr. Wiznitzer, TS has caused his mental retardation, autistic disorder, epilepsy, and behavioral problems. Tr. at 229. This is what one sees in children with TS. Tr. at 230.

Trevor has seizures involving the right side of his body because he has tubers in his left frontal region, and may also have tubers in his left parietal region. *Id.* He has an EEG focus on his right side which implies that there is something more going on in his brain than we know. *Id.* There is an anatomic and clinical correlation between tuber location and seizure focus. *Id.* When Trevor's left tuber was removed, his seizures stopped. *Id.* There is a one-on-one correspondence. Tr. at 231. Fifty percent of TS resections result in seizure control. *Id.* After more than five years, Trevor had a seizure relapse because another epileptic tuber took over. *Id.* 

Three of Dr. Wiznitzer patients have had resections and all of them relapsed due to irritants in the brain. *Id.* No external factor prompted the new onset of their seizures. Tr. at 232. TS caused Trevor's mental retardation. *Id.* In children with a small number of tubers, 40 percent of them have mental retardation and seizures. Tr. at 232-33. The seizures that Trevor had after he was immunized were ongoing from October 1985 through February 1986 (at least four months) with more partial seizures that later became infantile spasms. Tr. at 233-34.

Trevor has severe mental retardation. Tr. at 234. At the age of five years, he behaved at a year to a year and one-half level. *Id.* Trevor's ongoing seizures do not explain his severe loss. *Id.* The Mayo Clinic recorded him as having an intact cognitive level on January 22, 1986. Tr. at 235-36. They describe him as alert and active approximately one month after the onset of seizures. Tr. at 235. This is not descriptive of developing a significant encephalopathy at that time. Tr. at 236.

Autism is distinct from mental retardation. Tr. at 237. The cause of Trevor's mental retardation is his TS. Some "wiring" issue has caused his autistic disorder. His ongoing seizures may contribute as well. *Id.* Doctors are not sure what the wiring problem is that causes autism, but there is one. *Id.* One tuber can cause seizures. Tr. at 239. It depends on the rest of the brain's wiring whether there will be mental retardation. *Id.* Trevor's first seizures were partial. *Id.* There was a clearly defined anatomic focus. Tr. at 239-40. TS caused them because Trevor had a lesion on the left side of his brain. Tr. at 240. If a tuber is going to "act up," it will act up. *Id.* There is no human biologic model that shows that DPT causes seizures. *Id.* Trevor had an epileptogenic focus in his brain. *Id.* His partial seizures led to infantile spasms. Tr. at 241.

Trevor's swelling at the vaccine site, fussiness, and low fever were a localized reaction to DPT. Tr. at 242. He was still feeding and interactive. *Id.* He did not have a global problem such as encephalopathy. Tr. at 243. We do not know what his temperature was at the time. *Id.* A temperature of 103 to 104° will trigger seizures, but a low-grade temperature of 100° will not. *Id.* Even if we assume that Trevor's fever caused his first seizure after DPT, it still has no impact on his current condition. *Id.* He was destined to develop seizures and they stopped but then resumed. Tr. at 243-44. We cannot account for all of Trevor's problems by saying there is a dementing process due to his seizures. Tr. at 244. After his seizures stopped, Trevor did well. *Id.* 

On cross-examination, Dr. Wiznitzer stated that seizures could be a role in Trevor's mental retardation; he cannot exclude them. Tr. at 245. Perhaps ten percent of the mental retardation is due to seizures and 90 percent is due to his TS, but this is conjectural. Tr. at 245-46. Dr. Robert A. Zimmerman, examining Trevor's recent MRI (June 17, 1998), opined he had a "forme fruste," which Dr. Wiznitzer interpreted as a limited expression rather than a full-blown picture of TS. Tr. at 247. Subcortical tubers can cause seizures. *Id.* It depends on how subcortical they are. *Id.* One would not expect Trevor's severe outcome based on his MRI. *Id.* Trevor is significantly impaired. Tr. at 248. Trevor has key areas of the brain where the wiring is not normal. Tr. at 251.

Dr. Marcel Kinsbourne testified for petitioners. Tr. at 258. His opinion is that DPT caused Trevor's seizures and contributed significantly to his eventual condition. *Id.* Trevor had a good outlook before DPT because he had only one tuber, yet today he is severely mentally retarded. Tr. at 258-59. Dr. Kinsbourne thinks Trevor has a very unremarkable case of TS. Tr. at 259.

As for Trevor's irritability after DPT, Dr. Kinsbourne thought maybe it meant local irritation at the vaccine site or even the effect of the vaccine on the brain or maybe both. Tr. at 260. DPT caused Trevor's fever, but Dr. Kinsbourne would not ascribe any consequence to the fever. *Id.* Whether Trevor's seizures stopped before his brain resection does not affect Dr. Kinsbourne's opinion. Tr. at 261. Trevor's seizures stopped for seven years and Dr. Kinsbourne concludes that a single tuber was the source of those seizures. *Id.* In TS, all seizures have a focal onset. *Id.* Seizures at an early stage have a damaging effect on early development. Tr. at 262. Dr. Kinsbourne opined that Trevor's mental retardation is due to his infantile spasms.

Dr. Kinsbourne agreed with the court's prior holding that there is no mathematical relationship between the number of tubers and a patient's condition. Tr. at 264. He does not believe, nor does anyone, that tubers are the only problem in TS. Tr. at 266. There are also other problems. *Id.* 

Dr. Wiznitzer, on rebuttal, stated that he has patients with infantile spasms who have stopped seizing but none are at the level of disability of Trevor. Tr. at 270-71. An EEG showed that the majority of Trevor's seizures are on the left side of his brain, but there are also discharges coming from the right side of his brain. Tr. at 272. Autistic people have immature wiring patterns. Tr. at 273. They have too many brain cells and, thus, no pruning back effect. *Id.* There are frontal, parietal, and temporal lobes involved. Tr. at 273-74. The limbic system also has abnormal wiring. Tr. at 74. It is immature with no dying back of excess brain cells. *Id.* The cerebellum is abnormal. *Id.* 

Dr. Wiznitzer stated that TS patients have wiring problems. Tr. at 275. If the problems involve particular areas of the brain, they become autistic. *Id.* If they involve other areas, they become mentally retarded. *Id.* The tubers contribute to this to some degree. *Id.* No postnatal toxin causes autism. Tr. at 276. In Dr. Wiznitzer's opinion, DPT had no effect on Trevor. *Id.* 

#### DISCUSSION

On January 10, 2000, petitioners moved the undersigned to strike the TS Omnibus testimony of Dr. Manuel Gomez. The undersigned denied this motion on January 24, 2000. In order to make the record explicit, the undersigned discusses the reasons for the denial.

Petitioners' motion attempts to distinguish their Motion to Strike from petitioners' ground for appeal before the Federal Circuit which that court rejected in <u>Hanlon</u>, <u>supra</u> 1349-50. Counsel herein asserts that the Federal Circuit considered only Dr. Gomez's relationship to counsel in <u>Hanlon</u> rather than to counsel's clients, the Hanlons themselves, whereas here, the Hulberts are directly affected.<sup>4</sup>

The focus of the Federal Circuit's opinion was whether Dr. Gomez possessed confidential information that would prejudice petitioners. Although he was a treating physician for Trevor Hulbert, his TS Omnibus testimony in 1997 dealt with the whole area of TS and not with any confidential information he may have gleaned from the Hulberts.

Since 1991 when he gave his first testimony, Dr. Gomez "changed his opinion in light of recently published medical literature," <u>Hanlon</u>, <u>supra</u>, at 1350. Under § 300aa-12(d)(3)(B)(iii), a special master may require the testimony of any person and the production of any documents as may

<sup>&</sup>lt;sup>4</sup> The Hulberts took Trevor to see Dr. Gomez at the Mayo Clinic. In his initial testimony in 1991, Dr. Gomez opined that if Trevor's seizure onset occurred within three days of his DPT, it was very likely that DPT precipitated or triggered his seizures. See Gomez Tr. at 88. He differentiates between triggering factor and cause. *Id.* at 83. Dr. Gomez also opined that lesions in the brain cause mental retardation. *Id.* at 30. Dr. Gomez views autism as an organic disorder. The brain has a disconnection and cannot put things together. TS patients frequently have autism. *Id.* at 131. The court assumes in light of Dr. Gomez's testimony in 1997 on the TS Omnibus issues that he has changed his mind about DPT as a trigger. In any event, neither side produced Dr. Gomez at trial on January 28, 2000, and the undersigned restricts its holding to the evidence produced at that hearing.

reasonably be necessary. Therefore, the undersigned denied petitioners' Motion to Strike. The undersigned would remind petitioners that the purpose for the January 28, 2000 hearing in this case was to determine the evidence both sides produced in response to the undersigned's Order of September 22, 1997, not to relitigate the TS Omnibus issues.

On October 18, 2000, petitioners filed a Motion for Findings of Fact and Conclusions of Law. The first four findings petitioners proposed are already either in the court's previously unpublished opinion on the issue of onset, its Order of September 27, 1997, or in the testimony of Dr. Wiznitzer, to wit, that Trevor received his two-month DPT vaccination on September 26, 1985, suffered an on-Table seizure, had localized redness, heat, and swelling at the vaccine site, a low fever, and some fussiness, and his seizures began with a focal component.

However, petitioners' fourth proposed finding is not in the testimony of Dr. Kinsbourne, although petitioners state it is. Petitioners state that Dr. Kinsbourne testified that

"Trevor's seizure was indirectly provoked by the DPT shot, by virtue of the fever, which was the direct consequence of the DPT shot, and there is no other causal explanation for why Trevor seized within 72 hours of the shot. (Testimony of Dr. Kinsbourne.)

Noticeably, in petitioners' third proposed finding of fact, petitioners cite the transcript page on which Dr. Wiznitzer's statement on focality may be found, but petitioners do not cite the transcript page on which Dr. Kinsbourne' supposed opinion that DPT "indirectly" caused the first seizure by causing a fever. The explanation for this page omission is clear. Dr. Kinsbourne never said it.

When asked about the fever, Dr. Kinsbourne testified that DPT caused it but he would not venture further about what consequence, if any, the fever may have had (see Tr. at 260). The

undersigned does not appreciate petitioners' distortion of the record. The undersigned does not hold this to be a finding of fact.

Petitioners' proposed finding of fact number six (Trevor was born with TS) is not at issue. Number seven (TS children with eight or more tubers have an increased risk for seizing and mental retardation) deals with an TS Omnibus issue which the undersigned decided in her TS Omnibus decision.

Finding number eight, pertaining to the number of Trevor's tubers, is too precise for a holding. Trevor has had at least two tubers: one was resected and he seems to have at least one other or perhaps two more. Petitioners' ninth proposed finding that Trevor was not at risk for seizure or mental handicap is denied. Findings 10 through 14 deal with TS Omnibus issues.

Petitioners' 15<sup>th</sup> proposed finding of fact, that it is not possible to rule out DPT as the cause, is an incorrect statement of the law. The undersigned already has stated that petitioners benefit from the statutory presumption that DPT caused Trevor's onset of seizures. The burden of proof shifted to respondent to prove that TS is the cause in fact of Trevor's seizures or, if not, the cause in fact of his current condition. (Cf. Flanagan v. Secretary, HHS, 2000 WL 1207256 (Fed. Cl. Spec. Mstr. Aug. 4, 2000), <u>aff'd</u>, 48 Fed. Cl. 169 (Nov. 6, 2000), in which the undersigned held that DPT caused the onset of seizures but not Ashley Flanagan's current condition which TS caused.)

The issue is not whether respondent's evidence rules out DPT as a possibility, but whether a known factor unrelated, i.e., TS, is more likely than not the cause of Trevor's seizures and current condition. Once respondent proves that more likely than not TS is the cause of Trevor's seizures and current condition, petitioners need to impeach that evidence, not assert that DPT might possibly be the cause. Accordingly, the undersigned rejects petitioners' 15<sup>th</sup> proposed finding of fact.

Petitioners' 16<sup>th</sup> proposed finding of fact pertaining to fever is not borne out by their own evidence. Dr. Wiznitzer specifically addressed the question of whether a low grade fever would cause the onset of seizures and denied it would. Dr. Kinsbourne would not offer an opinion as to the consequence of having a fever. There is no evidence to support petitioners' proposed finding that by causing a low-grade fever and local inflammation, DPT induced a focal seizure.

Petitioners' 17<sup>th</sup> proposed finding of fact is similarly not borne out by their own evidence. Dr. Wiznitzer testified that the seizures were multifaceted and eventually became infantile spasms. He did not opine that DPT caused them to develop into infantile spasms nor did Dr. Kinsbourne.

Petitioners' 18<sup>th</sup> proposed finding of fact refers to residual seizure disorder. But the issue is whether Trevor had an on-Table significant aggravation of his TS, not an on-Table residual seizure disorder. As the more credible evidence shows, Trevor was born with TS which manifested itself in the form of seizures, and ultimately mental retardation, epilepsy, autism, and behavioral disorder, all well within the expected course of a child with TS.

Petitioners' 19<sup>th</sup> proposed finding of fact assumes that Trevor's seizures damaged him. However, the credible testimony from Dr. Wiznitzer is that Trevor did quite well until after his brain resection, when he was seizure-free for seven years, yet he became significantly delayed.

Petitioners' 20<sup>th</sup> proposed finding of fact does not conform with the evidence in this case, to wit, that Trevor's seizures were in themselves harmful. The undersigned rejects petitioners' 21<sup>st</sup> proposed finding of fact that no one can predict when Trevor would have seized absent the DPT vaccination. Dr. Wiznitzer gave credible evidence that Trevor would have seized. Seven years after the tuber that had been responsible for his initial seizures was resected and Trevor was seizure-free,

he started to seize again. He still has one or two left-sided tubers. Trevor obviously did not need a DPT vaccination to prompt his second onset of seizures.

Similarly, petitioners' 22<sup>nd</sup> proposed finding of fact does not rest on the evidence in this case. The undersigned denies it as well as the 23<sup>rd</sup>, 24<sup>th</sup>, and 25<sup>th</sup> proposed findings of fact.<sup>5</sup> In sum, the undersigned denies petitioners' Motion for Specific Findings of Fact and Conclusions of Law since so many of them are not consistent with the holdings below, which are indeed the undersigned's findings of fact and conclusions of law.

Petitioners' summation brief reargues many of the issues that the undersigned has previously tried and decided in her Omnibus TS Decision. Petitioners' counsel ignores the affirmances both in the U.S. Court of Federal Claims and in the U.S. Court of Appeals for the Federal Circuit on these very same issues.

This case concerns the testimony of two experts dealing with the issue presented in the Order of September 27, 2000: whether Trevor's post-DPT symptoms of swollen, hot, and red vaccine site, mild irritability, and low-grade fever were more than a transient reaction. The far more credible evidence comes from respondent's expert, Dr. Wiznitzer, who is a clinical pediatric neurologist, a teacher of pediatric neurology, an examiner for the American Board of Psychiatry and Neurology, and a reviewer for peer-reviewed medical journals. His specialty is autism, one of the issues in this case. He treats and has treated TS patients. Dr. Kinsbourne, on the other hand, has not practiced clinical medicine for many years and teaches non-medical subjects at the New School for Social

<sup>&</sup>lt;sup>5</sup> Number 22 states there is no proof that Trevor was predestined to seize. Number 23 states that his Table injury caused him serious deterioration of health. Number 24 states most TS children escape mental handicap in the absence of early onset seizures. (This ignores that TS which results in mental handicap also causes early seizures.) Number 25 states that Trevor's Table injury caused his autism and current condition.

Research (petitioners did not file Dr. Kinsbourne's CV, but his background is familiar to the undersigned from other cases. See <u>Flanagan</u>, <u>supra</u>, at 13.)

This is not a situation where a vaccinee's developmental progress made a rapid and steady decline post-vaccination reaction. The records show that Trevor began seizing at two months of age. Five weeks later, on October 31, 1985, he was having seizures every half hour. By January 22, 1986, he was seizing at least every 20 minutes, but he could laugh out loud, coo, and began to roll over alone. When he was seven months of age, on February 4, 1986, he could smile, follow well visually, sit with support, roll over, push up to prone, pull to sit, and briefly stand supporting his weight. These developmental milestones occurred even though Trevor was having infantile spasms every one to two hours.

Although Trevor developed slowly, he did not regress or lose milestones. His regression began when he was approximately eight months of age, six months post-vaccination, when he began a seven-month course of ACTH. He became severely irritable, lost interest in his surroundings, developed severe muscle weakness (steroid myopathy), and showed moderate to severe cerebral atrophy, all of which was felt to be secondary to his ACTH treatment. He had resection of a left frontal mass on May 16, 1986. Trevor's seizures stopped and his EEGs improved. When Trevor was weaned off ACTH, he began to develop again although slowly. By the time he was 23 months of age, he could walk and play with toys.

By the age of five years, although seizure-free, Trevor displayed autistic features. He had been seizure-free for seven years and without medication for four years when, at the age of seven in May 1993, he began seizing again. He has multifocal and generalized epileptiform abnormalities on EEG. Counsel from both sides have been overly simplistic in emphasizing tuber count. There is no magic number - not eight, or seven, or four. The undersigned expressly rejected respondent's tumor count threshold for the onset of seizures and the host of other adverse consequences of TS in her TS Omnibus Decision. Surely, all reputable physicians agree that the more numerous the tubers, the more likely are severe consequences. But TS still has aspects that are insufficiently studied. As discussed in the undersigned's TS Omnibus Decision, location and size of tubers, besides number, influence the misfiring of neurons in the brain.

In the instant case, petitioners' counsel presses the tuber count issue, asserting that Trevor had too few tubers to result in seizures and severe consequences merely from his TS. But, in <u>Flanagan, supra</u>, not all of Ashley Flanagan's tubers were firing, yet she had a seizure disorder and subsequent mental retardation. The number of tubers does not necessarily correlate to the clinical damage since only a portion of the tubers present may misfire at a time. In Trevor's case, his left cortical tuber was the culprit for his initial seizures. But seven years after it was resected, Trevor began seizing again.

Dr. Kinsbourne testified that if it were not for DPT, he could not find a cause for Trevor's seizure onset. But Dr. Kinsbourne never ascribed a cause for Trevor's second seizure onset in 1993. The neuroradiologists disagree over whether he still has one or two remaining tubers on the left side of his brain. But Trevor's EEG shows epileptiform discharges emanating as well from the right side of his brain. Trevor's TS is not a benign condition even with a low tuber count. He has a malfunctioning brain.

Dr. Wiznitzer attributes Trevor's autism to bad wiring and stated that autism is a frequent occurrence in TS patients as are seizures and mental retardation. The degree of Trevor's mental

retardation and autism did not depend on his having seizures. He manifested slow developmental gains while he was seizing, but got progressively worse after his seizures were brought under control. Dr. Kinsbourne never explained this, but Dr. Wiznitzer testified that TS is well-known to cause seizures, autism, and mental retardation and the fact that Trevor's condition worsened when he no longer was seizing is consistent with TS being the cause of his problems.

In answer to the undersigned's question in the Order of September 24, 1997, asking for expert testimony regarding Trevor's post-vaccinal symptoms, the court holds that Trevor's red, hot, and inflamed vaccine site, slight irritability, and low grade temperature were a benign and transient reaction to his vaccination, having no relationship to his seizures. His low-grade fever after DPT was not the 103° temperature in <u>Flanagan</u>, <u>supra</u>, which caused Ashley to seize.

Dr. Wiznitzer's testimony that TS is the cause of Trevor's seizure disorder, autism, mental retardation, and behavioral difficulties is more credible than Dr. Kinsbourne's. Tubers, misfirings, disconnections, faulty wiring all bode ill for the children who have the misfortune of being born with TS. But the undersigned can see nothing in this case that would prompt her to hold that DPT significantly aggravated Trevor's TS. The working out of his developmental delay and autism took months and years, and was compounded temporarily by his ACTH treatment. His initial seizures did not prevent his gradual accumulation of milestones. When he had his brain resection and was weaned off ACTH, Trevor continued to gain milestones. Yet, even though he had a seizure-free hiatus of seven years, he became severely handicapped. There was no outward "stressor" such as a vaccination for the resumption of his seizures. He still has at least one tuber remaining. The most credible explanation for Trevor's course is his preexisting TS and its consequences.

Respondent has rebutted the statutory presumption that DPT caused Trevor's onset of seizures. Respondent has fulfilled its burden of proving that TS is the cause in fact of Trevor's current condition and, indeed, of his initial and subsequent seizures.

### CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

### IT IS SO ORDERED.

Dated: \_\_\_\_\_

Laura D. Millman Special Master