

OFFICE OF SPECIAL MASTERS

September 18, 1997

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THOMAS J. SUEL AND AMELIA K.
SUEL, PARENTS AND NEXT FRIENDS
OF DAVID J. SUEL,

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Petitioners, * No. 90-935V
* PUBLISHED
vs. *

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SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

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Respondent. *

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Richard Gage, Cheyenne, WY, for petitioners.

Karen P. Hewitt, Washington, DC, for respondent.

DECISION ON REMAND

MILLMAN, Special Master

Statement of the Case

On October 18, 1963, this court issued a decision dismissing the petition on behalf of David J. Suel (hereinafter, "David") that petitioners filed for compensation under the National Childhood Vaccine Injury Act of 1986⁽¹⁾ (hereinafter, the "Vaccine Act" or the "Act"). Petitioners alleged that David suffered significant aggravation of his pre-existing tuberous sclerosis (TS) in the form of an encephalopathy and a residual seizure disorder within the Table time limits of the Act. 42 U.S.C. § 300aa-14(a)(B),(D),(E).

Petitioners appealed the dismissal and, in a decision dated December 21, 1993, the U.S. Court of Federal Claims, per the Honorable James F. Merow, reversed and remanded the case for the determination of damages. This court held a hearing on January 27 and 28, 1997. Testifying for petitioners were Thomas Suel, Helen Woodard, and Ann Lovegrove. Testifying for respondent were Dr. Robert A. Zimmerman, Dr. Marianne Guggenheim, Dr. John MacDonald, and Shari Grote. Petitioners submitted in exhibit form rebuttal from Dr. Marcel Kinsbourne. P. Ex. 49 (March 22, 1997).

Respondent's position is that it is willing to pay for anticonvulsants per Judge Merow's finding that David's seizures constitute a significant aggravation of his TS, but it is not liable for David's other damages (i.e., autism and mental retardation) because these are part of the sequelae of his underlying disease, TS, rather than of his seizure disorder.⁽²⁾

The lengthy passage of time between the decision on appeal and the hearing on remand occurred because respondent was preparing and presenting evidence in the Omnibus TS cases concerning its defense that DPT (or other vaccines) does not significantly aggravate a vaccinee's pre-existing TS if the number of tubers in the vaccinee's brain is eight or more. Respondent, through testimony and the presentation of epidemiological articles, argues that a child with eight or more tubers will develop a seizure disorder as well as other deleterious effects of TS, which can include mental retardation, autism, attention deficit disorder, etc., regardless of vaccination.

During the summer of 1996, when respondent and petitioners in the Omnibus TS proceedings were engaging in discovery of the witnesses' testimony for the hearing that occurred October 8-11, 1996, the court asked respondent's counsel if respondent intended to move the Honorable James F. Merow to reopen his decision reversing this court on the issue of entitlement in Suel in order to evaluate respondent's new evidence pertaining to the effect of a tuber count of eight or more on the vaccinee's ultimate condition. The court advised respondent that the undersigned did not have jurisdiction to revisit the issue of entitlement since judgment had been entered. Patton v. Secretary, HHS, 25 F.3d 1021 (Fed. Cir. 1994).

Respondent declined to move Judge Merow to reopen the case on the issue of entitlement on the basis of newly discovered evidence, preferring to present the same evidence that it would present at the Omnibus TS hearing in October 1996 during the remand hearing of this case in January 1997, assuming that evidence as to lack of significant aggravation pertaining to entitlement was equally applicable to lack of sequelae pertaining to damages.

The undersigned advised respondent that its authority was restricted solely to the issue of damages, and it would be extraordinary to ask this court to rule that, accepting that DPT vaccine significantly aggravated David's TS as Judge Merow ruled, still there were no sequelae of that significant aggravation for which to award damages.⁽³⁾

TESTIMONY ON SEQUELAE

Dr. Manuel Gomez, the world's expert in TS as well as David's consulting pediatric neurologist, testified for petitioners on October 21, 1991. Dr. Gomez's testimony on TS was taken at the Mayo Clinic and is described in Costa v. Secretary, HHS, No. 90-1476V, slip op. at 10-17, 1992 WL 47334 (Ct. Cl. Spec. Mstr.), remanded, 26 Ct. Cl. 866 (Ct. Cl.), on remand, 1992 WL 365421 (Ct. Cl. Spec. Mstr. 1992). (For a description of Dr. Gomez's textbook and article on TS, see pages 5-10 of the Costa I slip opinion.)

Dr. Gomez testified that TS is not an encephalopathy. Gomez tr. at 99. Rather, TS is a genetic disorder which is either inherited or results from a mutation. Gomez tr. at 96. Brain growth controls tuber growth. Tubers exist at birth and do not multiply. Gomez tr. at 97. The most common presenting symptom of TS

is seizures. Gomez tr. at 100. There is a demonstrable correlation between the presence of many low attenuated lesions and the frequency and severity of seizures and mental retardation in an infant less than one year old. Gomez tr. at 101.

The most common age for onset of seizures in TS children is the first year of life. The most common symptom of presentation is infantile spasms. Infantile spasms are age-dependent seizures occurring between ages three and eight months, regardless of the cause. Gomez tr. at 103.

Dr. Gomez stated that David has multiple calcifications in the subependymal areas of his brain, and tubers in addition to subependymal nodules. Dr. Gomez noted cerebral tubers in both hemispheres of David's brain. Gomez tr. at 71-72.

Dr. Gomez testified that David's lesions are much worse in number and size than those of the Decker twins, Damian and Destry (about whom Dr. Gomez wrote in one of his articles).⁽⁴⁾ Gomez tr. at 75. If David's seizure occurred shortly (such as three days) after his DPT vaccination, Dr. Gomez thought it very likely that the DPT precipitated or triggered David's seizure. Gomez tr. at 88. Dr. Gomez testified that DPT vaccine may trigger (bring on) or aggravate the symptoms of TS, although it would not aggravate the disease. Gomez tr. at 88-89.

Dr. Gomez would not relate David's 100°F fever to his seizure. David suffered an infantile spasm not a febrile seizure. Gomez tr. at 152. Eyes rolling back and up is indicative of a myoclonic seizure. Gomez tr. at 153.

Dr. Gomez testified that the more lesions a child has, the more likely the child is going to manifest seizure activity. The more cortical lesions the child has, the more likely the child is going to have severe neurologic dysfunction. Gomez tr. at 102. When one sees many multiple lesions in the brain (more than five lesions observable on MRI), most likely the patient will have seizures. Gomez tr. at 20.

Brain lesions cause mental retardation. Gomez tr. at 30. Dr. Gomez stated that he had never seen an MRI as severe as David's where the child was normal. Gomez tr. at 154.

Dr. Gomez has never seen a TS patient who was mentally retarded who did not have a seizure disorder. Gomez tr. at 30. The mechanism by which this damage occurs is that a child with many seizures would have a defect in the formation of the proper amount of protein, nucleic acid, and myelin. These children's brains do not grow as well as a child who never had these amounts of repetitive seizures daily. Thus, repetitive seizures do lasting brain damage to infants. Gomez tr. at 35-37.

Dr. Gomez has never recommended giving pertussis vaccine to a child he knows has TS out of caution not to chance the development of seizures. Gomez tr. at 48. He has recommended for the past nine years not immunizing TS children against pertussis. Gomez tr. at 109.

Having seizures early in life is likely to lead to mental underdevelopment or mental retardation. Gomez tr. at 84. Autism is a frequent occurrence among TS patients. Dr. Gomez has never seen an autistic TS child who did not have seizures. Gomez tr. at 131.

Respondent submitted an informal letter from Dr. Gomez to one of respondent's counsel, dated February 2, 1995 (R. Ex. D). In that letter, Dr. Gomez states that TS children often spontaneously develop partial or generalized seizures (infantile spasms are a type of generalized seizure). When a TS child's onset of seizures is in the first years of life, and the seizures are frequent, prolonged, or persistent despite treatment, his mental development will probably be impaired and he will have subnormal intelligence

and behave abnormally. R. Ex. D at 1-2.

Because of this difficulty, it is advisable to "make all possible efforts to prevent the onset of infantile seizures," and to try to arrest them if they develop. Eliminating a trigger is easier than stopping the seizures once they begin. When a seizure-free TS child receives DPT and begins seizing within seventy-two hours, Dr. Gomez believes it preferable to have avoided the immunization. Id. at 2.

He does not recall seeing a TS child with a single infantile spasm within the first seventy-two hours of vaccination who days or weeks later develops clusters of infantile spasms. A TS child can have one or more febrile seizures and not develop infantile spasms. Id.

TS children should not receive pertussis antigen until we know more about the cause and effect relationship between pertussis antigen and the onset of infantile spasms since the pertussis antigen is a suspected triggering agent. Id.

Dr. Gomez reviewed for the first time the testimony he gave in 1991 (not having been sent the transcript before) and found that there were errors in transmission or lack of clarity in the discussion of issues. To set the record straight, he presented in the rest of the letter his views on TS, immunizations, and infantile spasms. TS children with many cortical tubers are likely to have frequent, severe, and intractable generalized seizures such as infantile spasms, myoclonic or tonic seizures. Soon after the onset of the seizures, these children do not progress or make little progress in psychomotor development. Parents may note evident regression in some cases. Id. at 3.

Seizure onset is most often in the first year of life, usually between months three and nine. This may occur without a trigger or may occur within the first seventy-two hours of a DPT vaccination. To protect Mayo's patients, they maintain that DPT is a trigger of infantile spasms although there is no concrete evidence for this belief. The exact date of seizure onset may be difficult to recall. Parents convinced of the culpability of the DPT may put the onset date close to that of vaccination. Id. at 3-4.

The number of cortical tubers cannot be estimated with accuracy and much less in the brain of a child younger than two years of age because myelination has not been completed. The exact lobar location of the cortical tubers within the brain may be more important a predictor of final outcome than the number of cortical tubers or even the total volume that the cortical tubers occupy. It is impossible at the time of Dr. Gomez's letter to make an accurate estimate of the number, size, or location of cortical tubers in a TS child's brain, "let alone to know the age when seizures will start and the severity of mental deficit the patient will have if and after the infantile spasms begin." A "rough estimate" of the extent and importance of the pre-existing condition can be made in determining if the condition of the child is primarily due to his underlying disorder. Id. at 4.

Testifying first for respondent at the hearing on January 27, 1997 was Dr. Robert L. Zimmerman, a neuroradiologist. Tr. at 31-32. He examined a March 13, 1989 MRI of David and counted twenty tubers (nine on the right, eleven on the left) scattered around David's cortex. Tr. at 33. David's parietal, frontal, and temporal lobes were affected. Id.

This number of tubers puts David in the upper two-thirds region (about seventy percent) of the number of tubers in TS patients Dr. Zimmerman has seen. Tr. at 36. There is more TS in the population at large but they are not mentally retarded. Tr. at 37-38.

Respondent's second witness was Dr. Mary Anne Guggenheim, a pediatric neurologist. Tr. at 42-43. She has had patients with TS and autism. Tr. at 43. Autism is a behavioral profile and a symptom. Tr. at 44,

46. She has had five to ten autistic patients a year. Tr. at 44. TS is related to autism; it is one of the three or four common causes of autism. Tr. at 47.

David has a well-controlled seizure disorder. Tr. at 49. He is on a low dose of anticonvulsant. Id. David is moderately retarded. Tr. at 50. He speaks a few words, but is not at an age appropriate level in school. Id. David has autistic behavioral problems, especially poor social interaction, a lot of oppositional and aggressive behavior, poor self-help skills such as toilet training and dressing, and a major deficit in social communication. Tr. at 50-51.

~~In Dr. Guggenheim's opinion, DPT uncovered David's seizures.~~ Tr. at 52. (CK THIS W/ LAURA b/c DR NOT REALLY SAY THAT) But, from a medical perspective, the seizures are a symptom of TS. Id. Dr. Guggenheim prepared a paper (R. Ex. EE) showing that David's tuber count, being above 18.2, would have resulted in his current condition even without vaccination. Tr. at 59-60. She derived the 18.2 count from data in the C.W. Shepherd, O.W. Houser, and M.R. Gomez paper, "MR Findings in Tuberous Sclerosis Complex and Correlation with Seizure Development and Mental Impairment," AJNR 16:149-55 (1995). Tr. at 53-54, 59-60. In that paper, the authors did an analysis of TS children and found that the average number of tubers in clinically normal individuals with TS was 9.9, and the average number of tubers in mentally disabled individuals with TS was 18.2. R. Ex. E, at 152-53.

David's seizures, mental retardation, and autism are symptoms of a bad case of TS. Tr. at 61. Dr. Guggenheim does not know of medical data to support the view that the early onset of seizures is worse. Tr. at 61. There is medical data from Dr. Lamm that was not available when Dr. Gomez testified in 1991 and it could affect his opinion.⁽⁵⁾ It is more likely than not that David would have seized before age one without the DPT. Tr. at 63. His condition would not be any different without the immunization. Tr. at 64. She cited the Riikkonen paper (R. Omnibus Ex. Ex. 3)⁽⁶⁾ to the effect that the severity of infantile spasms depends on the underlying disease, not the age of onset. Tr. at 65-66.

Dr. Guggenheim stated that David's current seizures are a sequela of his TS, as are his mental retardation and autism. Tr. at 70. TS, not seizures, causes autism. Tr. at 75-77. Mental retardation is not an active process; it cannot cause autism. Tr. at 78. Autism is a developmental, behavioral syndrome with deficiency in language, social interaction, and communication. Tr. at 71. The worse the disease, the more severe the symptoms. Tr. at 87.

The number of tubers is helpful as a predictive variable. Tr. at 92. Someone with a late onset of seizures has a better prognosis, but that correlates with fewer tubers. Tr. at 92-93. Seizures are a symptom, not a cause. Tr. at 93. If someone has the onset of seizures before the age of one year, that is worse than if the onset is after one year. Tr. at 95. If the seizure manifestation is infantile spasms, that is worse than if the manifestation were another type of seizure. Id. Mental retardation and autism have to do with the development of the brain. Tr. at 99. They become apparent only at a later age. Id.

Infantile spasms have a very poor outcome. Tr. at 101. Their peak occurrence is from three to eight months. Id. The cortical tubers in TS can be very epileptogenic, disrupting neuronal networks in the brain, resulting in mental retardation. Tr. at 124. But seizures do not cause mental retardation. Id.

Respondent's third witness was Dr. John T. MacDonald, a pediatric neurologist who has been David's treating doctor since he was four or five months of age. Tr. at 137-38. David is mentally retarded and autistic. Tr. at 138. His conditions are all related to or associated with TS. Tr. at 138-39. In the future, he needs to be followed by a neurologist to monitor his seizure medication. Tr. at 139. He has mild partial seizures which are not incapacitating and are fairly well-controlled. Tr. at 140.

Dr. MacDonald would alternate David's neurology visits with visits to a pediatrician so that a doctor is seeing him every three to four months. Tr. at 141. He does not have any special need for dental care. Tr. at 142. David is on Valproic acid or Depakote. Tr. at 143. Dr. MacDonald does not foresee hospitalizations for David. Id.

David is on medication for autism (Cylert) which is not very effective. Tr. at 145. He is also on Mellaryl, an anti-psychotic, but is on a high dose which is not effective. Tr. at 145-46. He is switching to Resperol. Tr. at 146.

David will need residential care in the future. Tr. at 147. He will always need someone to look after him. Id. There are group homes for autistic individuals in Minneapolis. Id. David is not toilet-trained at almost ten years of age. Tr. at 150. He will not benefit from individual counseling, although his parents might. Tr. at 151. A camp would be a nice experience for David, but not therapeutic. Tr. at 151-52. Dr. MacDonald sent David to Dr. Gomez because he was still seizing and having developmental problems. Tr. at 154.

Listening to the testimony on sequelae, but not testifying, was Dr. Marcel Kinsbourne, pediatric neurologist, for petitioners. He subsequently submitted a written report (P. Ex. 49) which petitioners entitled, "Rebuttal Testimony." In letter form, Dr. Kinsbourne stated that Dr. Guggenheim did not quantify a correlation between tuber count and severity of outcome. Id. at 1. Dr. Lamm in his paper (see note 4, supra) did not calculate a correlation coefficient between tuber count and outcome (i.e., if there is a perfect positive linear relationship between two variables, their correlation coefficient should equal 1, Dr. Kinsbourne wrote). Id. Instead, Dr. Lamm proposed a relative risk of five in a TS child's becoming symptomatic if he or she had eight or more tubers. Id. But, to Dr. Kinsbourne, this higher propensity to develop symptoms means the child with eight or more tubers is at greater risk for seizing due to contributory factors, i.e., a trigger. Id.

Discussing the significance of age of onset in determining the outcome of a TS child, Dr. Kinsbourne stated that Dr. Gomez, in his text, presented a regression curve showing a correlation coefficient of .733 between age of onset of seizures and outcome. Id. at 2. Dr. Kinsbourne described this as a high correlation, meaning that age of seizure onset is responsible for as much as fifty percent of the "variance in outcome." Id.; R. Ex. I, p. 30 (figure 3.2). ⁽⁷⁾

In an article in the American Journal of Neuroradiology ⁽⁸⁾, Drs. Shepherd, Houser, and Gomez state that age of seizure onset correlates with the degree of mental retardation. Id. at 2; R. Ex. E at 149-50. That paper also surmised that the average number of tubers among those clinically normal was 9.9. R. Ex. E at 152-53.

Dr. Kinsbourne wrote that the presence of tubers does not explain mental retardation. P Ex. 49 at 2. Rather seizures, particularly if frequent, cause mental disability. Id. This conclusion is consistent with Drs. Shepherd, Houser, and Gomez. Id. at 3. Disagreeing with Dr. Guggenheim, Dr. Kinsbourne wrote that mental retardation is detectable in infancy. Id. In addition, while the seizures that DPT causes are mostly febrile, literature shows that some are not. Id. The National Childhood Encephalopathy Study (NCES) included afebrile seizures in its grouping of serious neuropathies following DPT vaccination. Id. The Redbook of the American Academy of Pediatrics states that a seizure, whether febrile or afebrile, within three days of DPT vaccination is a contraindication to further vaccination. Id.

DISCUSSION ON SEQUELAE

The neurological testimony as to the sequelae of David's significant aggravation of his TS that is most significant to the court is that of Dr. Manuel R. Gomez, the world's expert on TS and also a consulting

pediatric neurologist to David. In 1991, when Dr. Gomez testified in general about TS and DPT vaccination, he also testified in particular about David. In addition, he has written a textbook on TS⁽⁹⁾ and numerous articles, including the one he co-authored with Drs. Shepherd and Houser, which cover a number of the issues in this case.

Regardless of Dr. Gomez's concerns about muddling of issues or transcription errors about which he remarks in his letter to respondent's counsel dated February 2, 1995, Dr. Gomez viewed DPT as a trigger of infantile spasms in a TS child. Although the parties have fought furiously over the issue of whether DPT can cause infantile spasms, the statutory presumption of causation removes that as an issue ab initio when the initial onset is within Table time, as the undersigned held occurred when David rolled back his eyes.

Dr. Gomez also described in his testimony in 1991 how physiologically repetitive seizures (infantile spasms) cause brain injury. That David did not experience repetitive seizures until weeks after his DPT vaccination (having only a single rolling back of his eyes the first time, followed by a rolling back of his eyes the next day, followed by excessive sleeping the following week) did not appear to be of much significance to the Honorable James F. Merow. What was of significance to Judge Merow was the testimony (which includes that of Dr. Gomez) that a doctor wants to prevent a TS child from seizing for as long as possible because the earlier a child seizes, the worse his prognosis.

A TS child with multiple tubers will never be normal. In Dr. Gomez's 1991 testimony, he said five or more was the threshold of abnormalcy; in his 1995 paper, he and his co-authors wrote that the average number of tubers in mentally abnormal TS children was 18.2; in the respondent's expert Dr. Lamm's calculations, the number of tubers for abnormalcy is eight or more.

The TS child is more likely than not to manifest infantile spasms. The conundrum is that infantile spasms manifest themselves only from the age of three to eight or nine months. Therefore, if a child is going to seize within his first year, infantile spasms are the most likely form of that seizure and those are the very type of seizure, because of their repetitiveness, that damage the young brain. If a child were to seize at an older age, the seizures would not be infantile spasms if they occurred past the ninth month. Thus the effect on the child's brain would be less damaging both because the brain is older and because the nature of the seizure is less nefarious.

In nine years up until the time of his testimony in 1991, Dr. Gomez had never recommended that a TS child receive DPT vaccination for fear of triggering a seizure. Although he now appears to recant from this position (or at least to claim little scientific basis for it), the position seems a solid one in the medical community. That is, a child who is prone to seize uncontrollably is not an appropriate candidate for whole cell pertussis vaccine, as Dr. Kinsbourne stated by reference to the Redbook of the American Academy of Pediatrics.

Respondent's view that David's extremely high number of tubers (20) necessitates the holding that his current condition is a sequelae of his TS, rather than of his vaccine injury, is not credible for two reasons. First, Judge Merow's holding that David's onset of seizures was an on-Table significant aggravation of David's TS means that DPT vaccine significantly aggravated the disease, not just the symptom of seizures. And, as earlier noted, Dr. Gomez described the deleterious effect of infantile spasms (which David later went on to have) on an infant's brain, producing the very condition that David has: mental retardation, autism, and seizure disorder.

Secondly, there are other variables that Dr. Gomez and others have emphasized which the tuber count analysis does not concern: location and size of the tubers. Dr. Gomez has stated, both in his 1991

testimony and his 1995 article, that tuber location may be a more important predictor of severity of outcome than number of tubers.

Moreover, Dr. Gomez, in his 1995 letter, stated it was impossible to make an accurate estimate of the number, size, or location of cortical tubers in a TS child's brain or to know when would be the age of seizures if infantile spasms were to begin. He opined that only a rough estimate could be made because the child is too young to have a fully myelinated brain.

A rough estimate of tuber count with no reference to location or size of tuber and the significance thereof is an insufficient basis for this court to use to hold that David's current condition is a sequelae of his TS unrelated to the significant aggravation of his DPT vaccination. If the world's expert on TS cannot use number of tubers alone to predict outcome, surely this court cannot. The science of predicting ultimate outcome is still nascent.

Even if the court were to accept the concept that a high number of tubers is sufficient by itself to predict outcome, the court would be faced with picking the appropriate number of tuber beyond which lies inevitable mental abnormality. In Dr. Gomez's testimony in 1991, he said five or more. In Dr. Gomez's 1995 article in which the authors commented that they had presented the best data available, the average number of tubers among the mentally abnormal was 18.2, while the clinically normal had an average number of tubers of 9.9 (which assumes, as Dr. Kinsbourne wrote, that some clinically normal patients had more than 9.9 tubers). To Dr. Lamm, respondent's expert, eight or more tubers is a biomarker for severe neurologic outcome.

~~An editorial accompanying the publication of Dr. Lamm's paper (see note 4, supra), "Tuberous Sclerosis: Function Follows Form," by Roach, E.S., 12 J. Child Neurol. 75-76 (1997), reviews the main thesis of respondent as expressed in the Lamm paper (that patients with moderate or severe epilepsy and mental retardation are five times likelier than patients with mild neurologic disease to have eight or more tubers) and, yet, cautions against concluding finality of outcome from tuber count. Dr. Roach stated that he has seen individuals with very abnormal brain scans who function well and children with mildly abnormal scans who are very impaired. He also stated that epilepsy plays perhaps a major role in the retardation.~~

~~Continuing, Dr. Roach wrote: "There is enough individual variation of both the clinical outcome and the radiographic appearance that the magnetic resonance scan alone generally cannot be used to establish the prognosis for an individual patient." He closed his editorial with a call for more studies to determine if location and size as well as number of the tubers play a significant role in outcome. (DON'T THINK THIS WAS FILED) This is Dr. Gomez's own conclusion in his letter to respondent in 1995.~~

David's twenty tubers exceeds the number that Dr. Gomez's 1995 article would determine puts him in the category of mentally abnormal. However, the court does not know the other variables that affect his outcome: the significance of the location and size of his tubers and when, absent the trigger (or unmasking, according to Dr. Guggenheim) of DPT, David would have seized. The choice was never between David's being well and being sick. It was most probably between his being sick and being sicker. Judge Merow's holding determined that DPT made David significantly sicker. The court has no basis to conclude that David's current condition is not a manifestation of that significant aggravation but the natural outcome of David's TS because of the presence of twenty tubers in his cortex.

If there were a distinction between DPT's significant aggravation of David's TS and the effect of TS itself (and the court doubts conceptually that there is), the burden of apportioning damages is respondent's. Costa I, supra. Respondent has failed to meet that burden. Respondent believes that DPT

exacerbated only one part of David's TS, i.e., his seizures, but not the rest of David's medical problems (mental retardation and autism). Yet all the witnesses attested to the fact that mental retardation, seizures, and autism are integral to TS. Dr. Gomez testified that repetitive seizures damage the brain. Two of the consequences of that damage are mental retardation and autism.

The court holds that respondent has failed to prove that David would be exactly in his current condition absent the DPT so that all the sequelae he experiences flow from his TS, rather than DPT's significant aggravation of his TS. Respondent takes its victim as it finds him. This is not unusual, being a traditional concept in tort law. It is also the underlying assumption for Congress's enactment of the Vaccine Act. Presumably, all children (even without TS) who develop seizure disorders after DPT have some inborn problem that made them susceptible to vaccine injury. Otherwise, the onset of seizure disorders among vaccinees would be universal. Congress decided to compensate these vaccinees, regardless of the argument that could be made that, being born with a propensity to seize, it was only a matter of time (perhaps another trigger) until the child seized.

Congress's concern to compensate injured vaccinees extends even when the preexisting illness or propensity is known. Thus, it enacted that part of the statute dealing with significant aggravation. In effect, Congress was stating that when a vaccinee has a known disease that would injure him (e.g., produce seizures), respondent must pay damages if the vaccine significantly aggravated that preexisting illness. The example Congress gave of its intent depicts a vaccinee who was seizing before the immunization, but whose seizures increased after the vaccination. Since Congress was willing to compensate someone who was already seizing before vaccination, *a fortiori*, it is consistent with its legislative intent to compensate someone who never seized before vaccination, and developed a seizure disorder (for which his underlying condition predisposed him) after the vaccination.

Congress defined "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). In order for Judge Merow to hold that DPT vaccine significantly aggravated David's TS, he had to find that David experienced greater disability, pain, or illness accompanied by a substantial deterioration of health.

The legislative history providing insight into Congress' interpretation of "significant aggravation" is as follows:

The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16, reprinted in U.S.C.C.A.N. 6344, 6356-57.

Although no one would consider TS a "minor event" in David's medical history, that he never seized before the DPT vaccination, and did seize after it within Table time is sufficient to assume that DPT caused the deleterious process whereby the TS disease becomes clinically manifest, i.e., his seizure. Certainly, his subsequent symptomatology of excessive sleeping and repetitive seizing (infantile spasms) a week to three weeks later is consistent with the course of the disease. His current symptoms are also characteristic of his disease.

The court holds that David be compensated fully for the damages he has suffered as a consequence of the significant aggravation of his TS. These sequelae include his seizure disorder, autism, and mental retardation. [\(10\)](#)

TESTIMONY ON DAMAGES

Thomas Suel was petitioners' first witness. Tr. at 160. He described a day in David's life. Tr. at 162. On a school day, his parents get David up at 7:00 a.m. Id. They change his diapers and brush him. Id.

They use pressure therapy, which is a calming strategy that organizes him. Id. They pick out David's clothes which are loose-fitting and generally sweat suits. Tr. at 163. David cannot use buttons or snaps. Tr. at 163-64. He has cereal for breakfast and can feed himself. Tr. at 164-65. David can say "Chex" and "Cheerios." Tr. at 165. He can also ask for more and say all done. Tr. at 165-66. David likes to be fed. Tr. at 166. He uses a spoon primarily and a bowl. Tr. at 166. He does not use a knife except for butter. Id.

David gets medicine twice a day, after breakfast and on return from school. Tr. at 167. They crush up the medicine and put Tang in it. Tr. at 168. They have to hold David down and tilt his head back to get the medicine down. Id. He then has playtime for fifteen to twenty minutes. Id. There is a swing set in the basement. Tr. at 168-69. David watches two tapes, Barney and where they went for camping. Tr. at 169. He swings in the basement and is fine. Id.

David does not like going to school. Id. It takes two people to get his coat on because he does not want to go to school. Tr. at 170-71. David tolerates their brushing his teeth. Tr. at 169-70. David takes a special education bus to school at 8:00 a.m. Tr. at 171-72. He is easily distractable so they have to walk him to the bus in the driveway. Tr. at 171. A school aide is assigned to David. Tr. at 172. He is mainstreamed in home room for fifteen minutes and for music. Id. David comes home at 3:45 or 4:00 p.m. Id. They take him off the bus and give him his medicine. Id. He has a snack of popcorn or a potato. Tr. at 173. David takes a bath and normally loves to (he loves suds). Tr. at 173-74. He puts towels and toilet paper in the tub, as well as a boom box. Tr. at 175. He cannot clean himself. Tr. at 175-76. He does not like having his hair washed. Tr. at 176.

David swings in a hammock daily. Tr. at 177. His favorite story is "1001 Dalmatians," and he hears it daily. Tr. at 178. Bedtime is 6:30 to 7:00 p.m. Id. One parent lies down with him for fifteen to thirty minutes. Id. On Thursday, David watches Lawrence Welk, whom he likes, from 7:30 to 8:30 p.m. Tr. at 179. He sleeps through the night. Id.

David likes to ride in a car and loves traveling. Tr. at 180. He plays alone, not with his three siblings. Id. He is not interested in their activities, but in disrupting them. Id. The Suels' three other children are on the honor roll. Tr. at 181.

David likes to twirl. Id. If he gets angry, he will throw things. Id. He likes to sit at a counter. Id. If he gets angry, he will throw things off the counter. Id. He bangs his head on the counter or floor. Tr. at 182. David yells or screams a lot. Tr. at 183. They will put him in the shower or roll him up. Tr. at 183. An occupational therapist showed them how to roll him tightly in a large piece of foam which calms him. Id. They cannot reason with David. Tr. at 184. He has a short attention span. Tr. at 184-85.

David is much happier when there is no school. Tr. at 186. He gets up at 5:00 a.m. in the summer and goes to his parents' bedroom. Tr. at 186. He shares a bedroom with his younger brother. Tr. at 189. David likes to swing outside in the summer and plays with the air conditioner. Id. Someone has to watch him or he will wander off. Tr. at 190.

David does not answer when you call him. Tr. at 191. He does not have a sense of danger. Id. He goes to summer school for three hours a couple of days a week. Tr. at 192. The parents split attending the other children's activities. Tr. at 193.

Puberty could be very difficult with David. Tr. at 194. David can plug in fans. Tr. at 196. The Suels hope to keep David until it is too difficult to manage him. Tr. at 193-94. They do not have a contingency plan. Tr. at 195. He walks well, and likes to jump. Tr. at 197-98. He jogs clumsily. Tr. at 197. David gets occupational therapy at school. Tr. at 198. The therapist works on his motor skills. Tr. at 199. David has transferred schools from Pearson to Central back to Pearson. Tr. at 198-99.

The Suels do not go out often because they find obtaining a babysitter for David difficult. Tr. at 220. They can go out when David is in school. Id. They change his diaper two to three times on a school day and five times on a weekend day. Tr. at 220-21. David kicks when he gets angry; he slaps and pulls hair. Tr. at 222. David does not get along with the dog. Id. He has not made any progress in toilet training. Id. He loves to climb up on window sills, tables, and countertops. Tr. at 223. He plays in the laundry room on top of the water heater. Id. He once climbed out a second story window and hung there. Tr. at 224-25. He loves playing in warm water but is not aware of depth. Tr. at 225. He does not swim. Id. David loves campfires. Id.

Helen Woodward testified next for petitioners on damages. Tr. at 232. David's health insurance premiums will be paid until he is 22 years old, after which time he will be on COBRA until he can go on Medicaid. Tr. at 241. You cannot place someone in a group home without insurance.⁽¹¹⁾ Tr. at 241.

Ms. Woodward stated it would be acceptable if David had Medicaid or Medicare in order to get into a group home. Tr. at 269. The costs of David's medication would exceed the costs of the insurance premium per year. Tr. at 274-76. The average premium would be \$1,237.98 per year. Tr. at 274-75. The premium plus the deductible plus a 20 percent co-pay would total \$2,539.00. Tr. at 276. The cost of David's medications without insurance coverage would be \$4,462.00 per year. Id.

David should see a pediatrician or internist six times a year. Tr. at 286; R. Ex. BB at 3. His pediatric neurologist Dr. MacDonald and Dr. Pistulka originally recommended MRIs. Tr. at 279-80. David had MRIs in 1992 and 1994. Tr. at 304. Dr. MacDonald likes to have MRIs done every two or three years. Tr. at 304.

The Dungarvin group home where petitioners want to send David has an extra cost for diapers. Tr. at 289. (Petitioners suggested foster care also has a separate fund for diapers.) Tr. at 307. There is no evidence that David will be toilet trained. Tr. at 289. Both parties agree on the cost of dental care (\$188 per year). Tr. at 290.

Dungarvin is monitored and licensed by the State of Minnesota Department of Developmental Disabilities. Tr. at 315. It is a big program and runs homes in several states. Tr. at 316. Respondent prefers Stephen Croft Homes, which are foster care homes run by the Volunteers of America . Tr. at 315-16. They accommodate people with autism and are not as monitored. Tr. at 316.

In a Dungarvin home are two handicapped people and two staffers for four hours per day. The rest of the day, there is one staffer. Tr. at 318-19. In the Stephen Croft homes, there are two staffers for four individuals. Tr. at 319. It requires the same day program. Id. The amount of activity and stimulation depends on the number of people in the home. Tr. at 320. In Ms. Woodward's opinion, David would do better in a smaller group than in a larger one. Id. Dungarvin addresses itself to mental retardation and autism. Id. So does Stephen Croft, but it does not deal with severe behavioral issues, i.e., aggressive

tendencies. Tr. at 320-21. Ms. Woodward praised Dungarvin because of the longevity of its program. Tr. at 322. She does not know how long Stephen Croft has been in existence. Id.

Occupational therapy directs sensory integration. Tr. at 338. It would include a calming room. Id. At a group home, there would be rehabilitation aides. Tr. at 343. A comprehensive development assessment would be done as David enters adolescence. Tr. at 350-51. His sensory integration would be reevaluated. Tr. at 351. He would have sheltered employment and a vacation program (two weeks a year). Tr. at 352-54. The sheltered workshop is provided by Dakota Inc. and would cost \$13,000 a year. Tr. at 354-55; R. Ex. BB at 8.

The Suels put David in a buggy now in the summer. Tr. at 372. He gets tired after half a block of walking. Id. They want a McClaron Major Buggy for him in the future when he is uncooperative. Id. The Suels want to keep David home until he is age 22. Tr. at 397.

David takes Depakote for seizures and Resperadol for behavior problems due to his mental retardation and autism. Tr. at 422-24. Petitioners request one hour of home health care assistance in the morning and three hours in the afternoon. Tr. at 426.

David needs a licensed practical nurse seventy days for the summer to administer medications. Tr. at 428-29. The two hour visiting rate of LPNs is \$65 so this would come to \$130 per day if she visited twice a day. Tr. at 431. Ms. Woodward does not know if Dungarvin has a hand held shower and a shower chair. Tr. at 471.

Shari Grote, David's current teacher, testified for respondent. Tr. at 200. She is a special education teacher for the moderate to severely retarded. Tr. at 201. She has been at Pierson for six years. Tr. at 201-02. She has been David's teacher since he was in the second grade. Tr. at 202. At the end of the fourth grade, David went on to the fifth-sixth grade building. Id. He returned to Pierson after Christmas. Id. David will stay there a year and then transfer to junior high school. Id.

David needs space, an area that can be closed off. Id. His behavior at home is better since he returned to Pierson. Tr. at 203. Home room begins David's day. Tr. at 203-04. After homeroom, they work on grooming. Tr. at 204. David needs a lot of guidance. Id. He is often distracted. Id. He has a library job: he collects books from each classroom. Id. David needs one-to-one assistance. Id. Five paraprofessionals work with him per week. Tr. at 205. He has a speech therapist two times a week. Tr. at 206. He has language sessions one hour a day. Id. David does not talk a lot. Tr. at 207. He is becoming more familiar with objects. Id. He has learned more tasks under one-to-one guidance. Tr. at 208. However, he failed to advance in toilet training. Id.

David is getting occupational therapy for his sensory-motor difficulties. Tr. at 209. The occupational therapy is on a consultative basis. Tr. at 210. If he is not brushed, David kicks and screams. Id. He likes to listen to music and enjoys using a computer. Tr. at 212. He uses a hammock swing. Tr. at 213. David's attention span is longer (ten minutes) for enjoyable activity than it is for drilling (five minutes). Tr. at 217.

Ann Lovegrove, a registered nurse and vice-president of catastrophic care, a certified case manager, testified for respondent. Tr. at 481-82. Currently, the Suels do not have assistance. Tr. at 488. Respite care did not work out. Id. They had a problem with the insurer paying for various therapies, so they stopped the therapies, including occupational therapy. Tr. at 488-89.

Stephen Croft is a group home. Tr. at 496. Its cost, including a day program, is \$63,281 per year. Tr. at

497. She does not know of a summer camp for autistic people although it can be appropriate. Tr. at 508-09. David is covered under insurance as a dependent child until he can obtain Medicare with a two-year bridge. Tr. at 509-10. He will need COBRA for those two years. Tr. at 510. He can get a high-risk policy until he is 42. Id. Dr. MacDonald changed his mind about the MRIs on the phone. Tr. at 511-12. He thought it was unnecessary unless there was an exceptional circumstance. Tr. at 512. Medicare will not cover the cost of drugs. Id. These will come to \$823.80 a year after age 43 to life (or when he went on Medicare). Tr. at 513.

She believes David will be toilet-trained. Tr. at 514. Dr. MacDonald told her David would be toilet-trained after he is through puberty. Tr. at 515. David will need behavioral counseling for ten years until he goes to the facility. Tr. at 517-18. Recreation for him is trial and error. Tr. at 518. His caregivers can do it. Id. As for physical therapy, Dr. MacDonald did not think anything outside the school was necessary. Tr. at 519.

Respondent agrees to occupational therapy only until age 21, not for life. Tr. at 526-27. When David is maximized on a functional level, occupational therapy should stop. Tr. at 527. David is hypotonic. Id.

David may or may not benefit from augmentative communication. Tr. at 528. Assistive technology includes wheelchairs and feeding equipment. Tr. at 527-28. Comprehensive development is incorporated as part of his special education program. Tr. at 529. He is already getting sensory integration. Tr. at 530. Day programming is part of his residence. Id. Most sheltered workshops would be too distracting for David. Id.

Ms. Lovegrove did not visit the Dungarvin home or Stephen Croft home. Tr. at 536. David would benefit from camp. Id. She thinks he would benefit from the augmentative communication assessment. Tr. at 537. As for behavioral counseling, the group home staff should be able to deal with that. Tr. at 542.

DISCUSSION ON DAMAGES

Insurance Coverage

David will be covered under his father's Triple Gold Health Care Plan until he is 19 years old. R. Ex. JJ. If at age 19, he continues to be financially dependent on his father and is handicapped, he can remain covered until he is age 25. Id. But, this court award will preclude that coverage because it will remove David's financial dependence on his father. Therefore, the court awards \$500.00 per year (the cost of David's deductible) from the present until David's dependent coverage ends at age 19.

For three years (from age 19-22), the court awards a COBRA extension for \$100.50 per month. After that, he can obtain insurance through the Minnesota Comprehensive Health Association and the average monthly premium is \$103.16 plus an annual deductible of \$500.00 per year. At age 43, he can qualify for Medicare Part B, which will cost \$46.10 per month or \$553.20 per year plus \$100.00 per year deductible (and respondent agrees with these figures and the age of commencement of coverage).

David's insurance plan does not cover vocational rehabilitation, development delay services, non-medical self-care and self-help training, learning disabilities and disorders, recreational therapy, and rehabilitation services that are not expected to make measurable or sustainable improvement. P. Ex. 45, p. 3.

Neurologist Visits

The parties agree that David should see a neurologist twice a year. From the present until David is 22 (Triple Gold coverage and COBRA extension) the cost \$148.00 per visit or \$296.00 per year of which David pays \$15.00 per visit or \$30.00 per year. From age 22 to age 43 (Minnesota Comprehensive Health coverage) the cost is \$148.00 per visit or \$296.00 per year of which David pays \$29.60 per visit or \$59.20 per year. At age 43 when David goes on Medicare, the cost will be \$148.00 per visit or \$296.00 per year of which David pays \$69.60 per visit or \$139.20 per year. Although petitioners recommend MRIs once every three years, the court cannot see the medical necessity for them. David does not have an ongoing neurological process. His tubers will not grow or increase in number. He has a static encephalopathy. Moreover, Dr. MacDonald has apparently changed his mind about their medical necessity.

Pediatrician/Internist Visits

The parties agree that David should see a pediatrician or internist three times a year. From the present until David is 22 (Triple Gold coverage and COBRA extension) the cost is \$46.50 per visit or \$139.50 per year of which David pays \$15.00 per visit or \$45.00 per year. From age 22 to age 43 (Minnesota Comprehensive Health coverage), the cost is \$46.50 per visit or \$139.50 per year of which David pays \$9.30 per visit or \$27.90 per year. Beginning at age 43 (Medicare coverage), the cost is \$46.50 per visit or \$139.50 per year or which David pays \$9.30 per visit or \$27.90 per year.

Dentist

The parties agree that David should see a dentist twice a year for life. The annual cost will be \$188.00 (\$89.00-\$99.00) per visit.

Prescription Medicine

The parties agree that David will take Depakote for the rest of his life. In addition, in their original life care plan, petitioners requested compensation for Haldol and Cylert. Dr. MacDonald testified that David is taking Depakote. Tr. at 143. However, was most likely taking David off Cylert. Tr. at 145. He also stated that he was switching David from Melaril to Resperidol. Tr. at 146. David was not on Haldol. Petitioners' life care planner also testified that David was off Haldol and was taking Depakote, Cylert and Melaril (which would soon be substituted with Resperidol). Tr. at 292-93. In their revised life care plan, petitioners request compensation for Depakote, Melaril and Cylert.

Dr. MacDonald is David's treating neurologist. His testimony is David will be taken off Cylert and will take Depakote and Respiradol. Petitioners have not provided the court with the cost of Respiradol. Therefore, the court only awards compensation for Depakote from the present to the end of David's life.

Petitioners did not break down the individual costs of the drugs they request so the court accepts respondent's position that from now until David is 43, his Depakote will costs \$144.00 per year. At age 43 when he goes on Medicare, the cost will be \$823.00 per year for the rest of his life.

Bowel and Bladder Supplies

Respondent expects David to be toilet trained after he reaches puberty. Petitioners do not know. The court cannot assume that a ten year old child is going to be more capable of self-discipline after puberty than before, considering David's behavioral handicaps. The court awards \$2,408.00 until age 14 and then \$2,590.00 for life for bowel and bladder supplies.

Blood Tests

The parties agree that David needs blood tests twice a year. His insurance should cover the cost from the present until he is 22, and from age 43 to life. From age 22 to 43 while David is covered by Minnesota Comprehensive Health Association, the blood tests will cost \$202.20 per test or \$404.40 per year of which David will pay \$80.88.

Home Health Care Assistance

For the 177 days per year when David is in school, the court awards two hours per day of a licensed practical nurse's assistance totaling \$65.00 and two hours per day of home health care assistance totaling \$32.00. The annual total for the 177 school days is \$17,169.00.

For 86 days each year (weekends and holidays), the court awards 8 hours of home health care assistance at a daily cost of \$128.00. The annual total for weekends and holidays is \$11,008.00.

For 72 days each year⁽¹²⁾ (summer months when David is not in school), the court awards 2 hours per day of a licensed practical nurse's assistance totaling \$65.00 and eight hours per day of home health care assistance totaling \$128.00. The annual total for 72 summer days is \$13,896.00.

The combined annual total for LPN and home health care assistance is \$42,073.00.

Respite Care

The court is impressed with the hard work David's parents have expended in caring for him and awards respite care of 24 days per year through age 21 at a cost of \$25.00 per hour or \$14,400.00 annually.

Individualized Supported Living Arrangement

The court is impressed with Ms. Woodward's testimony as to the preferability of the Dungarvin homes, with their more personal assistance (only two patients rather than four), over the Croft homes. In addition, Dungarvin has a history of competency, and is closely regulated by the state of Minnesota. Since the Suels intend to keep David home until he is 22 years old, the court awards \$84,052.00 annually for David from age 22 through life.

Summer Camp

Dr. MacDonald and both life care planners agree camp would be a good experience for David. The court awards \$390.00 per year for six days of summer camp.

Behavioral Counseling and Consultation

David's behavior is one of the most difficult aspects of living and dealing with him. The court agrees that he should receive 27 hours per year to age 22 when he enters a group home, and ten hours per year from age 22 to life. From the present until David is 22, the cost is \$112.00 per hour or \$3,024.00 annually of which David will pay \$492.80. From age 22 to life the cost is \$112 per hour or \$1,120.00 per year of which David will pay the full amount.

Independent Case Management

The parties agree that David needs twelve hours per year through age 21 at a cost of \$840.00 annually, twenty hours per year from age 22 through age 23 at a cost of \$1,400.00 annually, and twelve hours per year from age 24 to life for a cost of \$840.00 annually.

Recreational Therapy

Since David will be participating in a day program, the court assumes most of his time will be occupied with organized activities. The group home, Dungarvin, will presumably provide recreational activities for its two clients. Recreational therapy is therefore denied.

Physical, Occupational, and Speech Therapies

Respondent argued that David's Triple Gold insurance policy covers physical, speech, and occupational therapy services. Petitioners argue the therapies are not covered because the policy states the following services are not covered: "services primarily educational in nature", "developmental delay services", "self-care and self-help training (non-medical)", "learning disabilities and disorders", and "rehabilitation services that are not expected to make measurable or sustainable improvement within a reasonable period of time". In the court's view, these exclusions, especially the last one, prevent David's therapies from being covered. Moreover, Mr. Suel testified that they had attempted to provide occupational therapy to David in the past and insurance would not pay. Tr. at 490-91. Respondent's life care planner also testified that petitioners were receiving no assistance in part because in the past insurance would not pay for therapies as the "company was identifying it as being maintenance therapy rather than something that had functional gain or goals attached". Tr. at 488-89.

The court awards eight hours per year of physical therapy from the present until David is 22 at \$104.00 per hour for an annual total of \$832.00.

The court finds it appropriate to award one hour per week, 48 weeks per year of occupational therapy from the present until David enters a group home at the age of 22. The cost is \$104.00 per hour or \$4,992.00 per year.

Petitioners ask for two hours per month of occupational therapy from age 22 through life, whereas respondent would eliminate occupational therapy at that point. Since David will be in a day program at the group home, occupational therapy at that time would probably be superfluous.

The court awards eight hours per year of speech therapy from the present until age 22 at an hourly rate of \$104.00 for an annual total of \$832.00. [\(13\)](#)

Assistive Technology, Augmentive Communication, Comprehensive Developmental, and Sensory Integration Assessments

Petitioners request these assessments once in David's lifetime. Respondent does not recommend them. The court assumes that a sheltered employment or day programming would perform these types of assessments in order to conform David's daytime activities to his skills. The court sees no reason to award them as a separate item of compensation.

Sheltered Employment/Day Programming Services

Petitioners request five days per week, fifty weeks per year, from age 22 through work expectancy at a cost of \$52 per day or \$13,000 per year. Respondent does not recommend it and says it is included in the

program cost. The testimony shows that Michigan requires residents in group homes to have day programs and these programs cost supplemental to the homes' cost. The court awards \$13,000 annually for this type of program through David's work life expectancy. Neither party put in evidence as to David's work life expectancy. The court will assume that is fifty-five years (sixty-five minus David's current ten years).

Equipment

Petitioners request therapy balls, a Rifton scooter board with support blocks, sensory integration equipment, a trampoline, a language board, fine motor therapy equipment, a McClaron Major Buggy, a Rifton Adaptive Tricycle, a Rifton Hammock Swing Frame with Mats, adaptive swimming aids, a hand held shower, a bath/shower chair, an electric massager, mats/weighted blankets, weighted vests, ankle weights, oral motor activity equipment, relaxing music tapes, and light dimmer switches. Respondent does not recommend awarding any money for these items.

The court has awarded compensation for physical, occupational and speech therapy. A number of the above items should be part of David's therapies (therapy ball, sensory integration equipment, language board, fine motor therapy equipment, electric massager, mats/weighted blankets, weighted vests, ankle weights). Moreover, David has an established routine with his parents which is working and he will be moving into a group home in twelve years. It seems to the court that all these sources of therapy and caregiving will provide him with the appropriate equipment to perform that therapy and maintain that care.

The court does award a McClaron Major Buggy at age 12 (when David's current buggy needs replacing), at age 17, and at age 22. The court will not continue replacing the buggy once David enters a group home as he will be in a year-round day program and will use the buggy only sporadically. The cost from age 12 to age 22 is \$93.80 per year, and at age 22 there will be a one-time cost of \$469.00.

The court awards a hand-held shower for David to assist his parents with bathing him and to be replaced every seven years. The cost is \$22.00 and then \$3.14 per year. The court does not award a shower chair as the parents do not use one now and Mr. Suel was unsure if one would be helpful. Tr. at 385.

The court awards a Rifton Hammock Swing Frame with Mats once at age 22 when David enters a group home at a cost of \$995.00.

The court is not awarding compensation for a trampoline, Rifton Adaptive Tricycle, Rifton Scooter, adaptive swimming aids, oral motor activity equipment, relaxing music tapes, or light dimmer switches.

Neither party has presented a position on growth rate. The court's custom is to award a four percent growth rate for non-medical expenses and a six percent growth rate for medical expenses.

CONCLUSION

Respondent shall file a chart reflecting the award of the court no later than Friday, October 31, 1997.

IT IS SO ORDERED.

Dated:

Laura D. Millman

Special Master

1. 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.

2. Respondent's initial position was that it was not liable for any damages because David's current condition was completely a consequence of his TS. However, the undersigned rejected this position because in deciding damages on remand after the appellate court found significant aggravation, it cannot hold consistent with the appellate decision that David's substantial deterioration is not a sequela of his vaccine injury. Since, as Judge Merow held, DPT significantly aggravated David's TS, then all damages flowing from all clinical manifestations of the worsened TS are recoverable, whenever they occur, as long as the first symptom occurred within Table time (in order for petitioners to avail themselves of the statutory presumption of causation of the initial symptom).

Then, respondent modified its position to express a willingness to pay solely for anticonvulsants since, it posited, only seizures as a symptom manifested themselves within three days of vaccination and, therefore, the only significant aggravation was seizure onset. The court disagrees. To say there are no damages except for seizures is to deny liability for significantly aggravating the entire disease, TS, of which seizures are only the first clinical sign. The seizures are the symptom, not the disease. To pay only for the first symptom is to ignore the disease.

3. On July 24, 1997, respondent filed a Motion to Consider Omnibus Record. Petitioners filed a response on August 4, 1997. For the reasons set out above, the court denies the motion. Respondent also requested that the omnibus evidence be made part of the record in this case. The court grants this request and notes that respondent has already filed numerous omnibus exhibits in this case.

4. Gomez, M.R., Kuntz, N.L., and Westmoreland, B.F., "Tuberous Sclerosis, early onset of seizures, and mental subnormality: Study of discordant [m]o[n]ozygous twins," 31 *Neur* 604-11 (1982).

5. ~~Goodman, M., Lamm, S.H., Engel, A., Shepherd, C.W., Houser, O.W., "Cortical Tuber Count: A Biomarker Indicating Neurologic Severity of Tuberous Sclerosis Complex," 12 J. Child Neurol. 85-90 (1997)~~. (This version of paper is NOT in evidence in Suel -- only the prepublication version w/out Roach editorial) See LL 1/8/97)

6. R. Riikonen, "Long-Term Outcome of West Syndrome: A Study of Adults with a History of Infantile Spasms," 37(4) *Epilepsia* 367-72 (1996). Children with TS (fifteen of 214 studied) had high rates of mental retardation and intractable epilepsy. *Id.* at 371. The emphasis on the article was the difference in outcome between those with cryptogenic infantile spasms (no known cause) and those with symptomatic infantile spasms (known cause). The latter type of spasms produced a worse result. *Id.* at 370-71.

7. In his text, Dr. Gomez states, "The age of seizure onset and the presence and severity of the mental subnormality are directly related." R. Ex. I, p. 29.

8. Shepherd, C.W., Houser, O.W., Gomez, M.R., "MR Findings in Tuberous Sclerosis Complex and Correlation with Seizure Development and Mental Impairment," 16 *A.J.N.R.* 149-155 (Jan. 1995).

9. Gomez, M., Tuberous Sclerosis (2d ed. 1988). R. Ex. I.

10. ¹⁰ Both parties submitted numerous articles concerning TS, infantile spasms, etc., which are duplicates of the articles they submitted in the Omnibus TS hearing October 8-11, 1996. The court finds the most significant evidence to be the testimony it has already discussed, with articles already referenced.

11. ¹¹ Respondent's view is that David's policy will continue because he is a handicapped adult. After two years post-termination of his policy, David can go on Medicare. Petitioners' view is that David will not be dependent on his father financially after age 25 (22 years of age until coverage under his father's policy ends plus three years of COBRA). He will be in a high-risk insurance pool until his father is 67 years old and then can go on Medicare. Tr. at 254, 250-53.

12. The court notes that 177 school days + 86 weekend and holiday days + 72 summer days total 335. The remaining 30 days in the year are 6 days at camp and 24 days of respite care.

13. ¹³ Petitioners waive their originally requested music therapy, DuoSpa Hot Tub, Water treatment chemicals, and pump and heating elements.