

OFFICE OF SPECIAL MASTERS

No. 90-3409V

(Filed: May 30, 2000)

ROBERT LEE TURNER and *
SANDRA KAY TURNER, as Legal *
Representatives on behalf of *
ROBERT CLEVELAND TURNER, *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Scott R. Brann, Houston, TX, for petitioners.
Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master.

On September 18, 1998, the undersigned issued an Order vacating its prior decision dated August 18, 1998, in order to suspend the case while other tuberous sclerosis (TS) cases went to the Federal Circuit (and ultimately the United States Supreme Court) on appeal. In the undersigned's initial opinion, the court had dismissed this case.

On May 30, 2000, the Supreme Court denied certiorari in Hanlon v. Secretary, HHS, No. 99-1223. Since the Federal Circuit

has previously affirmed the undersigned's holdings in the TS cases, this case is dismissed. What follows is the material that the undersigned has previously described in the vacated decision of August 18, 1998.

History

On January 22, 1996, the undersigned issued a decision holding that Robert Cleveland Turner's seizures began in Table time of his DPT vaccination. (Robert Cleveland Turner is referred to as Bobby.) Since Bobby suffers from TS, this matter became part of the cases pending during the undersigned's Omnibus TS hearing dated October 8-11, 1996 and June 3-4, 1997. After the court's decision in the Omnibus case, dated September 15, 1997,¹ the undersigned determined what course to follow in this individual case. To determine liability in light of the findings after the Omnibus hearing, the court questioned the medical significance of Bobby's fever and crankiness in the context of his seizures.

To address the court's question, the parties submitted medical expert reports. Petitioners submitted a report from Dr. Marcel Kinsbourne, a pediatric neurologist. P. Ex. Q. Respondent submitted reports from Dr. Mary Anne Guggenheim (R.

¹ Barnes et al. v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997).

Exs. T, X), Dr. Steven H. Lamm (R. Ex. Y), and Dr. Martin H. Bellman (R. Ex. S). Petitioners' counsel requested that the court decide the matter on the record without a hearing.

EXPERT REPORTS

Respondent filed a report from Dr. Robert Zimmerman, a radiologist, as part of the Omnibus TS proceedings. R. Ex. Q. This report reflects that Bobby has a total of thirteen cortical tubers. Id. Dr. Zimmerman found four tubers in the right cerebral hemisphere of Bobby's brain, and nine tubers in the left cerebral hemisphere. Id.

On March 7, 1998, respondent filed the first of two reports from Dr. Guggenheim. R. Ex. T. In this report, Dr. Guggenheim opines that Bobby's infantile spasms were related to his underlying TS because he did not have an acute encephalopathy after his DPT vaccination. R. Ex. T, pp. 2-3. The fever that he had the evening of vaccination lasted for only a few hours and responded to symptomatic treatment. R. Ex. T, p. 2. Although Bobby cried and was fussy, irritable, and whiny, he fell asleep and was able to drink without difficulty. Id. The seizures were his only neurologic abnormality. Id.

Dr. Guggenheim further notes that infantile spasms, which usually begin between the ages of three and eight months, are the

most common form of seizure in TS children.² Id. As they age, TS children who have infantile spasms develop a persistent seizure disorder of a different form as well as mental retardation. Id. Dr. Guggenheim traces Bobby's neurodevelopmental impairment solely to his TS. R. Ex. T, p. 3.

Based on both clinical experience and the medical literature, Dr. Guggenheim does not believe that fever causes infantile spasms. R. Ex. T, p. 2. In Dr. Guggenheim's opinion, infantile spasms do not occur as acute reactions to an acute injury. Id. Rather, these seizures present weeks after an injury occurs. Id. Dr. Guggenheim concludes that Bobby's tuber count places him at a high statistical risk for neurodevelopmental problems. R. Ex. T, p. 3.

Petitioners filed a report from Dr. Marcel Kinsbourne dated May 28, 1998. P. Ex. Q. Dr. Kinsbourne states that the majority of TS individuals do not develop seizures; however, those who do develop them generally have infantile spasms. P. Ex. Q, p. 1. Dr. Kinsbourne further notes that although TS individuals with high tuber counts are more likely to seize, a tuber count by itself cannot be considered a valid predictor of seizure onset because there is so much variability and exception in each case.

² Bobby was four and one-half months at the time of his second DPT.

Id. Citing the National Childhood Encephalopathy Study (hereinafter NCES), Dr. Kinsbourne states that DPT can precipitate infantile spasms in previously normal children.³ P. Ex. Q.

Dr. Kinsbourne's report fails, however, to address whether Bobby's post-vaccination symptoms of fever, crankiness, and irritability had any neurological significance.

In reply to Dr. Kinsbourne's report, respondent filed a second report from Dr. Guggenheim dated July 27, 1998. R. Ex. X. In this report, Dr. Guggenheim notes that there are no specific references to support Dr. Kinsbourne's assertion that the majority of TS individuals do not develop seizures. R. Ex. X, p. 1. Rather, Dr. Guggenheim's experience reflects that most TS individuals do have seizures. Id. Citing a paper co-authored by Dr. John Osborne,⁴ Dr. Guggenheim states that the majority of TS

³ Dr. Bellman, respondent's expert, co-authored the NCES. In a submission dated March 20, 1996, Dr. Bellman contradicts Dr. Kinsbourne's statement by explaining the classification method used in the NCES. R. Ex. S. He states that children with TS were classified in the previously abnormal category even if they were clinically normal prior to the onset of their seizures. Id. The previously abnormal category was used for children with neurological abnormality. Id.

⁴ Dr. Osborne was one of petitioners' expert witnesses at the Omnibus TS hearing.

individuals will seize, with onset occurring in their first year of life. Id.

Dr. Guggenheim's report also addresses Dr. Kinsbourne's statement that a high tuber count is not associated with the occurrence of seizures. R. Ex. X, p. 1. Citing various studies, including a meta-analysis conducted for the Omnibus TS hearing, Dr. Guggenheim asserts that a high tuber count is associated with the severity of cerebral dysfunction in TS patients. Id.

Based on a 1983 paper co-authored by Dr. Bellman, Dr. Guggenheim further notes that DPT does not cause infantile spasms. R. Ex. X, p. 3. Dr. Guggenheim concludes her report by reiterating her prior opinion that TS caused Bobby's current neurological problems. Id.

Respondent submitted the expert report of Dr. Robert Lamm, an epidemiologist, in response to Dr. Kinsbourne's statistical arguments. R. Ex. Y. Citing two studies, Dr. Lamm concludes that a majority of TS patients do develop seizures.⁵ R. Ex. Y, p. 1. Dr. Lamm further states that TS individuals with more than seven cortical tubers are sixteen times more likely to have

⁵ In the first study, 78% of the TS individuals had seizures, while in the second study, 87% of the TS individuals developed seizures. R. Ex. Y, p. 1.

seizures which are difficult to control. Id. A similar study found the risk of seizure to be nine times as likely. Id.

Disagreeing with Dr. Kinsbourne's statement that the age of seizure onset can predict the severity of one's condition, Dr. Lamm opines that it is the type of seizure, not the age, that is the significant predictable variable. Id.

Referring to the Bellman data, Dr. Lamm states that the NCES shows no association between DPT and onset of infantile spasms. R. Ex. Y, p. 2. There was no significant difference between onset of infantile spasms after either DT or DPT vaccine.⁶ Id.

Dr. Lamm further notes that the failure of the NCES to detect all TS individuals occurred because the NCES was not searching for an underlying cause of neurological disorders. R. Ex. Y, pp. 2-3. Rather, the NCES sought a defined group of acute severe neurological disorders, including infantile spasms. Id. Dr. Lamm notes that various studies in the medical literature reflect that there is no association between DPT and TS or infantile spasms. R. Ex. Y, p. 3. He opines that this finding is strong evidence that TS is the cause of moderate to severe

⁶ Dr. Lamm's report also corrects Dr. Kinsbourne's assumption about the categorization of TS individuals in the Bellman study. R. Ex. Y, p. 2.

mental retardation and poorly controlled seizures in TS children.
Id.

DISCUSSION

Significant Aggravation

The reports that respondent submitted address specifically the significance vel non of Bobby's symptomatology, i. e., whining, fever, and fussiness, during the onset of his infantile spasms. Dr. Guggenheim clearly interpreted these symptoms as non-neurologic when compared to the infantile spasms.

Based on this court's holding in the Omnibus TS Decision, the court finds that post-vaccinal symptoms, other than seizure, must exist and be neurologically significant for petitioners to impeach respondent's evidence that TS caused in fact the onset of Bobby's seizures. Bobby's symptoms did not have neurological significance. His fever was low, lasting for a brief period of time. His crying and irritability are of neither significant magnitude nor duration to be important neurologically.

The undersigned remains unconvinced by petitioners' evidence. Petitioners' medical expert, Dr. Kinsbourne, failed to interpret Bobby's symptoms. Rather, Dr. Kinsbourne attempted to impeach the evidence that TS children frequently seize, that a

large cortical tuber count is a poor indicator of future normalcy, and that the NCES data and Bellman's interpretation thereof involving inter alia TS individuals and infantile spasms concluded that DPT had no relationship to the onset of infantile spasms. These issues were not what the court had asked the parties to address and were rearguments of the issues the undersigned had already decided in the TS Omnibus Decision. Drs. Guggenheim, Bellman, and Lamm, respondent's experts, not only clearly dealt with Bobby's symptomatology but also addressed Dr. Kinsbourne's undocumented assertions in their respective reports.

Petitioners have failed to impeach respondent's proof that TS, not DPT, was the cause of Bobby's seizures. The vaccination was purely coincidental. The court finds that DPT did not significantly aggravate Bobby's TS, and respondent has satisfied its burden of showing a known factor unrelated caused Bobby's onset of seizures and current condition.

CONCLUSION

This petition 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.

DATE:

**Laura D. Millman
Special Master**