OFFICE OF SPECIAL MASTERS

No. 90-867V

(Filed: May 30, 2000)

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JAMES A. COPELAND and LISA G. COPELAND PARENTS and NEXT FRIENDS of ASHLEY NICOLE COPELAND,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Robert Moxley, Cheyenne, WY, for petitioners.
Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Statement of the Case

On March 30, 2000, the undersigned issued an Order stating that were tuberous sclerosis (TS) cases not pending before the United States Supreme Court on petitions for certiorari, the undersigned would dismiss 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 Order of March 30, 2000.

History

Petitioners filed their petition on September 4, 1990, alleging that Ashley's second DPT was followed by the Table injuries of encephalopathy and residual seizure disorder (RSD). 42 U.S.C. § 300aa-14(a) of the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 et seq. Ashley has tuberous sclerosis (TS), a congenital disease.

The U.S. Court of Federal Claims in Costa v. Secretary, HHS, No. 90-1467V, 1992 WL 47334 (Cl. Ct. Spec. Mstr. Feb. 26, 1992), vacated and remanded, 26 Cl. Ct. 866 (1992), on remand, 1992 WL 365421, held that TS is a latent RSD as well as a latent encephalopathy, and any analysis of the evidence must be under the theory of significant aggravation. Following that holding, Special Master LaVon French, in a decision dated January 7, 1993, held that petitioners herein were entitled to compensation on the theory of on-Table significant aggravation of Ashley's preexisting TS. Copeland v. Secretary, HHS, 1993 WL 12894 (Fed. Cl. Spec. Mstr. Jan. 7, 1993). Special Master French also held that, if she were reversed on appeal, in the alternative, petitioners had proved causation in fact significant aggravation. Id. at *7, n.19.

On February 29, 1996, this case was transferred as part of the transfer of all TS cases to the undersigned for disposition. Subsequently, this case became part of the Omnibus TS hearing that lasted for a total of six additional 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. Barnes, et al. v. Secretary, HHS, No. 92-0032V et al., 1997 WL 620115 (Fed. Cl. 1997), aff'd sub nom., Hanlon v. Secretary, HHS, 40 Fed. Cl. 625 (March 20, 1998), aff'd, 191 F.3d 1344 (Fed. Cir. Sept. 8, 1999), reh'g denied (Oct. 20, 1999), petition for cert. filed Jan. 18, 2000 (No. 99-1223); and Plavin v. Secretary, HHS, 41 Fed. Cl. 671 (Aug. 25, 1998), aff'd, 184 F.3d 1380 (Fed. Cir. Sept. 8, 1999), reh'g denied (Oct. 20, 1999), petition for cert. filed Jan. 18, 2000 (No. 99-1223).

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. Because Ashley experienced on-Table infantile spasms with irritability and crying, the undersigned issued an Order dated September 22, 1997 subsequent to the undersigned's Omnibus TS Decision, ordering the parties to submit additional affidavits regarding whether Ashley's irritability and crying constituted a neurologic effect of the DPT vaccine or were mere transient symptoms unconnected to Ashley's seizure onset. It has taken the parties over two years to submit their final reports and summary briefs.

Petitioners' summation brief reargues all of the issues that the undersigned has previously tried and decided in the 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. The undersigned will not allow petitioners' counsel to relitigate these matters but restricts this opinion to the evidence both sides have produced in response to the undersigned's Order of September 22, 1997.

The undersigned notes that petitioners' counsel's insistence that the undersigned cannot hold differently than Special Master French's earlier decision on entitlement flies in the face of the law, particularly in this Program where the special masters are invested with inquisitorial authority. 135 Cong. Rec. H9476 (daily ed. Nov. 21, 1989). All of the issues and articles presented to Special Master French were discussed at length during the Omnibus TS hearing. Dr. Manuel Gomez, upon whose opinion Special Master French relied greatly in her entitlement decision, testified during the Omnibus TS hearing that he had come to the opposite conclusion he previously articulated due to subsequent medical studies and his own earnest wish to testify truthfully.

Petitioners' insistence that "the law of the case" forbids the undersigned to hold any differently than Special Master French misconceives the nature of that doctrine. The law of the case is appropriate where an appellate court has decided an issue (such as the Honorable Moody R. Tidwell in Costa, supra) and the lower court is bound to follow its holding. But where the same court, such as the Office of Special Masters, is involved, and the case is continuing after the accumulation of much more scientific evidence over the passage of years, to follow petitioners' interpretation of "the law of the case" to preclude reevaluation of entitlement would flout the prior holdings of the Federal Circuit, the U.S. Court of Federal Claims, and the undersigned.

"Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand." Hanlon, supra, 40 Fed. Cl. at 630.

"Whether or not to reconsider, prior to issuance of a final decision, an announced finding of entitlement in a vaccine case is left to the discretion of the special master." Hanlon, supra, 40 Fed. Cl. at 629.

The Federal Circuit stated in Hanlon that "it is not an abuse of discretion to consider new pertinent medical evidence that was not available at the time of the original petition," citing McAllister v. Secretary, HHS, 70 F.3d 1240, 1244 (Fed. Cir. 1995). Hanlon, supra, 191 F.3d at 1350. Petitioners' counsel has repeatedly made the same argument and repeatedly failed to persuade any court of its validity from the Office of Special Masters to the U.S. Court of Claims to the Federal Circuit, and now back again to the Office of Special Masters.

Petitioners further object to respondent's submission, in response to the undersigned's Order of September 22, 1997, of the opinion of respondent's expert Dr. Mary Ann Guggenheim, a pediatric neurologist. Petitioners claim Dr. Guggenheim is biased for presumably not believing that DPT causes permanent neurologic damage. The undersigned has previously held that whether Dr.

Guggenheim believes that DPT can cause permanent damage is irrelevant since Congress obviously believes that it can. The Vaccine Act controls the undersigned's evaluation of the vaccine cases. The only interest the undersigned has in Dr. Guggenheim's opinion (as well as in petitioners' expert Dr. Kinsbourne's opinion) is whether Ashley manifested a neurologic reaction to her second DPT vaccine and the basis for each expert's opinion.

Lastly, in reference to petitioners' assertion that the undersigned must rule in accordance with Special Master French because she held in the alternative that petitioners proved that DPT caused in fact Ashley's significant aggravation, the undersigned reminds petitioners that the holding of the Omnibus TS Decision (affirmed on two appellate levels) is that respondent satisfied her burden of proving that TS caused in fact the seizures and subsequent symptoms of the vaccinees who manifested afebrile seizures without other specified symptoms, such as fever, anorexia, etc. As the Federal Circuit stated in Hanlon, "There is ample support in the record for this determination [that TS was the actual cause of Michael Hanlon's seizures]." Hanlon, supra, 191 F.3d at 1349.

When other specified symptoms accompany the onset of seizures in TS cases, the undersigned stated in the Omnibus TS Decision that she would take further medical evidence on the neurological significance vel non of these symptoms. Thus, the only question before us here is whether Ashley's unusual irritability, not feeling well, and crying constituted a neurologic reaction to her second DPT vaccine.

Submissions

The submissions of the parties following the undersigned's Order of September 22, 1997 include the following:

1. Respondent's expert Dr. Robert A. Zimmerman's review of an MRI dated December 26, 1991, stating he saw six tubers. R. Ex. S.

2. Respondent's expert Dr. Zimmerman's review of an MRI dated May 14, 1998, six and one-half years after the prior MRI, stating he saw ten tubers. R. Ex. T.

3. Petitioners' expert Dr. Roy D. Strand's review of the MRI dated May 14, 1998, stating that on standard imaging sequences, he could not find tubers, but on the very sensitive FLAIR imaging, he found three to five tubers. Nonetheless, Dr. Strand concluded that Ashley's brain image was essentially normal "with the above caveat." P. Ex. 5.

4. Petitioners' expert Dr. Marcel Kinsbourne's statement that Ashley's TS was mild and she should have had a good outcome except for her onset of infantile spasms. Dr. Kinsbourne's basis for his opinion is that Ashley had no tubers (the 1991 MRI) or "the possibility of three to five nonspecifically abnormal cortical high signal sites on the FLAIR imaging" (the 1998 MRI). Dr. Kinsbourne considers Ashley's TS to be "very mild, with no definite tubers present." He opines that her extreme irritability post-vaccination indicates that DPT caused her seizures, and concludes that DPT significantly aggravated her TS because "[t]he only documented additional factor that could have contributed substantially to the causation of Ashley's seizure disorder and psychomotor retardation was the second DPT vaccination." P. Ex. 6.

5. Petitioners submitted a medical article entitled "Seizures following childhood immunizations," by D.G. Hirtz, et al., *J. Pediatrics* 102:14-18 (1983), discussing 40 children who had seizures after vaccinations with DPT or measles vaccines. Thirty-nine of them had seizures associated with fever, often high. The one child who did not have a fever had a history of breath-holding spells. No child developed epilepsy. The authors conclude that the seizures resemble closely febrile seizures which are common in early childhood. In trying to explain why a few children with immunization-associated seizures have bad outcomes, the authors surmise that DPT, which can cause fever, may also cause a lengthy febrile seizure, and a lengthy febrile seizure can also

cause hypoglycemia, which can cause a lasting deficit. P. Ex. 7.

6. Respondent submitted the expert medical report of Dr. Mary Anne Guggenheim, a pediatric neurologist. R. Ex. U.[1] Dr. Guggenheim' s opinion is that Ashley's TS caused the onset of her infantile spasms. Her basis is that TS disturbs the neurons of the cerebral cortex. Even a single cortical tuber may institute seizures. The more tubers, the more likelihood of clinical symptoms, but location and size of the tubers also play a role in the manifestation of clinical symptoms. Moreover, the type of seizure Ashley manifested, infantile spasms, is the most common initial seizure type of TS children in their first year of life.

The NCES (National Childhood Encephalopathy Study)[2] data as well as the Institute of Medicine do not correlate a causative relationship between DPT and infantile spasms. A world expert in infantile spasms, Dr. Peter Kellaway, opines that infantile spasms are not a response to an acute event. Vaccinations are an acute event. Lastly, Dr. Guggenheim questions Dr. Kinsbourne's opinion that DPT was the only additional factor that contributed to causing Ashley's seizure disorder and retardation. She states that she is unaware of any support for Dr. Kinsbourne's opinion. She

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[1] Dr. Guggenheim gave a history of the facts: Ashley's mother recalled that Ashley had unusual eye movements the day after she received her second DPT vaccination. Mrs. Copeland took Ashley to see her pediatrician, Dr. Schenk, three weeks later and reported that Ashley had problems with shaking and tremor which seemed unassociated with anything. Dr. Schenk's evaluation of Ashley was that she was normal. Mrs. Copeland returned to Dr. Schenk 11 days later because of her concern about Ashley's spells. Dr. Schenk referred her to a pediatric neurologist, Dr. Hille, who diagnosed Ashley as having infantile spasms. Neither in the parental history nor in the medical records is there an indication that Ashley had an acute encephalopathy after her second DPT vaccination.

[2] R. Alderslade, et al., "The National Childhood Encephalopathy Study: A report on 1000 cases of serious neurological disorders in infants and young children from the NCES research team," Department of Health and Social Security, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunization (London: Her Majesty's Stationery Office, 1981).

further states that the natural history of TS children who do not receive immunizations is comparable to Ashley's course.

With reference to Dr. Kinsbourne's conclusion that Ashley's extreme irritability meets the criteria set up in the Omnibus TS Decision for vaccine causation, Dr. Guggenheim states that during the six weeks between the onset of Ashley's infantile spasms and Dr. Hille's diagnosis of her condition, her course did not change dramatically except for the spasms themselves. Dr. Schenk recorded in his examination of December 7, 1987 that Ashley was alert, active, with normal muscle tone and good eye movement. In his examination of September 18, 1987, Dr. Schenk wrote that Ashley was alert and playful, with nothing abnormal neurologically. Dr. Hille noted on January 5, 1988 that she had an even disposition. Mrs. Copeland kept a baby book and, in her six-month entry for Ashley, she wrote "your [sic] having seizures but despite that your [sic] a good baby." Dr. Guggenheim concludes that TS is the sole cause of Ashley's infantile spasms.

Respondent filed Dr. Guggenheim's curriculum vita as Ex. V. Dr. Guggenheim is a pediatric neurologist in private practice. She is board-certified in both pediatrics and in neurology with special competence in child neurology. She is a clinical professor of pediatrics and neurology at the University of Colorado School of Medicine. She has been on the executive committee of the Child Neurology Society since 1979.

7. Petitioners submitted the supplemental report of Dr. Kinsbourne, dated December 4, 1999. P. Ex. 8. He challenges Dr. Guggenheim's statement on the relationship of the number, location, and size of tubers and clinical symptoms as being unspecific to Ashley's case. Furthermore, he asserts that neuroimaging does not reveal Ashley to have any tubers, referencing Dr. Strand's report.

He asserts that Dr. Guggenheim's claim that DPT does not cause infantile spasms and the onset of infantile spasms after brain injury takes weeks relates only to cryptogenic infantile spasms.

Ashley's infantile spasms are not cryptogenic because their cause, TS, is known. TS children are more vulnerable than normal infants and infants with other forms of brain damage. Dr. Kinsbourne insists that DPT is a trigger of infantile spasms, and the brain insult occurring to the TS child's brain occurs early in fetal development. He decries comparing Ashley to non-vaccinated TS children in the similarities of their courses.

8. Petitioners submitted Ex. 9, "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," by C.L. Cody, et al., *Pediatrics* 68:650-60 (1981). The authors conclude that minor reactions are significantly more frequent after DPT vaccine than after DT vaccine. These minor reactions include fretfulness (56.2% of DPT vaccinees), persistent crying, and unusual crying. Nine children had convulsions. Seven of those nine had elevated temperatures at the time. None of the convulsions was infantile spasms. All of these children returned to normal within 48 hours.

9. Respondent submitted the supplemental report of Dr. Guggenheim, dated January 30, 2000. R. Ex. GGG. She emphasizes that, unlike Dr. Kinsbourne's statement that he doubts that Ashley has any tubers, that Dr. Zimmerman has found 10 separate, cortical tubers in Ashley's brain. There are no controlled studies demonstrating an increased risk of infantile spasms within three days of DPT vaccination. Dr. Kinsbourne's hypothesis that DPT transforms TS into clinical symptoms is unsupported by clinical data or other studies. On the contrary, she states there is extensive evidence that the brain disruption occasioned by TS cortical tubers more likely causes neurologic symptoms.

DISCUSSION

Regarding the allegation that Ashley had an on-Table encephalopathy, nothing in the medical records or even the testimony supports a diagnosis of an acute encephalopathy post-vaccination. If

Ashley did not have a pre-existing illness, TS, and this case were to be analyzed under the theory of RSD, she would have a presumptive on-Table case. But, as the parties recognize, we are dealing with the question of significant aggravation of her TS because of the vaccine's purported triggering of the onset of her infantile spasms.

Petitioners' expert, Dr. Kinsbourne, presents two contrary positions in his two reports: that Ashley does not have cortical tubers, but that DPT significantly aggravated her TS. If indeed Ashley were so fortunate as to have no cortical tubers, then DPT could not have significantly aggravated her TS and we would be back to an on-Table RSD. However, there is ample and credible proof that not only does Ashley have TS, but also that it is not mild, but involves at least 10 tubers.

Dr. Zimmerman, respondent's expert pediatric neuroradiologist, counted 6 tubers in the 1991 MRI. He counted 10 tubers in Ashley's 1998 MRI. The increase in the number is due to the better detection of the MRI rather than an actual increase in the number of Ashley's tubers because, in TS, one is born with the number of tubers one has through life.

Petitioners' expert pediatric neuroradiologist, Dr. Strand, opines that Ashley's 1998 MRI shows an essentially normal brain with the caveat (his term) that FLAIR imaging showed three to five tubers. Dr. Kinsbourne, petitioners' expert neurologist, initially interprets the three to five tubers as signifying mild TS, but in his supplemental report, he forgets the caveat and runs with the "essentially normal" conclusion of Dr. Strand. But is that conclusion honest or credible? The undersigned believes it is not credible.

A caveat is a warning. About what is Dr. Strand warning the reader? That his conclusion that Ashley has an essentially normal brain is not true. FLAIR imaging is more sensitive than the

MRI.[3] Yet, Dr. Strand is willing to ignore both its results and Dr. Zimmerman's results (from both the 1991 and 1998 MRIs) and state that Ashley's brain is essentially normal.

Dr. Kinsbourne, being less than candid, posits his whole opinion on Ashley's having "very mild" TS (or an essentially normal brain) because he doubts that she has tubers. Since the basis of Dr. Kinsbourne's opinion is fallacious, i.e., Dr. Strand's report, his opinion is equally not credible.

Comparing the curriculum vitae of Drs. Zimmerman and Strand is also instructive in determining who is the more credible of the two. Dr. Zimmerman's curriculum vita is 137 pages long. R. Ex. R. He is board-certified in radiology with added qualifications in neuroradiology. He is the Chief of Pediatric Neuroradiology and Pediatric MRI at the University of Pennsylvania, The Children's Hospital of Pennsylvania.. He is editor-in-chief of USA *Neuroradiology* and is on the editorial boards of *Neuroradiology*, *Pediatric Neurosurgery*, the *American Journal of Neuroradiology*, and *Critical Reviews in Neurosurgery.* He was a member of the National Board of Medical Examiners - AAN/ANA Test Committee for twelve years. He graduated medical school summa cum laude.

Dr. Zimmerman has authored or co-authored 354 papers including articles on MRI imaging of TS (no. 261), solitary cortical tubers (no. 287), and pediatric brain tumors (nos. 256, 260, 266, 284, 291, 311, 315, 321, 327). He is the sole author of an article on FLAIR imaging to which the undersigned referred in footnote 3. He has written 78 chapters or reviews in textbooks including medical imaging of pediatric brain tumors for the Proceedings of International Symposium on

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[3] FLAIR stands for fluid-attenuated inversion recovery imaging. It is "a technique that increases the sensitivity of magnetic resonance imaging to detect central nervous system (CNS) diseases characterized by an increase in interstitial water content such as brain tumors, cerebral infarcts, and gliotic scars." R.A. Zimmerman, "Recent Advances in MR imaging: FLAIR imaging," *Critical Reviews in Neurosurgery* 8:188-92 (1998). C. Ex. 1. See also C. Exs. 2-4 on the greater visualization of brain images with the use of FLAIR imaging.

Pediatric Neuro-Oncology in 1986 (no. 32). He wrote the chapter on phakomatoses in a textbook on TS (no. 45). He co-authored the chapter on pediatric cerebral anomalies for a textbook on MRI (no. 51). He co-authored a literature review on MRI imaging of TS (no. 57). He co-authored a chapter on brain tumors for a text on neurosurgery in 1996 (no. 68). He was the sole author for a chapter on brain tumor imaging for a handbook of clinical neurology in 1997 (no. 71). He was the sole author for three chapters in a text for which he is one of three editors on cranial MRI and CT in 1999, and two of those chapters deal with craniocerebral anomalies and pediatric brain tumors (no. 76). He participated in 170 conferences and has taught numerous courses in the United States and overseas. He participated in a 1994 conference that dealt with hamartomas of the brain stem and hypothalamus (no. 138). He spoke at the annual conference of The Society for Pediatric Radiology on "Improved Visualization of the Lesions of Tuberous Sclerosis with Unenhanced Magnetization Transfer Suppression T1-weighted Images" in 1995 (no. 142). He spoke on FLAIR imaging at the 1999 Congress of the European Society of Neuroradiology (no. 167). He has a 64-page listing of lectures by invitation.

Dr. Strand, on the other hand, has an 11-page curriculum vita. He voluntarily resigned from the Boston Children's Hospital and is currently a staff neuroradiologist at Walter Reed Army Medical Center. He consults at Children's National Medical Center. He is on the editorial staffs of *Radiology* and *The American Journal of Neuroradiology*. He has authored or co-authored 54 articles and 9 chapters or reviews. He has made 2 video presentations, both in 1995. P. Ex. 12. Compared to the colossal credentials of Dr. Zimmerman, Dr. Strand is not in the same stratosphere. Their credentials as well as the inherent dishonesty of Dr. Strand's interpretation of Ashley's 1998 MRI weigh heavily in Dr. Zimmerman's favor. The undersigned is confident that Dr. Zimmerman is far more capable in interpreting Ashley's MRI and finds his conclusion that she has 10 tubers to be

more credible than Dr. Strand's conclusion that Ashley is essentially normal (with the "caveat" of three to five tubers on FLAIR imaging).

The issue that prompts the present determination is whether or not Ashley's irritability, feeling unwell, and crying constitute a neurologic reaction to her second DPT vaccination so that her onset of infantile spasms is more than an expected result of her TS. As petitioners have shown in their Ex. 9, the Cody article, irritability afflicts over half of DPT vaccinees. Irritability and crying are customary transient reactions to DPT. Dr. Kinsbourne has not provided any credible information to believe otherwise. Petitioners' Exs. 7 and 9 (the Hirtz and Cody articles), show that febrile seizures sometimes follow DPT vaccination, but do not include any reaction of infantile spasms.

Dr. Guggenheim's opinion, that Ashley's course is consistent with the course of other TS children in the first year of their lives, is more credible than Dr. Kinsbourne's. Ashley has a sizable number of tubers. The onset of her infantile spasms came at the typical age for TS children to experience them. She had no abrupt change in her affect or behavior to suggest that anything other than the clinical manifestation of TS was occurring over the weeks between vaccination and diagnosis. Dr. Kinsbourne's theory that some external stimulus "must" be present in TS children in order for them to begin to manifest clinical symptoms is neither supported nor credible.

Numerous tubers in the brain distort brain function and that distortion often takes the form of seizures, particularly infantile spasms. The credible evidence in this case is that Ashley has numerous tubers, that they disrupted her brain at the typical age that TS children with numerous tubers begin to manifest infantile spasms or other afebrile seizures (such as occurred in Michael Hanlon and Rachel Plavin), and that TS is the factor unrelated to the DPT vaccine that caused Ashley's seizures.

Respondent has successfully rebutted petitioners' prima facie case that DPT significantly

aggravated Ashley's preexisting TS by proving that TS is the cause in fact of her seizures and her current condition.

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: _____

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Laura D. Millman
Special Master