United States Court of Federal Claims

No. 90-1126V
(Filed November 6, 2000)

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VERONICA FLANAGAN, as parent and next friend of ASHLEY FLANAGAN,	*	Vaccine; motion for review; delayed onset of symptoms; burden of proof.
Petitioner,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
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Robert T. Moxley, Cheyenne, WY, for petitioner.

Kathleen P. Hewitt, Washington, DC, with whom was Assistant Attorney General David W. Ogden, for respondent.

ORDER

MILLER, Judge.

Petitioner challenges the special master's denial of compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1-34 (1994 & Supp. IV 1998) (the "Vaccine Act"), on the basis that the special master abused her discretion in finding that the infant did not develop chronic epilepsy at the time of her vaccination and that the special master erred by imposing an evidentiary burden on petitioner to establish that the infant's symptoms following vaccination were of "neurological significance." Argument is deemed unnecessary. The court sustains the special master's decision.

FACTS

The record before the special master reveals the following facts. On September 21, 1990, Veronica Flanagan ("petitioner") filed for compensation under the Vaccine Act on behalf of her daughter, Ashley Flanagan ("Ashley"). Petitioner alleged that diphtheria, pertussis, and tetanus ("DPT") and measles, mumps, rubella ("MMR") vaccinations significantly aggravated Ashley's genetic disease, tuberous sclerosis ("TS").

Ashley was born on September 4, 1980. She received her first two DPT vaccinations without incident. On March 26, 1981, at age six months, she received her third DPT vaccination. Within six hours, Ashley suffered convulsions.

Ashley was admitted to the Stormont-Vail Emergency Room with a temperature of 101.2 degrees F. The admission history notes that she received a DPT vaccination that day and became feverish, vomited, and appeared listless throughout the evening. Ashley's extremities jerked and she became unresponsive to verbal stimulation. On admission, however, Ashley had eye contact, rolled over, and tried to crawl. She seemed alert and happy. Dr. David Kelly, the staff physician, had the impression that Ashley had suffered a febrile convulsion, ruling out TS.

Four days later, on March 30, 1981, Ashley underwent a neurological examination, the results of which were completely normal. The medical history notes that Ashley had depigmentation and a computed tomography ("CT") was scheduled for a TS evaluation.

Ashley's CT results, noted in her medical records on April 3, 1981, showed the presence of tubers. She had multiple high density areas, the largest on the brain's left side, a smaller density area on the right side, and other tiny density areas. Ashley's April 16, 1981 electroencephalogram ("EEG") results were normal.

On May 22, 1981, Ashley was taken to Dr. Joseph M. Stein for a neurological consultation, where her fever of 103 degrees was recorded. When Ashley was admitted to the emergency room later that day, she suffered a second seizure. Her head and eyes turned to the right and she made sucking movements with her mouth. All four of her extremities exhibited tremulous movements. Dr. Stein concluded that Ashley had suffered a febrile seizure, 1/ possibly related to her underlying TS. Consequently, she was placed on Phenobarbital. Ashley remained in the hospital until May 24, 1981. Dr. Greggory J. Van

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1/ A febrile seizure is a seizure that is associated with fever.

Sickle analyzed Ashley's urine culture and found that she also had pyelonephritis, an inflammation of the kidney and its pelvis due to bacterial infection.

From June 1981 through December 1981, Ashley was diagnosed with a variety of respiratory infections and a viral syndrome, which were accompanied by fevers, vomiting and weight loss. During this period the medical records note that Ashley's developmental and neurological milestones were normal for her age. The physical examinations revealed no abnormalities and excellent growth.

On January 5, 1982, Ashley was given an MMR vaccination. Ten days later, on January 15, 1982, Ashley had a third seizure lasting 15 minutes, accompanied by a fever registering 103 degrees. Dr. Van Sickle concluded that she had suffered status epilepticus. She remained in the hospital for the next four days, during which time she continuously spiked night time temperatures of up to 104.5 degrees. She also had a rash which cleared in two days. Dr. Van Sickle diagnosed Ashley with TS and resolving viral syndrome. Ashley was continued on Phenobarbital.

From January 1982, through May 1983, Ashley visited the doctor for a variety of illnesses, including rhinorrhea, a bacterial upper respiratory infection, and a thigh abscess. She had high fevers during this time. Her developmental and neurological examinations were normal. Her language was age appropriate. In May 1983 Ashley had a 106-degree fever and seized for approximately an hour.

On April 18, 1985, Dr. R.E. Baska, a neurologist who examined Ashley, wrote to Dr. Van Sickle that Ashley had suffered, by that date, a total of five generalized seizures. Her last seizure had occurred 18 months before the visit and had lasted the longest, at least 60 minutes. The other seizures lasted from 15 to 20 minutes. Ashley had a short attention span, possibly related to the Phenobarbital she had been taking since infancy. She had normal intelligence, cranial nerve, motor, sensory, and cerebellar function and her EEG results were normal.

Ashley visited Dr. Van Sickle subsequently for colds, ear infections and bronchitis. On June 6, 1986, Ashley was five and three-quarters years old and could count to 100 and knew colors, her address, and her parents' names. She had been off Phenobarbital since January without incurring problems. She had a normal growth rate and a normal exam except for huge tonsils and adenoma sebaceum, which forms nodules on the face and is associated with TS.

From January 1988 through the end of 1989, Ashley's seizures occurred more frequently. The episodes varied, but exhibited focal jerking on her right side, throat gurgling,

urinary incontinence and inappropriate speech or muttering. The seizures lasted from 11 to 20 seconds. Because she had not been taking Phenobarbital, she was placed on Tegretol and later Depakote.

On June 23, 1989, Dr. Van Sickle noted that Ashley was having four to five seizures over a four-day period monthly. On November 11, 1989, Dr. Van Sickle sought another doctor's advice, questioning whether Ashley's predictable monthly seizures were related to hormonal fluctuations, even absent frank puberty. On April 24, 1990, Dr. Van Sickle noted that Ashley had seized during middle days of the previous four months, on January 22-24, February 13-15, March 17-19, and April 15-17. The seizures had also changed somewhat. During episodes she exhibited shrill cries and arm movements lasting 30 seconds. Following seizures Ashley suffered headaches.

Dr. Baska evaluated Ashley again on March 6, 1991. He wrote Dr. Van Sickle concerning her condition. Ashley had been having at least one seizure weekly and as many as four to eight seizures daily. Her seizures last a few seconds and consisted of right-arm flexion and guttural or throaty noises. During episodes Ashley lifted her left hand to her throat. Her school performance and behavior had deteriorated. Other children at school had been teasing her. Dr. Baska recommended increasing Ashley's dose of Diamox, which she had been taking since June 1990. Thereafter, her seizures continued to occur primarily toward the end of her menstrual month.

On June 15, 1991, Ashley saw Dr. Peter Huttenlocher, a pediatric neurologist and expert in TS, at the University of Chicago. Dr. Huttenlocher recommended that Ashley attend summer school, consider psychological counseling, and begin a trial of Depakote and Tegretol. If that combination failed to improve her seizure control, he suggested epilepsy surgery because Ashley's seizures had been stereoptyped and focal since early infancy and her large tuber in the left temporal area might well be triggering her attacks.

PROCEDURAL HISTORY

The procedural history of this case is significant. This case was one of over 60 TS cases filed under the Vaccine Act and assigned to the special master. Prior to 1995 the special master generally relied on the Court of Federal Claims' decisions in Suel v. Secretary of Dept. of Health & Human Servs., 31 Fed. Cl. 1 (1993), and Costa v. Secretary of Dept. of Health & Human Servs., 26 Cl. Ct. 866 (1992), to support the conclusion that any TS child who suffered an on-Table seizure was entitled to a presumption of significant aggravation of his or her TS. In this case, because Ashley suffered two on-Table seizures, Special Master Laura D. Millman concluded on June 30, 1993, that Ashley had suffered significant aggravation of her TS and was entitled to compensation. Flanagan v. Secretary of Dept. of

Health & Human Servs., No. 90-1126V, 1993 WL 264532 (Fed. Cl. Spec. Mstr. June 30, 1993).

In March 1995, however, respondent presented new evidence to the special master in all pending TS cases. That evidence concerned the relationship between the cortical tubers of TS patients and their seizures and mental retardation. Based upon this evidence, and a report from Dr. Manuel Gomez, a leading medical authority on TS, respondent moved the special master to take additional expert testimony that would apply to all TS cases.

On April 11, 1996, the special master issued an Omnibus Order consolidating the TS cases (including this case) for purposes of an expert hearing to determine if respondent's new evidence established the defense that the claimants' conditions were due to TS and whether petitioner therefore was statutorily precluded from compensation under the Vaccine Act. A TS Omnibus Trial was held October 8-11, 1996, and on June 3-4, 1997.

The special master issued her "TS Omnibus Decision" on September 15, 1997, ruling that in two "test" cases "[r]espondent has successfully rebutted petitioners' presumption of significant aggravation of preexisting TS from DPT vaccine by proving that TS caused in fact both petitioners' onset of seizures and current condition . . . ." Barnes v. Secretary of Dept. of Health & Human Servs., 1997 WL 620115 at *34 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). The special master found that respondent had shown that "the presence of tubers in the cerebral cortex, which is the hallmark of TS, leads to seizures in the majority of TS patients." Id. at *33. As she explained, "TS is the overwhelming cause of seizures in a child afflicted with the disease, unless he develops a fever or some other well-recognized reaction to a vaccination." Id. at *32. The Federal Circuit affirmed the Omnibus ruling. Hanlon v. Secretary of Health & Human Servs., 191 F.3d 1344 (Fed. Cir. 2000), cert. denied, Hanlon v. Shalala, 68 U.S.L.W. 3491 (U.S. May 30, 2000).

Shortly after issuing the Omnibus Decision, the special master issued an order in this case reconfirming her original June 30, 1993 decision. Flanagan v. Secretary of Dept. of Health & Human Servs., No. 90-1126V (Fed. Cl. Spec. Mstr. Sept. 24, 1997). The special master noted her findings of on-Table symptoms of "fever of 101.2 degrees Fahrenheit, vomiting, listlessness, and unresponsiveness to verbal stimulation." Id. at 2. She concluded that respondent had failed to rebut the presumption of causation. Id.

Respondent moved for reconsideration of that order on October 7, 1997, urging the special master to take specific medical expert evidence regarding the medical significance of Ashley's table symptoms. The special master granted the motion, ordering "production of medical reports to ascertain whether the symptoms in addition to the seizures are

significant neurologically or related to a transient reaction to DPT." Flanagan v. Secretary of Dept. of Health & Human Servs., No. 90-1126V at 2 (Fed. Cl. Spec. Mstr. Dec. 16, 1997).

Respondent submitted the written report of Dr. Gregory Holmes on June 23, 1998, asserting that Ashley's neurologic impairment was due solely to her TS and was not aggravated by either the March 26, 1981, DPT vaccination or the January 5, 1982, MMR vaccination. Petitioner's expert was Dr. Marcel Kinsbourne, whose report asserted that while Ashley's TS made her susceptible to seizures, the DPT immunization nevertheless caused her seizures. The special master took testimony from both experts at an evidentiary hearing held on September 2, 1999.

On August 4, 2000, the special master issued a final decision denying compensation and dismissing the case. Flanagan v. Secretary of Dept. of Health & Human Servs., No. 90-1126V, 2000 WL 1207256 (Fed. Cl. Spec. Mstr.) ("Final Decision"). This appeal followed.

DISCUSSION

1. Standard of review

When reviewing a special master's decision under the Vaccine Act, the Court of Federal Claims is authorized to "set aside any findings of fact or conclusion[s] of law of the special master found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B). As the Federal Circuit has stated:

> "These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by [the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the 'not in accordance with the law' standard; and discretionary rulings under the abuse of discretion standard."

Saunders v. Secretary of Dept. of Health & Human Servs., 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting Munn v. Secretary of Dept. of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

2. Petitioner's objections

Petitioner makes three objections challenging the special master's decision. First, petitioner broadly criticizes the special master's factual findings as arbitrary and capricious.

Petitioner argues that it was arbitrary and capricious for the special master to find that Ashley's post-vaccination seizure was isolated and had no neurologic significance.

The special master relied on the testimony of Dr. Holmes in finding that the March 26, 1981 post-DPT vaccination seizure was isolated and did not contribute to Ashley's current condition. Dr. Holmes agreed that the DPT did cause a fever 2/ in Ashley and that this fever "resulted in her onset of seizures." Final Decision at *13. Dr. Holmes testified that this seizure, along with the four other seizures Ashley had during the first five years of her life were febrile (meaning they were "associated with fever") and that Ashley was developing normally (maintaining her milestones and intelligence) during these five years. The special master found that these febrile seizures were not the cause of Ashley's current condition, noting that "[s]eizures are not necessarily harmful in all cases," when, for example, "there are initially very brief seizures that are not followed for years by developmental delay." Id. at *15.

Instead, the special master found that Ashley's later seizures, after she was five years old, were the actual cause of Ashley's eventual developmental delay and that these seizures were caused by her underlying TS. These seizures were afebrile and began after Ashley was taken off the anti-seizure medication Phenobarbital. The special master attributed these afebrile seizures to the "normal course of a TS-caused disorder unfortunately." Final Decision at *14. These seizures began five years after the DPT vaccination. Ashley's "decline in intelligence and other skills did not occur until she was ten years old, which was nine and one-half years after the onset of her seizures." Id. Dr. Holmes testified about this delay between Ashley's vaccination and the onset of the damaging afebrile seizures, and it was this delay to which the special master attached significance. As the special master noted, "This is not a case in which a TS child manifests infantile spasms 3/ and then experiences a decline in mental ability within weeks or months," id. at *14; "it begs credulity to link causally the appearance of the seizures in Ashley's first five years with her later developmental delay and mental retardation." Id. at *15.

Dr. Holmes also addressed Ashley's "blank stares," which are not in the medical records, but about which petitioner testified. Both petitioner and Dr. Kinsbourne, petitioner's

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2/ Petitioner did not make any arguments asserting that the "vomiting, listlessness, and unresponsiveness to verbal stimulation" Ashley experienced after the DPT were neurologically significant.

3/ "The bad outcome from early onset of seizures in TS occurs only in infantile spasms, which are bad for the brain." Final Decision at *8.

expert, believed that these blank stares were seizures, while Dr. Holmes did not. The special master resolved the issue in favor of Dr. Holmes, explaining that he

> has a clinical pediatric neurologic practice and current and past TS patients, and teaches at Harvard Medical School, whereas Dr. Kinsbourne has not been in practice for ten years and teaches non-medical students about the organic basis for psychological problems at the New School for Social Research, a non-medical school.

Final Decision at *13.

Dr. Kinsbourne disagreed with Dr. Holmes on a host of issues. He claimed that DPT lowered Ashley's seizure threshold and "that had she not seized at all, she would not have developed afebrile seizures years later and, therefore, never have suffered from developmental delay." Id. at *14. The special master found this argument "not [] credible." Id. Dr. Kinsbourne also presented a theory of DPT "invading the brain" which the special master found "inappropriate to the medical facts of this case." 4/ Id. at *14.

Petitioner argues that reliance on Dr. Holmes' opinion "exalt[ed] the messenger instead of the message." Pet.'s Br. filed Sept. 1, 2000, at 12. Petitioner objects to with the special master's reliance on the direct and cross-examination testimony of Dr. Holmes and claims that it was a "storybook fantasy." Id. at 8. Petitioner's argument is, at bottom, that Dr. Holmes' testimony is "not true!" Id. at 19. Thus, petitioner quarrels with the special master's findings of fact.

The special master's decision to credit Dr. Holmes' expert testimony is subject to reversal only if shown to be arbitrary and capricious. The special master has broad discretion to weigh expert evidence and make factual determinations. Bradley v. Secretary of Dept. of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). Once made, such determinations are "virtually unreviewable." Id.; Hambsch v. Dept. of Treas., 796 F.2d 430, 436 (Fed. Cir. 1986). This court finds that the special master considered the relevant evidence, drew plausible inferences, and stated a rational basis for the decision. See Hines v. Secretary of Dept. of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

4/ Dr. Kinsbourne's report did not implicate the January 5, 1982 MMR vaccination. When he was questioned by the special master at the September 2, 1999 evidentiary hearing, Dr. Kinsbourne did not have an opinion on the role of the MMR vaccine in Ashley's outcome.

Thus, the decision to credit Dr. Holmes' testimony in making factual determinations was not arbitrary and capricious. 5/

A related theme that pervades petitioner's argument that the special master's factual determinations were arbitrary and capricious seems to be that because the special master originally made findings of fact that the DPT significantly aggravated Ashley's TS, her later findings to the contrary are arbitrary and capricious. This is not the case. The special master made the findings of fact in her Final Decision after careful review of all the expert testimony, including expert testimony that was adduced in the proceedings leading to her earlier decisions. She weighed this testimony and also considered medical evidence that had been produced in the interim before her earlier and final decisions. Under § 300aa-12(d)(3)(B)(iii) of the Vaccine Act, a special master "may require the testimony of any person and the production of any documents as may be reasonable and necessary." Thus, it is not an abuse of discretion to consider new pertinent medical evidence that was not available at the time of the original petition. See McAllister v. Secretary of Dept. of Health & Human Servs., 70 F.3d 1240, 1244 (Fed. Cir. 1995) ("The question whether to consider new evidence on . . . any . . . point previously decided is committed to the special master . . . in the first instance."). The relevance of Dr. Holmes' testimony is clear, and it was within the special master's discretion to call him as a witness. She found Dr. Holmes credible and, relying on his testimony and other medical evidence, made findings of fact accordingly. The record demonstrates that these actions were not arbitrary and capricious. In these circumstances the fact that she issued an earlier decision allowing compensation and subsequently denied compensation is not sufficient to overturn the special master's findings of fact.

Petitioner's second objection is that the special master "improperly allocat[ed]" the burden of proof by requiring petitioner to show the "neurological significance" of Ashley's post-DPT fever. Pet.'s Br. filed Sept. 1, 2000, at 13-14.

To rebut the statutory presumption of causation established by Ashley's on-Table injury, respondent was required to show, by a preponderance of the evidence, that a factor unrelated to the vaccination caused the claimant's afebrile seizures and attendant developmental delay. See Knudsen v. Secretary of Dept. of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994); 42 U.S.C. § 300aa-13(a)(1)(B). In the Omnibus Decision,

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5/ Similarly, petitioner's argument that the court did not give proper weight to the evidence of Ashley's "blank stares" must also fail. The special master relied on Dr. Holmes' opinion to find that the stares were not seizures. This finding was not arbitrary and capricious.

the special master concluded that when a claimant with TS suffers from seizures during a Table time period, but suffers no other neurological symptoms indicative of vaccine injury, respondent successfully has shown that the claimant's condition is due to the pre-existing TS disease, not the vaccination. Barnes at *32. Thus, because Barnes (and subsequently Hanlon) set out this general proposition, the remaining issue presented by this case is whether Ashley's post vaccination fever is a neurological symptom indicative of injury caused by vaccination – or, as the special master put it, whether the fever was "neurologically significant" in relation to Ashley's eventual afebrile seizures and developmental deficit.

This approach did not shift the burden to petitioner. The special master carefully emphasized that petitioner still maintained the benefit of a statutory presumption of injury, stating "[t]o clear up any confusion, the court is not holding that petitioner ever had to prove DPT caused Ashley's first seizure, since that is statutorily presumed." Final Decision at *16. The burden was squarely on respondent to prove that "a known factor unrelated caused Ashley's current condition." Id. Respondent carried this burden by proving that Ashley suffered from TS, that her MRI revealed at least 23 cortical tubers, and that the DPT fever was not "neurologically significant," because the TS, not the DPT, caused the later developmental delays. In doing so, the special master relied on evidence adduced at the hearing and a correct statement of the law. The special master did not improperly allocate the burden of proof on petitioner, and thus, petitioner's second objection must fail.

Petitioner's third objection is that the special master's decision is "tainted throughout by manifest errors in legal reasoning." Pet.'s Br. filed Sept. 1, 2000, at 17. Petitioner argues that the special master ignored precedent and her reasoning was "deficient" and reversible error. Id. at 18. Presumably, petitioner is charging that the special master's decision is not in accordance with the law.

The special master relied on Lampe v. Secretary of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000), in finding that Ashley's condition was not significantly aggravated by the DPT vaccination. In Lampe the Federal Circuit affirmed the dismissal of a case based on causation in fact, and in the alternative, significant aggravation, focusing on the lengthy passage of time elapsing between vaccination and developmental delay. The Federal Circuit stated:

> The passage of time between an event and the consequences that are alleged to flow from it is often significant, and . . . it was not improper for the special master to attach some significance to the lengthy period of delay between the vaccination and the deterioration in [the vaccinee's] condition.

Id. at 1366.

The special master noted that the developmental delay in this case was three times as long as the "lengthy period of delay" of two years and eight months in Lampe. "For this reason alone, Dr. Holmes' testimony that there is no causal relationship between Ashley's initial seizures and her ultimate developmental delay is more credible than Dr. Kinsbourne's." Final Decision at *14.

The special master's decision, which relied on Lampe, as well as Jordan v. Secretary of Dept. of Health & Human Servs., 91-0113V, 1998 WL 106131 (Fed. Cl. Spec. Mstr. Feb. 23, 1998) (dismissing Vaccination Act claim where no causal relationship existed between vaccination injury and vaccinee's genetic disease and death), was in accordance with the law. The special master correctly analyzed and applied the applicable law in reaching her decision. Therefore, petitioner's third objection also fails.

CONCLUSION

Accordingly, based on the foregoing, the decision of the special master is sustained. The Clerk of the Court shall enter judgment for respondent in accordance with the decision of the special master.

IT IS SO ORDERED.

No costs on review.

Christine Odell Cook Miller
Judge