

In the United States Court of Federal Claims

No. 98-797V
Filed: February 7, 2006

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TODD NILSON, Parent and Legal
Guardian of JOSEPH EDWARD NILSON,
Deceased,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Richard H. Moeller, Sioux City, Iowa, for Petitioner.

Linda S. Renzi, Torts Branch, Civil Division, United States Department of Justice,
Washington D.C., for Respondent.

OPINION

HODGES, Judge.

Joey Nilson died on October 19, 1996 following the administration of three childhood vaccines on October 11. His father filed a claim under the National Childhood Vaccine Injury Act of 1986. See 42 U.S.C. §§ 300aa-10 to-34. He argued that his son's medical problems were Table injuries under the Act; or that the vaccines were the cause-in-fact of Joey's death. The

special master ruled against petitioner on both counts.¹ See Nilson v. HHS, No. 98-797V, slip op. (Fed. Cl. Spec. Mstr. Aug. 31, 2005). She stated,

[a]fter reviewing the medical records, petitioner's affidavits, and medical literature, and weighing the testimony of the two expert witnesses, the special master finds that petitioner failed to carry his burden of proving by a preponderance of the evidence that Joey suffered a Table injury or that Joey's collapse and death were caused in fact by any one or a combination of the vaccines he received on October 11, 1996. The testimony of respondent's expert convinced the special master by a preponderance of evidence that Joey's encephalopathy was caused by a factor unrelated to the vaccine.

Nilson, No. 98-797V at 2. She concluded, "Joey did not suffer a Table injury. Dr. Wiznitzer's testimony clearly showed that Joey's encephalopathy was caused by a metabolic disturbance and therefore, pursuant to the clear terms of the Vaccine Act, the encephalopathy cannot be considered to be a Table injury." Nilson, No. 98-797V at 32.

The special master's Opinion describes in careful detail why she ruled as she did on medical and scientific matters that were the subjects of expert testimony. Her findings of fact and conclusions of law support the ruling in this case, and they are well supported by the record. The special master did not abuse her discretion; we affirm the ruling on review.

BACKGROUND

Petitioner's son Joey Nilson was born on September 7, 1991. He began suffering from asthmatic bronchitis at the age of three. This condition required medical treatment and frequent visits to the emergency room with severe asthma attacks. On one occasion, Joey experienced a seizure and slipped into a coma. Doctors did not determine the cause of the seizure and the coma, but he recovered fully.

Joey received a Diphtheria vaccine (DPT) on October 11, 1996, along with Measles (MMR) and Polio vaccines the same day. On the way home from the playground the next day, his hands and face turned blue and he collapsed. He did not have a pulse and was not breathing when the paramedics arrived minutes later. The attending physician at the hospital made an initial assessment of Joey's condition and transferred him to the Pediatric Intensive Care Unit at McKennan Hospital. He never regained consciousness. When doctors at McKennan determined that Joey was brain dead, they took him off life support with the family's consent. Joey died on October 19, 1996.

¹ Petitioner abandoned his causation-in-fact claim during briefing before this court. "Nilson is limiting his request for review to the Table injury claim only, thereby accepting the decision as to his cause-in-fact claim."

Dr. Nancy L. Carroll was the attending physician in the Pediatric Intensive Care Unit where Joey was treated. She noted in his medical records that the “probable cause of death was ‘severe acute bronchospasm leading to respiratory and cardiac arrest.’” Nilson, No. 98-797 at 10. The family agreed to a limited autopsy, which was performed by Dr. Alfred E. Hartman. Dr. Hartman ruled that asthmatic bronchitis caused the cardiopulmonary arrest that led to Joey’s death.

The special master found that Joey’s attack of asthmatic bronchitis caused the cardiopulmonary arrest that brought about the encephalopathy. An encephalopathy occurring within three days of a DPT vaccination indicates a Table injury. Encephalopathy must last twenty-four hours and be characterized by at least two of the following symptoms: a significant change in mental state, a decreased level of consciousness, or seizures associated with loss of consciousness. 42 C.F.R. § 100.3(b)(2). Joey lost consciousness the day after he was vaccinated and remained unconscious until his death. The Government stipulates that Joey’s cardiorespiratory arrest and subsequent coma constituted an encephalopathy. Nilson, No. 98-797V at 23-24. It argues, however, that an asthma attack - not the vaccines - caused the cardiac arrest that preceded the encephalopathy.

The special master ruled that Joey’s encephalopathy was caused by factors unrelated to the vaccines. Petitioner’s appeal concerns the weight accorded respondent’s expert medical witness by the special master, and respondent’s burden of proof in a Table injury case where the Government attempts to show a cause independent of vaccines.

STANDARD OF REVIEW

The special master has broad discretion to weigh evidence and to assess witnesses’ credibility. Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). This court will set aside the special master’s decision only if it was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” 42 U.S.C. § 300aa-12(e)(2)(B). We do not substitute the court’s own judgment for that of the special master absent extraordinary circumstances. See, e.g. Hines on Behalf of Sevier v. Sec’y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991) (“[R]eversible error [is] extremely difficult to demonstrate.”); see also Finley ex rel. v. Sec’y of Health & Human Servs., 55 Fed. Cl. 355, 360 (2003) (“[T]his court will not reverse the decision of a special master unless the special master failed to consider relevant evidence, drew implausible inferences, or failed to state a rational basis for the decision.”). The special master’s decision will be upheld so long as it rests upon a rational basis. See Hines, 940 F.2d at 1528.

Petitioner claims that his son’s encephalopathy was caused by the vaccinations he received on October 11, 1996. He contends that the special master’s rulings to the contrary were “arbitrary, capricious, an abuse of discretion, and not in accordance with law.” 42 U.S.C. § 300aa-12(e)(2)(B).

One issue of concern in this case upon review has been whether the Government attempted to shift its burden of proving that “factors unrelated” to the vaccine caused the encephalopathy. A government expert testified that the cause of Joey’s cardiac arrest leading to encephalopathy was “immaterial.” That is, respondent must establish only that cardiac arrest led to encephalopathy.

Petitioner urges that (1) the Government must prove the cause of the cardiac arrest in a Table injury case, not merely the cause of the encephalopathy; and (2) the Government must prove the exact cause of the cardiac arrest, not alternative possibilities.

BURDEN OF PROOF

A petitioner is entitled to a presumption of causation under the Vaccine Act if he can demonstrate that a Table injury occurred. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i). For example, petitioner must demonstrate that Joey

sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table . . . and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table

Id.

Nilson can establish a Table injury if Joey received one of the vaccines listed on the Table and suffered the specified injury or an acute complication or sequella of that injury within the prescribed time frame. Id. § 300aa-13(a)(1)(A). The vaccinations he received are listed on the Vaccine Table, and Joey’s encephalopathy occurred within the requisite time after his receiving at least one of the vaccinations. The matter does not end there, however. Respondent can rebut the presumption by showing that a factor unrelated to the vaccines caused the injury. Id. at 300aa-13(a)(1)(B).

The law denies compensation when the Government can show by a preponderance of the evidence the injury was caused by “factors unrelated” to the vaccine. See Id. The burden of proof is on the Government in this phase.

DISCUSSION

The special master stated at the beginning of her Opinion that

[t]he key factors in the special master’s decision were the credentials and credibility of the expert witnesses, who presented diametrically opposed views at hearing. The testimony of respondent’s expert witness, a highly-credentialed and experienced pediatric neurologist, was far more persuasive than that of petitioner’s expert witness.

Indeed, the experts were grossly mismatched.

Nilson, No. 98-797V at 2. It is clear that the special master was impressed by the testimony of Dr. Wiznitzer, and that petitioner's case suffered from its comparison with that of his expert, Dr. Cave. Special masters are accorded great deference in determining the credibility and reliability of expert witnesses. See, e.g., Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1349 (Fed. Cir. 1999). "Determinations of credibility, especially of expert opinions, are uniquely within the purview of the special masters." Gurr v. Sec'y of Health & Human Servs., 37 Fed. Cl. 314, 320 (1997) (citing Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). Credibility determinations of this type are "virtually unreviewable" by this court. Bradley, 991 F.2d at 1575 (citing Hambusch v. Dep't of the Treasury, 796 F.2d 430, 436 (Fed. Cir.).

_____The special master found that respondent rebutted the Table's presumption of causation by proving that factors unrelated to the vaccinations caused Joey's death, as his encephalopathy likely was the result of an asthma attack resulting in cardiac arrest. Respondent's expert satisfied the special master that Joey's encephalopathy was caused by a metabolic disturbance.

The government expert offered alternative possibilities for the cause of the cardiac arrest. His view that the specific cause of the cardiac arrest was "immaterial" was based on a section of the regulation stating, "[a]n encephalopathy shall not be considered to be a condition set forth in the Table if . . . it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma" (emphasis added). 42 C.F.R. § 100.3(b)(2)(iii)(E). The special master evaluated carefully the evidence presented by medical experts.

The Experts

The Government's expert, Dr. Max Wiznitzer, is board-certified in neurology, pediatrics, and in psychiatry. He specializes in child neurology and neurodevelopment disorders. Dr. Wiznitzer previously has been involved in Vaccine Program cases. "He has reviewed cases and testified on behalf of respondent, he has testified on behalf of his own patients when he believed that their injury met the Table definition, and he has reviewed cases at the behest of a petitioner's counsel and the court." Nilson, No. 98-797V at 22.

Petitioner's expert was Dr. Stephanie Cave. She is board-certified in family medicine, and has not practiced in a hospital since 1996. She is interested in allergies and autism. Dr. Cave participates in a clinic-like practice, where she treats 2,500 autistic children. She is not board-certified in neurology or pediatrics. Nilson, No. 98-797V at 14. "Dr. Cave's expert testimony lacks appropriate validation and thus falls into the realm of speculation and conjecture. Thus, petitioner's theory of causation rests on 'personal opinion, not science.'" Nilson, No. 98-797V at 32 n.54. Regardless of how genuinely a theory is believed by an expert, the passion with which it is believed is no substitute for scientific support. Id.

Dr. Wiznitzer: Pre-Existing Conditions

Dr. Wiznitzer theorized that Joey's cardiac arrest was caused by pre-existing conditions that were unrelated to the vaccinations: "a bronchospasm due to reactive airway disease or he had a heart rhythm disturbance because of his abnormal heart." Nilson, No. 98-797V at 26. Dr. Wiznitzer could not conclude with certainty which caused Joey's cardiac arrest, but stated that lack of oxygen to Joey's brain caused by his cardiac arrest led to encephalopathy. Id. at 24. He defined Joey's arrest and ensuing encephalopathy as a "metabolic disturbance." Id.

Metabolic disturbances fall under the statutory exceptions applicable to Table injuries. See 42 C.F.R. § 300aa-13(a)(2)(B) ("Factors unrelated" to the vaccinations include "metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing petitioner's illness, disability, injury, condition, or death.") (emphasis added). Dr. Wiznitzer opined that Joey's asthma or an abnormal heart condition caused him to have the cardiac arrest that deprived his brain of oxygen and eventually led to encephalopathy. Nilson, No. 98-797V at 24. Both conditions create metabolic disturbances and neither is related to vaccines, according to the special master. Id.

Hypoglycemia

Dr. Carroll, who cared for Joey in the Pediatric Intensive Care Unit, listed among her impressions, "[p]robable severe acute bronchospasm possibly complicated by hypoglycemia leading to full cardiac arrest. . . ." Id. at 8. Dr. Laura A. Keppen, a pediatric endocrinologist, conducted a metabolic evaluation. She reported that Joey's episode on the playground "sounds like it could have been respiratory or cardiac." Id. She stated that the patient's history "does not sound like hypoglycemia, and does not sound consistent with an inborn error of metabolism that could cause hypoglycemia."² Id.

Dr. Cave: "Toxic Vaccines"

Petitioner's expert witness opined that Joey's encephalopathy was caused by toxic vaccinations. Dr. Cave did not think that Joey's collapse was caused by asthma or heart condition, but that Joey "was given very toxic vaccines." Nilson, No. 98-797V at 15. Dr. Cave theorized that Joey had a compromised immune system that would have lowered his ability to withstand a toxic vaccination. Id. at 16. Her theories relied in part upon the Vaccine Adverse

² Dr. Cave raised an issue concerning the possibility that hypoglycemia could have been a contributing factor to Joey's condition. The special master's rejection of this argument was well supported by the record.

Event Reporting System³ and upon articles that have not been peer reviewed, according to Dr. Wiznitzer. Id.

The special master found that the VAERS data has certain weaknesses and limitations because of the voluntary and unverifiable nature of the reports, inherent reporting bias, and a lack of an unvaccinated control group for comparison. Id. at 19 n.41. Petitioner’s expert pointed out that Joey’s own death was not reported to VAERS. Id. at 17 n.37. This may be explained by the fact that physicians who cared for Joey did not believe that his death was caused by the vaccinations. Id. Dr. Cave could not show that the vaccinations were a “toxic lot.” Id. at 18. Elements of Dr. Cave’s theory were based on autistic children. Joey was not autistic. Id. at 21.

Alternative Causes

Petitioner argues that defendant did not successfully rebut the presumption of causation because the Government did not identify the unrelated factor that caused Joey’s cardiorespiratory arrest; that is, whether it was caused by a heart condition or Joey’s asthma. The special master held that respondent was not required to identify with precision the cause of Joey’s encephalopathy, however. The Vaccine Act requires only that the Government prove by preponderance of evidence “that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.” 42 U.S.C. § 300aa-13(a)(1)(B).⁴

Factors unrelated cannot be “any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.” Id. at § 300aa-13(a)(2)(A). The term does encompass “metabolic disturbances which have no known relation to the vaccine

³ VAERS is “a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.” Nilson, No. 98-797V at 17 n.37.

⁴ See Lewis v. Sec’y of Health & Human Servs., 26 Cl. Ct. 233, 235 (1992), in which the special master had ruled that the Government did not meet its burden of proving “factors unrelated” because it presented alternative causes. This court stated that “[t]he Vaccine Act affords respondent the option to do so, but does not require respondent always to denominate one alternative cause.” Id. at 239. “Respondent’s burden, rather, is to show within the parameters set forth in section 300aa-13(a)(1)(2), that one or more defined non-vaccine-related illnesses or factors more probably than not caused the injury.” Id. at 238 (emphasis added).

involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing petitioner's illness, disability, injury, condition, or death." Id. at 300aa-13(a)(2)(B).

The Federal Circuit stated that the Government must show that the unrelated factor "whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1348 (Fed. Cir. 1999) (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-549 (Fed. Cir. 1999)). Petitioner admits that evidence in the case "identified bronchospasms as a probable cause of Joey's cardiorespiratory arrest," but adds that other evidence "indicates the cause of his arrest as 'unknown.'" Pet'r Br. at 11.

Prior Encephalopathy

Dr. Cave suggested that the encephalopathy could have occurred prior to cardiorespiratory arrest, but Dr. Wiznitzer testified that he saw "no evidence in the medical records of any pre-existing encephalopathy prior to the onset of the cardiorespiratory arrest." Nilson, No. 98-797V at 24. The special master accepted Dr. Wiznitzer's opinion on this point.

Dr. Alfred E. Hartman, a pathologist, performed a limited autopsy. The results caused Dr. Hartman to conclude that the official cause of death was "sudden cardiorespiratory arrest leading to cerebral medullary dysfunction." Id. at 10. He observed that Joey's condition was "compatible with the consideration of a chronic asthmatic bronchitis as the underlying cause of the initial cardiorespiratory arrest." Id.

Atypical Bronchospasms

We had some concerns upon review regarding an aspect of petitioner's descriptions of Dr. Wiznitzer's testimony. He cited excerpts of Dr. Wiznitzer's cross examination on the likelihood that Joey could have been suffering from bronchospasms on the playground even though testimony suggested that he was not wheezing or coughing. The excerpts show that Dr. Wiznitzer was limiting his responses to information in the medical records and conclusions made by doctors who treated Joey. See Pet'r Br. at 10. The concern was that an expert should be in a position to testify whether such a presentation were likely or possible. Petitioner omitted the following testimony of Dr. Wiznitzer, however, as described by the special master:

The medical records clearly reflect the physicians' conclusion that Joey suffered a bronchospasm prior to his collapse. According to Dr. Wiznitzer, even while he was in the hospital several days after his collapse, Joey "clearly showed evidence of the ability to have bronchospasms." Dr. Wiznitzer also explained that it is possible to have a bronchospasm without coughing or wheezing. Consequently, merely because Joey had an atypical asthma attack would not rule out bronchospasm as a cause of his collapse.

Nilson, No. 98-797V at 30 (citations to record omitted) (emphasis added).

Williams

Petitioner cites Williams v. Sec’y of Health & Human Servs., No. 00-123V, 2002 WL 1488750 (Fed. Cl. Spec. Mstr. June 20, 2002), stating that “respondent conceded that the child suffered an encephalopathy which led to his death, with the only issue being what caused the encephalopathy.” (Pet’r Br. at 19). According to petitioner, the Government’s expert witness in that case testified that the child had “some kind of cardiorespiratory compromise,” but she did not know whether respiratory failure or inadequate heart function caused the encephalopathy. Nilson concludes that the case turned on the lack of information concerning an “underlying cause of the cardiorespiratory event.” Id.

That case cites regulations concerning the definitions and applications of the term “encephalopathy,” including the length of time that the various elements of encephalopathy must present themselves. See generally, 42 C.F.R. § 100.3 (b)(2)(iii). The statute states, if “it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.” Id. This applies only if the Government cannot show that a known factor unrelated to the vaccine, such as a metabolic disturbance, caused the encephalopathy. The Government in Williams did not prove that a known factor unrelated to the DPT vaccine caused the child’s illness in that case.

The special master in Williams focused on whether she could find an encephalopathy even though no one had been in a position to observe the child with the necessary diminished capacity, such as a “significantly decreased level of consciousness.” 2002 WL 1488750. at *11; See also, 42 C.F.R. § 100.3b(2)(i)(D). Evidence of an encephalopathy might be decreased response to environment, decreased or absent eye contact, or absent responses to external stimuli. The special master stated,

[w]here an autopsy clearly shows encephalopathy and all the experts agree that the vaccinee had encephalopathy, it is unreasonable to insist that petitioners may not prevail on an on-Table encephalopathy theory because . . . no one observed the vaccinee have a lower level of consciousness, particularly in light of the evidence that a person experiencing encephalopathy would have manifest[ed] that sign. It would also be unreasonable to insist that petitioners may not prevail because the child did not live long enough to have encephalopathy for twenty-four hours.

Id., at *12.

The respondent in Williams argued that the child’s encephalopathy was off-Table “because he did not have clinical symptoms of encephalopathy and petitioners did not prove that DPT caused in fact Steven’s off-Table encephalopathy.” Id., at *11. The “clinical symptoms” referred to include the requirement that a “significantly decreased level of consciousness” be

present.

SUMMARY

Joey's medical history, particularly including his severe asthma, supports respondent's theory that an asthma attack was the cause of his cardiac arrest and encephalopathy. The basis of her findings are amply supported by the record and expressed in her Opinion. Based on the record and the testimony of the medical experts, the special master found that respondent successfully rebutted the presumption of causation. Therefore, "pursuant to the clear terms of the Vaccine Act, the encephalopathy cannot be considered a Table injury." Nilson, No. 98-797V at 32.

The special master acted well within her discretion in finding a preponderance of the evidence that Joey's encephalopathy was not caused by vaccinations. "Chronic asthmatic bronchitis, not the vaccines, was the underlying cause of Joey's initial cardiorespiratory arrest." Nilson, No. 98-797V at 13.

CONCLUSION

The special master had little doubt about the proper result in this case: "[T]he evidence at trial showed that petitioner cannot prevail because Joey's encephalopathy was caused by a factor unrelated to the vaccines he received on October 11, 1996 . . ." Id. The factor unrelated that she documented was "a metabolic disturbance brought about by [Joey's] cardiorespiratory arrest, which is described in the medical records and explained by respondent's expert pediatric neurologist. The vaccines neither caused nor contributed to Joey's cardiac arrest, encephalopathy, and death." Id.

The special master has broad discretion under the Vaccine Act to weigh the evidence and determine the credibility of witnesses. Bradley, 991 F.2d at 1575. Her decision was rationally based upon the record. The special master's decision is therefore AFFIRMED.

s/Robert H. Hodges, Jr.
Robert H. Hodges, Jr.
Judge