

OFFICE OF THE SPECIAL MASTERS
No. 96-0797V
(Filed on June 22, 1998)

CARMEN D. HELLER, Administratrix *
of the Estate of ISAIAH D. JONES, *

Petitioners, * **TO BE PUBLISHED**

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

Michael J. Kaplan, Akron, OH, for petitioner.

Linda S. Renzi, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

On December 20, 1996, Carmen D. Heller, on behalf of her son, Isaiah D. Jones (hereinafter "Isaiah"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986⁽¹⁾ (hereinafter the "Vaccine Act" or the "Act"). Petitioner has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, and (2) DPT vaccine was administered to Isaiah in the United States.

Petitioner alleges that DPT was the cause-in-fact of Isaiah's death. 42 U.S.C. §§300aa-11(c)(1)(C)(ii)(I). Respondent defends by asserting that DPT did not cause Isaiah's death.

At petitioner's counsel's request, the court rules on the records.

FACTS

Isaiah was born on January 29, 1996. Med. recs. at Ex. 1, p. 1. He received his first DPT vaccination on April 8, 1996 when he was two and one-quarter months old.⁽²⁾ Med. recs. at Ex. 4, p. 4. Isaiah died on April 9, 1996. Med. recs. at Ex. 8, p. 1.

Isaiah was taken to Children's Hospital Medical Center of Akron on April 9, 1996 at 8:55 a.m. Med. recs. at Ex. 6, p. 2. A history given reflects that Isaiah's formula was switched to Isomil on April 8, 1996 because he had vomiting associated with the use of Enfamil. Id. He had received his first set of immunizations on April 8, 1996. Id. The record further reflects that, on April 9, 1996, Ms. Heller gave Isaiah a bottle at 1:00 a.m. Id. Thereafter, she put him to sleep. Id. When Ms. Heller found Isaiah at 7:30 a.m., he was not breathing. Id. She called the Akron Fire Department which noted that Isaiah was apneic, and pulseless with rigor mortis/livid reticular. Id. They decided not to proceed with CPR. Id. There was no evidence of trauma on Isaiah's scalp. Id. The hospital questioned whether he died from SIDS. Id.

The initial death certificate states that the cause of Isaiah's death was "pending." Med. recs. at Ex. 8, p. 1. However, a supplementary medical certification dated May 6, 1996 reflects that the cause of death was SIDS. Med. recs. at Ex. 8, p. 3. The autopsy, which was performed on April 9, 1996, also diagnosed SIDS. Med. recs. at Ex. 9, p. 1. The autopsy further reflects that Isaiah had petechiae in his lung, thymus, and heart. Id. On gross description, his thymus weighed thirty grams which is very heavy for a two to three month old infant. Med. recs. at Ex. 9, p. 4. The surface of his thymus was covered with multiple, minute petechiae. Id. There was no evidence of inflammation or aspiration. Med. recs. at Ex. 9, p. 6. On microscopic examination, the section through the spleen showed congestion of the red pulp. Med. recs. at Ex. 9, p. 7. The clinical summary states that Isaiah was placed face down on a sheet when put to bed. Med. recs. at Ex. 9, p. 8.

AFFIDAVITS

Ms. Heller submitted an affidavit, dated November 15, 1996, which states that Isaiah was vaccinated on April 8, 1996 between 9:00 and 10:00 a.m. Med. recs. at Ex. 7, p. 1. When she found Isaiah on April 9, 1996 at 7:30 a.m., he was not breathing. Id.

Petitioner's counsel posed a series of questions to Ms. Heller regarding Isaiah's post-vaccination condition. Ms. Heller answered these questions in a handwritten supplemental affidavit. P. Supp. Aff. (filed March 12, 1998). In this affidavit, Ms. Heller said that Isaiah cried or screamed "a little off and on" after his vaccination. Id. He also slept more than usual. Id. Ms. Heller stated that Isaiah was a little pale; however, she was not impressed by his coloring. Id. She further noted that he threw up more than usual, was unresponsive, and had a slight fever after his DPT. Id. Prior to his vaccination, he was very playful and happy. Id. After the vaccination, however, he was quiet, slept, and cried. Id. Ms. Heller's acquaintances asked her why Isaiah slept for such long periods of time. Id. When she found Isaiah dead, there was blood on the sheets and around his mouth. Id.

MEDICAL EXPERT REPORTS

Petitioner submitted the medical expert report of Dr. A. Hugh McLaughlin, D.O.,⁽³⁾ Isaiah's doctor. Dr. McLaughlin's opinion is that, since there was no evidence to suggest a cause of death other than vaccination, the vaccinations caused Isaiah's death.⁽⁴⁾ Med. recs. at Ex. 10, p. 1.

Dr. McLaughlin submitted a supplemental report which states that the direct cause of Isaiah's death was SIDS involving both anaphylaxis and encephalopathy. P. Supp. Rprt. (filed January 23, 1998). Dr. McLaughlin noted that although the exact cause of SIDS is unknown, the vaccine has been shown to be

causally related. Id. For that reason, it is probable that the vaccine could have caused Isaiah's death. Id.

Petitioner also submitted medical articles in support of Dr. McLaughlin's opinion. The first article discusses a study in which the authors found a 7.3 elevation in risk for SIDS in the first four days after DPT immunization during the first year of life.⁽⁵⁾ Children who were not immunized had a SIDS mortality rate more than six times higher than those who had been immunized.⁽⁶⁾ The authors of the article admitted, however, that the relatively small number of SIDS cases in the present study permitted the possibility of substantial random error.⁽⁷⁾

Petitioner submitted a second article which discussed a Tennessee study conducted to determine if there were a meaningful association between DPT and four, sudden unexplained deaths.⁽⁸⁾ The authors found no evidence to indicate a causal relationship between DPT and SIDS.⁽⁹⁾ The overall incidence of SIDS did not increase in Tennessee during the time period that the suspect lot of DPT was used.⁽¹⁰⁾ Age distribution curves of SIDS cases in Europe where vaccination schedules differ from the United States are similar to the United States curve of SIDS cases, thereby indicating no association between DPT and SIDS.⁽¹¹⁾ The Centers for Disease Control reviewed the available evidence in the study, and concluded that no causal relationship had been established between DPT and SIDS.⁽¹²⁾ In addition, a National Institutes of Health case control study failed to show any increased frequency of DPT vaccinations in SIDS.⁽¹³⁾

Finally, petitioner submitted a paragraph summarizing a speech given by William C. Torch at a child neurology conference.⁽¹⁴⁾ This speech discussed a study on the relationship between DPT and SIDS.⁽¹⁵⁾ Torch concluded that DPT may be a generally unrecognized major cause of SIDS.⁽¹⁶⁾

Respondent submitted the expert medical report of Dr. M. Louis Offen. R. Ex. A. He concluded that Isaiah died from SIDS. R. Ex. A, p. 2. In Dr. Offen's opinion, Isaiah did not have encephalopathy or anaphylaxis. Id. Dr. Offen stated that a maternal history of smoking, such as Ms. Heller had, as well as placing an infant lying down to sleep in the prone position puts a child at an increased risk of SIDS. R. Ex. A, pp. 1-2.

DISCUSSION

The Vaccine Act affords petitioner three distinct theories of recovery, thereby allowing causation to be proven by showing that: (1) a Table injury occurred as a result of the vaccine, (2) a pre-existing condition was significantly aggravated by the vaccine, or (3) the vaccine was the cause-in-fact of the injury. Section 14(a) contains the Vaccine Injury Table (hereinafter "Table").⁽¹⁷⁾ If any of the various injuries in this Table occurs within the statutorily defined time period, a rebuttable presumption of causation has been proven. To rebut this presumption, respondent must provide affirmative evidence demonstrating that a known factor unrelated was the cause-in-fact of the petitioner's condition.⁽¹⁸⁾

Since the promulgation of the Act, the Table has been altered through a change in the regulations, making it more difficult to prove a Table encephalopathy.⁽¹⁹⁾ The requirements for proving anaphylaxis have similarly become more difficult.⁽²⁰⁾ Since petitioner filed her petition after the effective date of these regulations, the more restrictive standards apply to her claims.

Although petitioner initially began with the assertion that DPT was the cause-in-fact of Isaiah's death, Dr. McLaughlin's supplemental report opines that Isaiah died from SIDS accompanied by encephalopathy and anaphylaxis. Before addressing petitioner's cause-in-fact claim, Dr. McLaughlin's

reference to encephalopathy and anaphylaxis merit some comment. Timing and symptomatology are critical to whether petitioner has proven that a Table injury has occurred. In order to prevail on a Table theory, the injury must have occurred within the statutory time period. Once it is determined that timing is appropriate, the undersigned will evaluate the symptoms that petitioner exhibited. Using the definitions and interpretive aids set forth in the Act, the undersigned will then determine if the symptoms that petitioner experienced were sufficient to demonstrate that a Table injury occurred. Under the Act, the onset of anaphylaxis must occur within four hours of vaccination for petitioner to prevail on a Table injury theory. Isaiah did not suffer an on-Table anaphylaxis, as Dr. McLaughlin suggests, because he did not have a systemic allergic response within four hours of vaccination.

Since Isaiah died within seventy-two hours of vaccination, petitioner can, however, attempt to prove symptoms of an on-Table encephalopathy. But, Isaiah's symptomatology does not reflect twenty-four hours of significantly decreased level of consciousness. When Isaiah was brought to the hospital, Ms. Heller gave a history that she fed Isaiah at 1:00 a.m. that morning and then put him to sleep. There is no history that Isaiah failed to respond to the feeding or that he had any symptoms that would indicate abnormality. Following the strict language of the new regulations, the undersigned cannot hold that Isaiah's symptoms the day after vaccination rise to the level of a Table encephalopathy.

There is no doubt that Isaiah was dying after his vaccination. He manifested symptoms of a decreased level of consciousness that would merit a diagnosis of encephalopathy and he was undergoing a systemic process that was severe as is anaphylaxis. However, these manifestations were due to the agonal process. In other words, these symptoms were a consequence of dying rather than of vaccination. This conclusion is evidenced by the fact that Dr. McLaughlin did not mention that Isaiah suffered any of these symptoms prior to his death. Rather, he stated that anaphylaxis and encephalopathy accompanied Isaiah's death which he termed due to SIDS.

Death, in and of itself, is not a Table injury. Hodges v. Secretary, HHS, 9 F.3d 958 (Fed. Cir. 1993), and Hellebrand v. Secretary, HHS, 999 F.2d 1565 (Fed. Cir. 1993). In order for petitioner to prevail upon a Table injury theory, the injury must precede the death and not merely be a consequence of the dying process. Petitioner herein has failed to show the existence of a Table injury, thereby leaving the original claim that DPT was the cause-in-fact of Isaiah's death.

To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). "[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Dr. McLaughlin's initial affidavit states that since he could find no cause for Isaiah's death other than the vaccinations, the vaccinations must have caused his death. Pursuant to Grant, supra, this is legally insufficient to prove affirmatively that DPT caused Isaiah's death. Petitioner does not satisfy her burden by showing that no other cause for the death is known.

Moreover, reliance on temporality alone is legally insufficient even though the death followed the vaccination by one day. Strother v. Secretary, HHS, 950 F.2d 731 (Fed. Cir. 1991). That B follows A does not prove by that fact alone that A caused B.

Dr. McLaughlin's supplemental report states that, although no one knows the cause of SIDS, he thinks it

probable that DPT could have caused Isaiah's SIDS. Beyond being a sentence that contradicts itself, i.e., "probable" does not agree with "could," Dr. McLaughlin's thesis is not supported by the articles petitioner submitted. These articles do not confirm that DPT causes a higher incidence of SIDS among vaccinees as compared to non-vaccinees. Unfortunately, no one knows the cause of SIDS. The suggestion by Dr. Torch in his presentation is squarely opposed in an article on the same subject. There is no support for Dr. McLaughlin's thesis other than his musing on the possibility. In addition, his curriculum vitae is rather short on medical or scientific accomplishment, bearing on his credibility as a witness. The undersigned does not recall seeing a prior curriculum vitae of an expert in which he prominently lists doing a commercial for McDonald's. This type of background is not conducive to developing a sense of credibility in the witness.

Although respondent does not have the burden to prove what caused Isaiah's death, respondent's expert opined that this was a true case of SIDS. The autopsy report and the death certificate reach the same conclusion.

This is indeed a tragic case. Not only is Isaiah dead, but the cause of his death remains a mystery. It is unfortunate that the court cannot provide an answer for Mrs. Heller; however, the undersigned can only analyze the medical evidence and reports to determine whether the petitioner has met her burden of proving that DPT caused in fact Isaiah's death. The court finds that petitioner has not met her burden. She has not provided persuasive evidence in Dr. McLaughlin's reports that herein is a "logical sequence of cause and effect." Grant, supra, at 1148. **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

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. Isaiah also received his polio and hemophilus B influenza vaccinations at this time. Med. recs. at Ex. 4, p. 4.

3. Dr. McLaughlin's curriculum vitae includes a national television commercial for McDonald's Corporation in 1985 with an article in Time Magazine related to that commercial in the same year.

4. This report takes the form of an affidavit.

5. Walker, A.M., et al., "Diphtheria-Tetanus-Pertussis Immunization and Sudden Infant Death Syndrome," 77 Amer. J. of Public Health 945, 947 (1987) (filed February 23, 1998).

6. Id. at 947.

7. Id. at 948.

8. Bernier, R.H., et al., "Diphtheria-tetanus toxoids-pertussis vaccination and sudden infant deaths in Tennessee," 101 Clinical and Laboratory Observations 419 (1982) (filed February 23, 1998).

9. Id. at 421.

10. Id.

11. Id.

12. Id.

13. Id.

14. See Torch, William, C., "Diphtheria-Pertussis-Tetanus (DPT) Immunization: A Potential Cause of the Sudden Infant Death Syndrome (SIDS)," 32 Neurology A169 (1982) (filed February 23, 1998).

15. Id.

16. Id. at A170.

17. 42 U.S.C. § 300aa-14(a).

18. 42 U.S.C § 13(a)(1)(B).

19. 42 C.F.R. §100.3(b)(2)(I)(A) (see also Fed. Reg. 60, No. 26 at 7694-96 (Feb. 8, 1995), effective March 10, 1995). This section states that "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." Id.

Subsection (D) provides:

"[a] 'significantly decreased level of consciousness' is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater...: (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)."

Subsection (E) provides:

"The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging

fontanelle."

20. 42 C.F.R. §100.3(b)(1) (see also Fed. Reg. 60, No. 26 at 7694 (Feb. 8, 1995))

Under this section, anaphylaxis is defined as:

"an acute, severe, and potentially lethal systemic allergic reaction. . . Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse...."