

OFFICE OF SPECIAL MASTERS

No. 00-662V

(Filed: March 11, 2002)

SHERENA VALICO, Legal Representative *
of the Estate of Ahzja Dove, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Joel H. Lichtenstein, Bridgeport, Connecticut, for petitioner.

Traci R. Manning, Department of Justice, Washington, D.C., for respondent.

DECISION

HASTINGS, *Special Master.*

This is an action seeking an award under the National Vaccine Injury Compensation Program¹ (hereinafter “the Program”) on account of the death of the petitioner’s daughter, Ahzja Dove. For the reasons stated below, I conclude that petitioner is not entitled to such an award.

¹The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (1994 ed.). Hereinafter, all “§” references will be to 42 U.S.C. (1994 ed.).

I

BACKGROUND FACTS AND PROCEDURAL HISTORY

Ahzja Dove was born to the petitioner on July 29, 1997, and initially appeared to be a healthy newborn. On October 16, 1997, at age 2 ½ months, she received several vaccinations, including a DPT (diphtheria, pertussis, tetanus) immunization.

Seven days later, on October 23, 1997, Ahzja was taken to a hospital emergency room, where it was reported that she had suffered an episode involving rolling of her eyes and jerking of her arms and legs, which had lasted from one to two minutes. (Ex. 17, p. 1.²) Ahzja was reported to be “afebrile” (without fever) at the time, and she was diagnosed to have suffered an afebrile seizure. (*Id.*)

Over the next year, Ahzja continued to suffer from repeated seizures. The medical records indicate that her treating physicians found her seizure disorder to be “idiopathic”--*i.e.*, of unknown cause. (*E.g.*, Ex. 12, p. 11 (“idiopathic seizures”); Ex. 14, p. 2 (“[e]tiology of Sz is unclear”).)

On November 14, 1998, Ahzja again suffered a seizure. (Ex. 29, pp. 1-2.) Early the next morning, she was found in her crib, not breathing. (Ex. 34, p. 16.) She was rushed to a hospital, but attempts to resuscitate her were unsuccessful, and she was pronounced dead. (Ex. 29, p. 20.) Her death was found to be a result of her seizure disorder. (Ex. 5, p. 1.)

On November 8, 2000, the petitioner filed this Program proceeding, contending that Ahzja’s seizure disorder and her death were caused by her DPT vaccination of October 16, 1997. Respondent contested petitioner’s claim, and considerable evidence was introduced in documentary form. An evidentiary hearing was held on November 20, 2001, at which hearing was taken the testimony of two expert witnesses, to be discussed below.

II

STATUTORY BACKGROUND

Under the Program, compensation awards are made to individuals who have suffered injuries after receiving certain vaccines listed in the statute. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the “Vaccine Injury Table,” originally established by statute at § 300aa-14(a) and since modified administratively, occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a “Table Injury.” Alternatively,

²Petitioner filed Exs. 1 through 35, contained in two notebooks, on November 8, 2000. “Ex.” references will be to those exhibits.

compensation may also be awarded for injuries not listed in the Table, but entitlement in such cases is dependent upon proof that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

One of the vaccinations covered under the Program is the “DPT” vaccination, a vaccination against the three diseases of diphtheria, pertussis, and tetanus. The statute contains a version of the Vaccine Injury Table that applied to DPT vaccinations administered prior to the enactment of the Program and for several years after that enactment. However, the Vaccine Injury Table was administratively modified with respect to Program petitions, such as this one, that were filed after March 24, 1997. See 62 Fed. Reg. 7685, 7688 (1997); *O’Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996). That Table modification, along with an earlier administrative modification of the Table in 1995 (see 60 Fed. Reg. 7678 (1995)), significantly altered the “Table Injury” categories with respect to DPT vaccinations from the version of the Table contained in the statute. In this case, the petition originally alleged that Ahzja suffered the Table Injury known as “residual seizure disorder.” By the time of the hearing in this case, however, petitioner acknowledged (see, e.g., Tr. 44) that under the modified Table applicable to this case, none of the listed Table Injuries are applicable to Ahzja’s case.

Therefore, the dispute to be resolved here concerns only whether petitioner has demonstrated that it is “more probable than not” that Ahzja’s seizure disorder and death were *actually caused* by her DPT vaccination administered on October 16, 1997.

III

DISCUSSION

I conclude that petitioner has not met her burden of demonstrating that it is “more probable than not”³ that Ahzja’s seizure disorder and death were vaccine-caused. It appears quite likely that Ahzja’s seizure disorder caused her death, but the evidence does not demonstrate that her DPT vaccination caused her seizure disorder.

A. The required showing

In analyzing a contention of “actual causation,” the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on the petitioner to show that in fact the vaccination in question more likely than not caused the injury or death. See, e.g., *Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff’d* 950 F.2d 731

³Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a “preponderance of the evidence.” § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than not.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harland, J., concurring).

(Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). Thus, the petitioner must supply “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.” *Shaw*, 18 Cl. Ct. at 651; *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983), *cert. denied* 469 U.S. 817 (1984); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989). The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

B. Analysis of the evidence introduced in this proceeding

The evidentiary record of this proceeding consists of several items. The petitioner filed numerous exhibits, consisting mainly of medical records documenting Ahzja’s life and tragic death. One of those exhibits was petitioner’s own affidavit (Ex. 1), and another was the affidavit of Dr. Jeffrey Gross (Ex. 2), a neurologist who opined that Ahzja’s seizure disorder was caused by the pertussis⁴ portion of the DPT vaccination that she received on October 16, 1997.

The respondent filed (on May 8, 2001), an expert report of Dr. Yuval Shafir, a pediatric neurologist, who argued that the available evidence does not support a conclusion that the vaccine caused Ahzja’s seizure disorder. Dr. Shafir opined that it is simply impossible to say what caused Ahzja’s disorder. Respondent also filed a medical article on November 21, 2001.⁵

Finally, both experts testified orally at the evidentiary hearing held on November 20, 2001.

⁴There seems to be no dispute in this case that the DPT vaccination that Ahzja received on October 16, 1997, contained the “whole-cell” version of the pertussis vaccine. Until very recent years, the *only* type of pertussis vaccine in general use was the whole-cell pertussis vaccine. In the last several years, a new type of “acellular” pertussis vaccine has become available, and is now being substituted for the whole-cell pertussis vaccine in most diphtheria-pertussis-tetanus inoculations in this country. Such vaccinations containing the acellular pertussis vaccine are usually described as “DTaP” rather than “DPT” or “DTP” inoculations. In the balance of this opinion, however, when I refer simply to the “pertussis vaccine,” I will be referring to the whole-cell vaccine. Further, when I refer to the “DPT vaccine,” I will refer to DPT vaccine containing the whole-cell pertussis vaccine.

⁵That article was filed after the hearing on November 20, 2001, but in fact both experts had the article in front of them, and were familiar with it, as they testified on November 20. (See, *e.g.*, Tr. 37.)

The short summary of my analysis of the evidence introduced in this case is that it failed by far to satisfy petitioner's burden of demonstrating that it is "more probable than not" that Ahzja's seizure disorder was caused by her DPT vaccination.⁶

First, I simply found the testimony of Dr. Shafrir to be substantially more persuasive than that of Dr. Gross. Dr. Shafrir has somewhat better credentials concerning the issue to be resolved, since he is a pediatric neurologist while Dr. Gross is an adult neurologist. Dr. Shafrir also was better able, in my view, to explain the *reasoning* behind his opinion. Dr. Gross, on the other hand, did very little, in either his affidavit or his oral testimony, to *explain* his opinion--he merely stated his ultimate opinion with little discussion of the basis therefor.

On several specific points, moreover, I found Dr. Shafrir's testimony to be much more persuasive. First, Dr. Gross suggested that the fact that Ahzja was not given any more pertussis vaccinations after the onset of her seizure disorder indicated that her treating physician suspected the pertussis vaccine as a cause for the disorder. But Dr. Shafrir explained that it is standard practice that any infant with a seizure disorder of *any* kind, whether or not such disorder is suspected to be vaccine-caused, will not be given pertussis vaccine. (Tr. 37.) And Dr. Shafrir's testimony in this regard is consistent with what I have uniformly heard from pediatricians and pediatric neurologists in numerous Program cases.

Dr. Gross also suggested that the fact that Ahzja's seizures were "focal" in nature indicated the vaccine as the cause, but Dr. Shafrir refuted that point. (Tr. 29-30.) In addition, Dr. Gross seemed to suggest that the failure of Ahzja's physician to find another cause for her seizures implicated the vaccine as the cause, but Dr. Shafrir explained that seizure disorders without identifiable cause are extremely common in infants. (Tr. 27-28.)

I also note that the medical records of Ahzja's case support Dr. Shafrir's view of the case, not that of Dr. Gross. Dr. Gross acknowledged that he could find nothing in any of Ahzja's medical records indicating that any of her treating physicians thought that the vaccination was the cause of her seizure disorder. (Tr. 11.) To the contrary, those records indicate that Ahzja's treating physicians, like Dr. Shafrir, viewed her disorder as one of *unknown* cause. (See, e.g., Ex. 12, p. 11 ("idiopathic seizures"); Ex. 14, p. 2 ("[e]tiology of Sz is unclear").)

Finally, and most importantly, the references in the record to the *medical literature* on the topic of whether the pertussis vaccine causes seizure disorders also support Dr. Shafrir over Dr. Gross. Dr. Gross did not point to any medical literature supporting his view of the case. Dr. Shafrir, on the other hand, argued that considerable medical literature supports the conclusion that the pertussis vaccine does *not* cause seizures of the sort suffered by Ahzja here--*i.e.*, *afebrile* seizures (seizures without fever). (Tr. 26, 35.) Dr. Shafrir pointed specifically to the most recent

⁶Had it been shown that Ahzja's *seizure disorder* was vaccine-caused, I would have concluded that her *death* was vaccine-caused, since the record supports a conclusion that her death was the result of her seizure disorder.

medical study reaching that conclusion, which respondent filed as Ex. C. And Dr. Gross did not dispute Dr. Shafrir's argument that both that specific recent study and the medical literature in general fail to show any causal connection between the pertussis vaccine and *afebrile* seizures. (Tr. 37.) Dr. Gross, indeed, seemed to acknowledge an "absence of proof" supporting his opinion. (*Id.*) Dr. Gross' only response on this point was to plead that the available studies don't definitively prove that the pertussis *can't* cause afebrile seizures. (*Id.*) But it is not the *respondent's* burden to prove that the vaccine *could not* have caused Ahzja's seizure disorder; rather, it is *petitioner's* burden to show that the vaccine likely *did* cause the disorder. And the testimony of Dr. Gross simply did not offer substantial support to petitioner in her unsuccessful attempt to carry that burden.

C. Analysis of Ahzja's case in light of the overall medical literature

In subsection III(B) of this decision, immediately above, I have confined my discussion to the evidence introduced specifically into the record of this case. However, to be fair to petitioner's counsel and her expert, I should note that they, like respondent's counsel and expert, have approached the causation issue in this case with the understanding that I, as a special master of this court for more than a dozen years, would already be familiar with the basic medical literature concerning the *general* issue of whether the whole-cell pertussis vaccine causes neurologic injury. Neither side attempted to formally place into the record of this case the voluminous existing medical literature relevant to that topic. Both sides assumed, and fairly so, that I would evaluate the specific medical expert testimony offered in this case in light of my background familiarity with that medical literature. Thus, it is only fair to petitioner that I also apply my understanding of that general medical literature to Ahzja's case, and consider whether, apart from the specifics of Dr. Gross' presentation, the facts of Ahzja's case would offer support to a conclusion that her seizure disorder was vaccine-caused.

In one recent decision, I set forth an exhaustive discussion of the general topic of whether the whole-cell pertussis vaccine can cause chronic neurologic damage to a vaccinee. See *Liabie v. Secretary of HHS*, No. 98-120V, 2000 WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000). I will not reiterate in this opinion that extensive discussion contained in *Liabie*. I do note, however, that in the *Liabie* ruling, I concluded that the available evidence justifies a conclusion that if a neurologically-intact vaccinee (1) suffers, within seven days after a "whole-cell" pertussis vaccination, a neurologic episode that would have qualified as a "serious acute neurologic illness" under the National Childhood Encephalopathy Study (NCES); (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified; then it is appropriate to causally attribute the chronic neurologic dysfunction to the vaccination. 2000 WL 1517672 at *12-*13. And if the case of Ahzja Dove had fallen within that above-stated theory that I adopted in *Liabie*, I would conclude that her seizure disorder and her death *were* vaccine-caused.

Ahzja's case, however, does not fall within that theory set forth above. While Ahzja clearly did suffer the onset of her seizure disorder within seven days of her DPT inoculation, she did not suffer within that seven-day post-inoculation period a "serious acute neurologic illness," as that term was used in the *Liabie* opinion. As explained in *Liabie*, the term "serious acute neurologic illness"

was adopted in a 1994 report by the Institute of Medicine to describe a vaccinee who experienced one of the following conditions in the seven-day post-vaccination period:

1. Acute or subacute encephalitis, encephalomyelitis, or encephalopathy * * *;
2. unexplained loss of consciousness;
3. Reye syndrome;
4. convulsions with a total duration of more than half an hour, or followed by coma lasting 2 hours or more, or followed by paralysis or other neurologic signs not previously present and lasting 24 hours or more; or
5. infantile spasms (West Syndrome).

2000 WL 1517672 at *3 and *15 fn. 12. Ahzja Dove did *not* experience one of those five conditions in the seven days after her DPT vaccination. She did experience a *seizure*--the term "seizure" being used synonymously with the term "convulsions" as used in the fourth category above--but her seizure lasted only *one or two minutes*, not for more than half an hour as required under the fourth category above.

In other words, I have carefully considered whether the causation theory that I adopted in *Liabie* would apply to Ahzja's case, and I conclude that it does not. Moreover, I have considered *all* the information that I have received in many Program cases involving the potential causal relationship between the whole-cell pertussis vaccine and neurologic dysfunction, and I see no viable causation theory that would support the petitioner's claim here.

IV

CONCLUSION

The story of the short life of Ahzja Dove is a tragic one. Her family certainly is deserving of great sympathy for their grievous loss. Congress, however, designed the Program to compensate only the families of individuals whose injuries or deaths can be linked causally, either by evidence or a Table Injury presumption, to a listed vaccination. In this case, as described above, no such link has been demonstrated. Accordingly, petitioner here is not entitled to a Program award.⁷

George L. Hastings, Jr.
Special Master

⁷In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment against petitioner.