

established by statute at § 300aa-14(a) and since modified administratively (see fn. 2 below), 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, 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).

In this case, petitioners’ claim is that Scott’s severe neurologic condition was caused by one of the vaccinations that he received on February 21, 1995. Those vaccinations are listed in the Vaccine Injury Table, but petitioners do not allege that Scott suffered any of the injuries listed in the Table for any of those vaccinations, so this case does not involve an allegation of a “Table Injury.” Instead, the issue here is whether petitioners have successfully demonstrated that Scott’s neurologic condition was “more probably than not”² *caused by* one or more of those vaccinations.

II

FACTS

Scott Saunders was born on August 11, 1994, to the petitioners, Paul and Delores Saunders. On February 21, 1995, at age six months, Scott was brought to his pediatrician with the report of a sudden onset of fever of up to 103°, vomiting, and disorientation. (Ex. 1, p. 4.³) Scott was diagnosed to be suffering from “pharyngitis” (inflamed throat) and/or “early otitis” (ear infection), and was given a prescription for an antibiotic. (*Id.*) At that visit he was also administered several vaccinations: diphtheria/tetanus (“DT”), hemophilus influenza (“HIB”), and oral polio (“OPV”).

On the next day, Scott was again brought to his pediatrician’s office, with the complaints of fever and “purple hands, mouth, and feet.” (Ex. 1, p. 5.) From the pediatrician’s office Scott was taken to the hospital, where he was admitted. He was found to be suffering from a very serious condition, including intracranial hemorrhaging--*i.e.*, bleeding within the area confined by the skull. (Ex. 1, p. 16.) Scott was transferred to another hospital, where, on February 23, 1995, an emergency procedure known as a “ventriculostomy” was performed in order to release the excess fluid and excess pressure in his brain, saving his life. (Ex. 3, p. 89.) He remained hospitalized until March 4, 1995.

Tragically, Scott emerged from that hospitalization with severe neurologic deficits. He is blind and suffers from severe developmental delay, conditions thought to be a result of that frightening episode of intracranial hemorrhaging and related symptoms in February of 1995. Scott’s physicians have never reached a definite conclusion as to the cause of that episode.

²Petitioners have 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) (Harlan, J., concurring).

³Petitioners filed exhibits numbered 1 through 21 on November 24, 1997. “Ex.” references will be to those exhibits.

III DISCUSSION

A. Applicable case law

_____ It should be noted, initially, that in analyzing a contention of "causation-in-fact," the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on a petitioner to show that in fact the vaccination in question more likely than not caused the injury. *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 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-1 (1989). Thus, a 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." *Strother, supra*, 21 Cl. Ct. at 370; accord, *Hines, supra*, 940 F.2d at 1525; *Grant v. Secretary of HHS*, 956 F. 2d 1144, 1148 (Fed. Cir. 1992); *Carter, supra*, 21 Cl. Ct. at 654; *Hasler v. United States*, 718 F.2d 202, 205-6 (6th Cir. 1983); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989). Temporal association alone is *not* sufficient. *Strother, supra*, 21 Cl. Ct. at 370; *Shaw, supra*, 18 Cl. Ct. at 650-651 (1989); *Carter, supra*, 21 Cl. Ct. at 654. Moreover, "similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table injuries can have causes other than administration of a vaccine." *Strother, supra*, 21 Cl. Ct. at 370.⁴ However, a petitioner need not demonstrate that the vaccination was the *sole* cause, or even the *primary cause*, of the injury. Instead, a petitioner need only show that the vaccination was a *substantial factor* in causing the injury, and that *but for* the vaccination the injury would not have occurred. *Shyface v. Secretary of HHS*, 165 F. 3d 1344 (Fed. Cir. 1999).

B. Summary of parties' positions in this case

Petitioners' rely primarily upon the opinion of Dr. Charles Poser, a physician specializing in adult and pediatric neurology. Dr. Poser filed written reports, and also testified at the evidentiary hearing held on June 12, 2001. Dr. Poser opined that Scott's devastating episode in February of 1995 was the result of one of the vaccinations that he received on February 21, 1995. Dr. Poser explained that all types of vaccinations are capable of producing immune-inflammatory adverse reactions, which can damage the vaccinee's central or peripheral nervous system. He opined that such a reaction happened to Scott. Specifically, he stated that Scott suffered an episode of "acute hemorrhagic leukoencephalopathy," or "AHLE," which is a severe form of "acute disseminated encephalomyelitis"

⁴ The legislative history confirms this interpretation of the statute, providing that "simple similarity to conditions or time periods listed on the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation * * * ." H.R. Rept. No. 99-908, 99th Cong., 2d Sess, pt. 1, at 15 (reprinted at 1986 U.S. Code Cong. and Admin. News at 6356).

or “ADEM.” Dr. Poser testified that this episode of AHLE resulted in Scott’s blindness and developmental delay. (See, *e.g.*, Tr. 26-33.⁵)

Respondent, on the other hand, relied on the testimony of Dr. John Bodensteiner, a physician specializing in pediatric neurology. Dr. Bodensteiner agrees that Scott’s current blindness and developmental delay are a result of his devastating neurologic episode in February of 1995. He also agrees that it is possible for a vaccination to produce an immune-inflammatory reaction that could damage the vaccinee’s nervous system. (Tr. 96.) But he opined that such a phenomenon did not happen to Scott. Dr. Bodensteiner testified that instead, Scott’s devastating episode in February of 1995 probably resulted either from trauma or a ruptured “arterial venous malformation” (AVM). (See, *e.g.*, Tr. 107-08.)

C. Resolution

After careful analysis of all of the evidence of record, I have concluded that petitioners have failed to carry their burden of demonstrating that it is “more probable than not” that Scott’s devastating episode in February of 1995 was vaccine-caused. The short summary of my reasoning is that I simply found the testimony of Dr. Bodensteiner to be substantially more persuasive than that of Dr. Poser.

The strongest point made by Dr. Bodensteiner was that there simply is no substantial evidence to support Dr. Poser’s theory that Scott suffered from an episode of AHLE, or any form of ADEM. Dr. Bodensteiner agrees that an episode of ADEM could be caused by a vaccination. (Tr. 113.) But he emphasized that if Scott had suffered an AHLE, that would have been obvious upon examination of the MRI (magnetic resonance image) scans of Scott’s brain; those scans would have shown hemorrhaging in the white matter areas of Scott’s brain. (*E.g.*, Tr. 88-89⁶, 98-99⁷, 110-111.) I found that this argument was persuasive, and not adequately refuted by Dr. Poser. To be sure, Dr. Poser explained that in days prior to modern scanning techniques, the diagnosis of AHLE was made (Tr. 34), but he never adequately explained how a person could have AHLE without that being evident when an MRI scan was in fact done.

In this regard, it is important, too, that, as Dr. Bodensteiner also emphasized, though Scott was treated by some excellent neurologists at three different hospitals, none of his treating physicians ever concluded that Scott had AHLE or any form of ADEM. (Tr. 92-93.) Dr. Poser himself acknowledged that in his examination of the medical records, he found no record in which any treating physician either attributed the episode to a vaccination or diagnosed an AHLE. (Tr. 50, 141.) Indeed, Dr. Bodensteiner noted that no physician even listed AHLE in a “differential

⁵“Tr.” references are to the pages of the transcript of the evidentiary hearing held on June 12, 2001.

⁶I note that in the transcript at p. 88, lines 13-14, I am quoted as using the term “hemorrhagia.” However, I believe that I said “hemorrhaging.” I also believe that in other places in the transcript the term “hemorrhagia” is used where the speaker actually said “hemorrhaging.”

⁷At p. 99, line 7, of the transcript, I believe that the question referred to an “ADEM-like illness,” not an “AVM-like illness.”

diagnosis"-- *i.e.*, a list of *possible* causes of Scott's episode. (Tr. 93, 108.) And Dr. Poser, when asked how Scott's treating physicians could somehow have missed evidence of an AHLE, acknowledged that he could not explain that. (Tr. 65-67.)

Another important point is that Dr. Poser seems to have reached his conclusion--that an AHLE occurred--in substantial part by a process of exclusion of other potential causes. (See, *e.g.*, Tr. 26-33.) But Dr. Poser failed to persuasively explain why he eliminated the two causes found most likely by Dr. Bodensteiner--*i.e.*, trauma or a ruptured AVM. As to trauma, Dr. Poser simply did not explain why he excluded that possibility.⁸ As to ruptured AVM, Dr. Poser argued both that a ruptured AVM would not explain all of Scott's symptoms (Tr. 28), and that the onset of Scott's symptoms was not sudden and explosive enough and did not result in a loss of consciousness (Tr. 28, 35-38). But Dr. Bodensteiner persuasively rebutted those arguments. He explained that a ruptured AVM could, in fact, account for all of Scott's symptoms. (Tr. 90-92.) He also stated that in an *infant*, a ruptured AVM would not necessarily be as sudden or explosive as Dr. Poser suggested (Tr. 91), nor would it necessarily have resulted in a loss of consciousness (Tr. 106). Dr. Poser failed to respond to these rebuttals by Dr. Bodensteiner.

Finally, I note that Dr. Poser, in defending his view that an AHLE occurred, pointed out that Scott obviously did suffer brain damage from the horrendous episode in question, even though Dr. Bodensteiner had argued that the MRI scans failed to show evidence of hemorrhaging in the white matter area. (Tr. 133.) But when I asked Dr. Bodensteiner to respond to this point (Tr. 141-142), Dr. Bodensteiner had what seemed to me to be a persuasive answer. Dr. Bodensteiner explained that while it is typical for brain damage resulting from *trauma* to yield no white matter lesions visible on MRI, brain damage due to *ADEM* typically *would* be accompanied by such MRI findings. Thus, in Dr. Bodensteiner's view the presence of brain damage in the absence of white matter MRI findings supports his, not Dr. Poser's, theory of the case. (Tr. 142.) To this explanation of Dr. Bodensteiner, Dr. Poser did not respond.

In reaching my conclusion, I certainly have not ignored the feature of this case which seems, at least on its face, to be favorable to a "causation" conclusion in petitioners' favor--*i.e.*, the close temporal relationship between Scott's vaccinations on February 21, 1995, and the onset on the very next day of his devastating neurologic episode. This striking temporal relationship, of course, would certainly make anyone *suspect* that the vaccinations caused the tragic episode. However, the testimony of numerous medical experts that I have taken, in the course of resolving medical causation questions in Program cases over the past 12 years, teaches that a *causal* relationship cannot be automatically inferred from a *temporal* relationship. Infants in our society receive many vaccinations, and also are extremely vulnerable during those months of infancy to suffering neurologic injuries from a variety of causes. Thus, the onset of many neurologic injuries in infants will take place shortly after a vaccination *by pure chance*. Therefore, a *causal* relationship can reasonably be inferred from a *temporal* relationship with respect to a particular injury only when sufficient *medical evidence* exists indicating that a vaccination of the type received by the injured party is known or suspected to cause the type of injury suffered, in the time frame after vaccination in which the injury was suffered. In other words, with respect to some injuries or diseases, there exists in medical literature enough

⁸Dr. Poser remarked twice in passing that the possible cause of "Shaken Baby Syndrome" had been "eliminated." (Tr. 28, 33.) But he did not explain these remarks, and did not explain why *accidental* trauma could not have been the cause.

evidence to conclude that Factor A *can* cause Injury B. Therefore, in a situation where Injury B followed temporally closely after the occurrence of Factor A in a particular individual, there may be good reason to conclude that Factor A caused Injury B in that individual. But only where such medical evidence exists can we infer a causal relationship from a temporal relationship.

With respect to the case of Scott Saunders, unfortunately for the petitioners, when I compare the vaccinations he received to the type of neurologic episode he suffered, there does not exist medical evidence permitting me to infer a causal relationship. There is no substantial evidence in the record before me indicating that any of the vaccinations that Scott received on February 21, 1995, have been known or suspected to cause the type of episode from which Scott actually suffered. To be sure, both Dr. Poser and Dr. Bodensteiner agree that in theory all vaccinations are capable of producing immune-inflammatory reactions that could damage a vaccinee's nervous system. But the testimony of Dr. Bodensteiner in this case persuades me that if such a phenomenon were to take place, the victim would *not* have an MRI like that of Scott, without any obvious white matter changes. Also, Scott's treating neurologists would have at least listed AHLE or ADEM in their differential diagnoses of Scott's case. Therefore, the evidence in this case does not support a conclusion that the onset of Scott's tragic episode a day after his vaccinations was more than a mere coincidence.

IV

CONCLUSION

The story of the severe neurologic deficits of Scott Saunders is a tragic one. It is impossible not to have the utmost sympathy for Scott and his parents, who seem to be very fine people, admirably dedicated to Scott's welfare. Congress, however, designated the Program to compensate only those individuals who can demonstrate either the existence of a "Table Injury" or satisfactory evidence of a causal link between an injury and a listed vaccination. And in this case the petitioners have failed to demonstrate such a link with respect to Scott's condition, for the reasons discussed above. Therefore, I conclude that petitioners are not entitled to a Program award.⁹

George L. Hastings, Jr.
Special Master

⁹I do note that, despite the petitioners' ultimate lack of success in this claim, I find that this case was brought "in good faith" and upon a "reasonable basis." Accordingly, petitioners will be entitled to an amount of attorneys' fees and costs incurred in this action pursuant to § 300aa-15(e). This amount will be awarded in a supplemental decision after the judgment "on the merits" becomes final. See Vaccine Rule 13.