

OFFICE OF SPECIAL MASTERS

No. 01-239V

(Filed: January 29, 2003)

MELODY STACEY and ROGER STACEY, *
Legal Representatives of their minor daughter, *
EMILY ANN STACEY, *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Curtis Webb, Twin Falls, Idaho, for petitioners.

Melonie McCall, Department of Justice, Washington, D.C., for respondent.

RULING CONCERNING "ENTITLEMENT" ISSUE

HASTINGS, Special Master.

This is an action in which the petitioners seek an award under the National Vaccine Injury Compensation Program (see 42 U.S.C. § 300aa-10 et seq¹), on account of an injury to their daughter, Emily Ann Stacey. For the reasons stated below, I conclude that petitioners are entitled to such an award, in an amount yet to be determined.

¹The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 et seq. (2000 ed.). Hereinafter, for ease of citation, all "\$" references will be to 42 U.S.C. (2000 ed.).

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by certain vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered an injury thereafter; and has received no previous award or settlement on account of the injury. Finally--and the key issue in most cases under the Program--the petitioner must also establish a causal link between the vaccination and the injury. One method by which the petitioner may establish this link is by demonstrating the occurrence of what has been described as a "Table Injury." That is, the statute provides for the creation of a "Vaccine Injury Table," consisting of a list of specified types of injuries for each type of vaccination covered by the statute, along with a specified time period after vaccination in which such an injury must occur. The petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the Vaccine Injury Table with respect to the vaccination in question, and that either the first symptom of the onset of that injury, or the first symptom of a "significant aggravation" of that injury, occurred within the required time period after the vaccination. If so, the "Table Injury" is *presumed* to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is shown affirmatively that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

Alternatively, if no injury falling within the Vaccine Injury Table can be shown, the petitioner may establish the causal link by showing that the vaccine recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii).

II

BACKGROUND FACTS

Emily Ann Stacey was born on December 26, 1996. The petitioners, Melody and Roger Stacey, are her parents. Emily was delivered by emergency cesarean section because her heart rate slowed during an attempt at vaginal delivery. At seven or eight hours after birth, Emily experienced three episodes of apnea--*i.e.*, she stopped breathing. These episodes required stimulation to restore breathing. She also suffered prolonged seizure activity. Emily was transferred by air ambulance from the hospital at which she was born, in Muskogee, Oklahoma, to a neonatal intensive care unit at a hospital in Tulsa, Oklahoma. She was kept hospitalized for 14 days after birth, until January 9, 1997. She was diagnosed as having suffered from "hypoxic/ischemic encephalopathy" or "anoxic

encephalopathy”--*i.e.*, damage to her brain, resulting from deprivation of oxygen prior to her delivery. (Exs. 2, 3.²)

Over the next sixteen months, Emily generally progressed well, although developmental testing determined that she was somewhat behind other children of her age in developmental skills, by percentages of 25% to 40%. (Ex. 10C, p. 11.) Emily did not experience any seizures during that period, and in mid-1997 she was taken off of anti-seizure medication. (Ex. 5, pp. 3, 4, 7; Ex. 7, p. 5, Ex. 17, p. 1; Tr. 26.)

On April 24, 1998, Emily received a number of immunizations, including an “MMR” (measles, mumps, rubella) inoculation. On May 3, 1998, she was rushed to the emergency room at the hospital in Muskogee, after she stopped breathing and experienced symptoms of extreme stiffness and jerking. At that hospital, she was found to be suffering from seizures and apnea. She continued to experience repeated seizure activity over a period of time at the Muskogee hospital, despite administration of anti-seizure medications. (Ex. 6, p. 1.) Emily was then air-lifted again to the hospital in Tulsa, where she was not discharged until six days later. (Ex. 7, pp. 1-2.)

After the seizure/apnea episode of May 3, 1998, Emily continued to experience seizures. She had seizures on June 3, 1998, October 10, 1998, and then on many occasions in 1999 and later years, beginning in January of 1999. (Ex. 4, pp. 13, 16; Ex. 5, pp. 10, 15-22; Ex. 8, p. 3.) Subsequent measures of her developmental skills also showed that she was falling further behind children of comparable age. For example, an evaluation on October 25, 1999, indicated that Emily’s development was then behind her peers between 44% and 62% in all categories, with the deficit in most categories in the range of 59% to 62%. (Ex. 10E, p. 18.)

Emily continues to the present to suffer from a severe neurologic disorder, including frequent seizures. Developmentally, she continues to lag far behind other children of her age.

III

ISSUE TO BE ADDRESSED

Petitioners argue that they are entitled to a Program award on Emily’s behalf, by either or both of two theories. First, they contend that Emily suffered the Table Injury of “significant aggravation” of “encephalopathy,” with respect to the MMR vaccination of April 24, 1998, pursuant

²Petitioner filed exhibits numbered 1 through 8 with the petition, and additional, consecutively-numbered exhibits on several occasions thereafter. Respondent filed Exhibits A and B. “Ex.” references will be to those exhibits. “Tr.” references will be to the pages of the transcript of the evidentiary hearing held on July 11, 2002.

to the version of the Vaccine Injury Table applicable to this petition.³ In the alternative, they argue that the MMR vaccination of April 24, 1998, “caused-in-fact” a significant worsening of Emily’s neurologic disorder.

I have determined that petitioners are entitled to an award pursuant to petitioners’ theory of “causation-in-fact,” so that I do not need to address their Table Injury theory. My reasoning concerning that “causation-in-fact” theory will appear in the following section of this Ruling.

IV

“CAUSATION-IN-FACT” ISSUE

After careful consideration of the entire record in this case, I conclude that it is “more probable than not” that Emily’s MMR vaccination of April 24, 1998, “caused-in-fact” a significant worsening of Emily’s neurologic condition. The shortest summary of my reasoning behind this conclusion is that I simply found the testimony of petitioners’ expert, pediatric neurologist Dr. Marcel Kinsbourne, slightly more persuasive than that of respondent’s expert, pediatric neurologist Dr. John Sladky. A more detailed explanation will follow.

A. Summary of experts’ opinions

Dr. Kinsbourne in his written report (Ex. 17) and in his hearing testimony (Tr. 22-32, 56-57, 62-63) indicated the view that while Emily clearly had sustained brain damage during her anoxic encephalopathy at birth, she likely was further neurologically damaged by the episode of seizure and breathing cessation of May 3, 1998 (hereinafter the “seizure/apnea episode” or on the “May 3 episode”). Dr. Sladky, on the other hand, in his written report (Ex. A) and hearing testimony (Tr. 33-55; 59-62), opined that Emily’s anoxic encephalopathy at birth was most likely the cause of *all* Emily’s neurologic problems since then, and that he sees no reason to conclude that either Emily’s MMR inoculation of April 24, 1998, or her seizure/apnea episode of May 3, 1998, had any significant affect on her long-term neurologic status. Although the question is a very close one, I find Dr. Kinsbourne’s approach to be slightly more persuasive.

³The statute contains a version of the Vaccine Injury Table that applied to vaccinations administered prior to the enactment of the Program and for several years after that enactment. (See § 300aa-14(a).) 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 MMR vaccinations from the version of the Table contained in the statute. The portion of the new Table applicable to this case, listing “encephalopathy” as a Table Injury for the MMR vaccination, appears at 42 C.F.R. § 100.3(a)(III)(B) (10-1-97 edition of C.F.R).

B. The seizure/apnea episode was likely caused by the MMR vaccination

First, I find it very likely that Emily's *seizure/apnea episode* of May 3, 1998, was caused by her MMR vaccination of April 24, 1998. I note that there seems to be no dispute that the May 3 seizure was caused by Emily's *elevated temperature*. And Dr. Kinsbourne explained that Emily's fever peaked on May 3, nine days after her MMR vaccination, exactly when one would expect a fever triggered by an MMR vaccination. (Ex. 17, p. 2.) Dr. Sladky responded that whether Emily's fever was due to the MMR immunization is "a matter of speculation" (Ex. A, p. 2), but he did not further contest Dr. Kinsbourne's conclusion that the MMR vaccination caused the fever, nor did Dr. Sladky suggest any other possible reason for the elevated temperature.⁴ I conclude that Emily's *fever* was very probably caused by her MMR vaccination, and thus that her *seizure/apnea episode* of May 3, 1998, also was caused by her vaccination.

C. The seizure/apnea episode likely caused a worsening of Emily's neurologic condition

In part B above, I conclude that Emily's *MMR vaccination* was the likely cause of her *seizure/apnea episode* of May 3, 1998. Accordingly, the next question, and the key question in this case, becomes whether that *seizure/apnea episode* of May 3, 1998, in turn, caused a *significant worsening* of Emily's neurologic condition. I find it likely that it did so, based upon Dr. Kinsbourne's opinion, for a number of reasons.

1. Severity of seizure episode

The first important factor is the *severity* of the seizure/apnea episode that Emily suffered on May 3, 1998. Dr. Miller, Emily's treating neurologist, described Emily as experiencing "severe seizures" on that day. (Ex. 18, p. 1.) Dr. Kinsbourne described the episode as "uncommonly severe" (Tr. 29), constituting a "life-threatening neurological emergency" (Tr. 24). Dr. Sladky, too, acknowledged that Emily experienced "a severe seizure, potentially life-threatening." (Tr. 61.) And those descriptions of Emily's seizure episode are supported by the hospital records. The physicians at the Muskogee hospital found Emily's condition to be so severe on that day that they found it necessary to rush her by helicopter to the hospital in Tulsa with greater capacity to handle the case. (Ex. 6, p. 1.) And the physicians at the Tulsa hospital kept Emily hospitalized for six more days. (Ex. 7, p. 1.) This severity of the episode adds support to the theory that it was severe enough to cause permanent neurologic damage to Emily.

⁴I also note that Emily's treating pediatric neurologist, Dr. Steve Miller, stated that "no other etiology for her fever," other than the MMR vaccination, was determined, and that Emily's seizures were "initiated due to a febrile illness as a consequence of her immunizations, including MMR." (Ex. 18, p. 1.)

2. *Duration of seizure episode*

A second factor is the *duration* of Emily's seizure/apnea episode of May 3, 1998. The testimony of both Dr. Kinsbourne and Sladky indicated that the duration of febrile seizures is important, with febrile seizures of short duration being unlikely to cause permanent injury. (Tr. 44,⁵ 56.) In reaching his opinion concerning this case, Dr. Sladky seemed to be relying upon a statement of one neurologic consultant that Emily's seizure episode of May 3 lasted about 12 minutes. (Tr. 43; see Ex. 7, p. 6--"Duration of the seizure was approximately 10-12 minutes.") But a closer look at the whole record indicates that Emily's seizure episode must have lasted much longer than that. First, the testimony of Emily's mother indicates that Emily was stiff, not breathing, "convulsing," and/or "jerking" for a period of time at her home before the ambulance was called; for an additional period of at least seven minutes until the ambulance arrived; for an additional period of 10 to 15 minutes or more that it took to transport Emily to the Muskogee hospital; and for an additional period of time at the Muskogee emergency room. (Tr. 9-12; Ex. 1, paragraphs 9-13.) This testimony would indicate a seizure duration of much longer than 12 minutes, and Mrs. Stacey at one time apparently estimated the total seizure period as about 80 minutes. (Ex. 17, p. 1.)

More importantly, the emergency room record at the Muskogee hospital makes it *clear* that Emily's seizure episode lasted much longer than 12 minutes. That record states first that Emily had seizure activity--"apparently seize with her eyes turning off to one side or jerking some"--prior to arrival at the hospital. (Ex. 6, p. 1, first paragraph.) The record goes on to say that Emily "intermittently showed signs of seizure activity while the child was here in the emergency room," and describes steps taken to stop the seizures, as well as consultations with the physicians at the Tulsa hospital, and the decision to transfer Emily there. (*Id.* at second paragraph.) The record then states that even *after* those anti-seizure efforts and those consultations between physicians concerning Emily, "the child showed more seizure activity," and even more anti-seizure efforts had to be made. (*Id.* at third paragraph, first line.) Then, still later, Emily "continued to show seizure activity off and on," so even more treatment was necessary. (*Id.* at third paragraph, second line.) This hospital record, thus, very clearly indicates an extended period of seizure activity *far longer* than that apparently assumed by Dr. Sladky. And the fact that Emily suffered such a prolonged seizure adds support to the view that the seizure episode probably caused lasting consequences.

3. *Apnea*

Another factor is that Emily's seizure activity on May 3, 1998, was marked by periods of *apnea*--that is, she stopped breathing. For example, the Muskogee hospital's records indicate that when Emily arrived there, "the child was apneic." (Ex. 6, p. 1, first paragraph.) The same record later repeats that Emily was "found to be somewhat apneic." (*Id.* at second paragraph.) The record of the Tulsa hospital confirms that Emily earlier in the day had "stopped breathing" and had suffered "respiratory failure." (Ex. 7, p. 1.) Therefore, because periods of breathing cessation can deny

⁵I believe that in the question transcribed at Tr. 44, line 12, Ms. McCall used the word "febrile," not "afebrile" as transcribed.

oxygen to the brain and thereby cause brain damage (see, *e.g.*, Tr. 50), the fact that Emily's May 3 episode involved apneic periods also adds support to a conclusion that the May 3 episode resulted in lasting neurologic damage to Emily.

4. Seizure-free period prior to May 3, 1998

Another factor is that Emily never had any seizures during the approximately 16-month period between her anoxic encephalopathy at birth and her seizure/apnea episode on May 3, 1998; then soon after the May 3 episode she began to have frequent seizures that have plagued her to the present time. The medical records show that Emily went on to have seizures on June 3, 1998, on October 10, 1998, and then on many occasions in 1999 and later years, beginning in January of 1999. (Ex. 4, pp. 13, 16; Ex. 5, pp. 10, 15-22; Ex. 8, p. 3.) The records also show that Emily was seizure-free during the 16-month period prior to May 3, 1998, even though she was taken off of anti-seizure medication for the latter half of that period. (Ex. 5, pp. 3, 4, 7; Ex. 7, p. 5; Ex. 17, p. 1; Tr. 26.) This absence of any seizures for a sixteen-month period, followed by the onset of a severe seizure disorder soon after the May 3 episode, again lends weight to Dr. Kinsbourne's conclusion that the May 3 episode worsened Emily's condition.

5. History of developmental skills

Yet another factor is the history of Emily's developmental skills. It is clear, of course, that subsequent to her anoxic encephalopathy at birth, Emily suffered from delay in her developmental skills. For example, an assessment of Emily's development performed on April 8, 1998, just prior to the vaccination in question, indicated that Emily was behind children of her age by 25% to 30% in four developmental areas, and by 40% in a fifth area. (Ex. 10C, p. 11.) However, a later evaluation, on October 25, 1999, indicated that Emily's development was then behind her peers between 44% and 62% in all categories, with the deficit in most categories in the range of 59% to 62%. (Ex. 10E, p. 18.)

Further, Emily's mother described a regression in Emily's developmental skills that began immediately after the seizure/apnea episode of May 3, 1998. (Ex. 1, paragraph 17; Tr. 13-14.)

Concerning this topic, Dr. Sladky has opined that Emily's development probably would have continued to diverge from that of her peers merely as a result of her anoxic encephalopathy at birth, regardless of the 1998 seizure/apnea episode. He believes that Emily's skills did not "regress" after the May 3 seizure/apnea episode--*i.e.*, she did not *lose* skills that she previously had. Dr. Sladky had an explanation for the fact that the April 1998 testing showed most of Emily's deficits in the 25-30% range, while the October 1999 testing showed most deficits in the 59-62% range. Dr. Sladky stated that as other children's developmental abilities increased with age, Emily's skills also increased rather than regressed, but simply did not increase by *as much* as those of other children; therefore, Emily fell further behind other children on a *percentage* basis, but all as a result of the anoxic episode at birth. (Tr. 45-46, 54-55.)

In this regard, Dr. Sladky strongly relied on a record of Emily's treating neurologist, Dr. Miller, who wrote after seeing Emily on May 27, 1998, that she had "made an unremarkable recovery" from her seizure/apnea episode of May 3, 1998. (Ex. A, p. 2; Tr. 40, 41; Ex. 5, p. 8.) Dr. Sladky indicated that he interprets this statement in Dr. Miller's records to mean that after the May 3 episode Emily did not seem developmentally any different from her condition prior to the episode. (Tr. 41.) However, I note that Dr. Miller himself has written that "Emily's skills regressed" after the May 3 episode. (Ex. 8, p. 1.) Although he does not say exactly when or how swiftly they regressed, Dr. Miller, a pediatric neurologist, used the specific term "regressed." Further, a report of a speech pathologist who examined Emily on April 28, 1999, also states that Emily "regressed" in feeding skills, and that her "[s]peech and language skills also regressed as well as independent walking and play activity." (Ex. 10D, p. 14.)

Accordingly, considering the testimony of Dr. Sladky, Dr. Kinsbourne, and Mrs. Stacey concerning this issue, along with the written report of Dr. Miller and the medical records cited above, I find it probable that Emily did actually "regress" in her development after the May 3 episode, and that such regression, along with her greater developmental divergence from the norm demonstrated in her testing of October 1999, adds further weight to Dr. Kinsbourne's conclusion that the May 3 seizure/apnea episode significantly worsened Emily's neurologic condition.

6. Dr. Miller's opinion

Next, I note that Dr. Miller, Emily's treating pediatric neurologist, provided a written opinion concerning Emily's case, in which he stressed the severity of the May 3 seizure/apnea episode, noted that Emily's skills regressed thereafter, and then stated that—

it is clear that Emily's development regressed with the onset and progression of her refractory seizures that were initiated due to a febrile illness as a consequence of her immunizations, including MMR.

(Ex. 18, p. 1.) This statement seems to indicate the general support of Dr. Miller for Dr. Kinsbourne's theory that Emily's overall neurologic condition significantly worsened as a result of her MMR vaccination and the resultant episode of May 3, 1998. This support of Emily's own treating pediatric neurologist, who knows her case the best, and who is not acting as a hired expert in this case, adds extremely important weight to Dr. Kinsbourne's theory.

7. Summary

In summation, while this is a very close question, as to which reasonable minds can differ, I find that it is more probable than not that the *seizure/apnea episode* of May 3, 1998, significantly worsened Emily's preexisting neurologic condition; therefore, I also conclude that Emily's *MMR vaccination* of April 24, 1998, which caused the seizure/apnea episode, significantly worsened Emily's neurologic condition.

As both Dr. Kinsbourne and Dr. Sladky testified, Emily certainly sustained brain damage as a result of her anoxic encephalopathy at birth. And it is certainly *possible* that Dr. Sladky is correct in his opinion that Emily's neurologic course since May of 1998 was solely the result of that anoxic encephalopathy at birth, and was not significantly affected by either her MMR vaccination of April 24, 1998, or her seizure/apnea episode of May 3, 1998. However, taking into account all of the evidence in the record in this case, I find it more likely that Dr. Kinsbourne is correct that Emily's overall neurologic course was, in fact, significantly worsened by her MMR vaccination of April 24, 1998, and the resulting seizure/apnea episode of May 3, 1998. I base this conclusion upon all the factors set forth above, but I will stress several points in summation here.

First, I note that Dr. Sladky acknowledged that not all children who suffer hypoxia at birth and have an EEG pattern similar to that of Emily as a neonate, go on to experience severe developmental delay. (Tr. 48; see also Tr. 46.) And Dr. Kinsbourne testified that a "clear majority" of children with neonatal anoxic encephalopathy end up developing normally, with only an "unfortunate minority" ending up with severe delay, as Emily ultimately experienced. (Tr. 30.) Also, the two experts in essence agreed that some victims of neonatal anoxic encephalopathy would not end up with seizure disorders, although some would. (Tr. 30, 48, 52.⁶) Therefore, the fact that Emily has ended up with a worse neurologic outcome than might have been predicted, after her anoxic encephalopathy at birth, adds weight to the conclusion that her neurologic course was due in part to a later occurrence--*i.e.*, the seizure/apnea episode of May 3, 1998.

Further, I note that Dr. Sladky acknowledged that Emily's condition changed for the worse on May 3, 1998. (Tr. 47.) He acknowledged both that prolonged seizures can cause brain damage (Tr. 51), and that deprivation of oxygen during a seizure episode can cause brain damage (Tr. 50). And I conclude that, as Dr. Kinsbourne testified, Emily's prolonged seizure episode and periods of apnea on May 3, 1998, probably did significantly further damage her brain.

Finally, I note that I found credible the testimony of Emily's mother concerning the *regression* of Emily's developmental skills after the May 3 episode, given the support for those assertions by the statements of both Dr. Miller and the speech pathologist that Emily's skills "regressed." (See discussion at p. 8 above.) But, in addition, I note that Dr. Kinsbourne explained that there is considerable evidence for the proposition that lengthy, severe seizures in infancy can damage the brain even in the *absence* of acute, immediate evidence of a regression in skills. (Tr. 58.) And Dr. Sladky did not refute that point.⁷

⁶Although, to be sure, Dr. Sladky opined that a majority of such individuals would later have seizures (Tr. 48, 52), while Dr. Kinsbourne seemed to indicate the view that a majority probably would not (*i.e.*, would "develop normally") (Tr. 30).

⁷Another point of interest is that Dr. Sladky remarked that Emily's seizure/apnea episode of May 3, 1998, "lowered her resistance to seizures." (Tr. 52.) Unfortunately, Dr. Sladky never explained this statement, and therefore I have not given it any substantial weight in my final conclusion. However, on its face, it would seem that an incident that "lowered a person's resistance

In short, for all the reasons set forth above, I find it “more probable than not” that Emily’s MMR vaccination of April 24, 1998, “caused-in-fact” a significant worsening of Emily’s preexisting neurologic condition. I find that Emily’s neurologic course since that time has resulted in significant part from her MMR vaccination,⁸ as well as in part from her anoxic encephalopathy at birth.

V

FURTHER PROCEEDINGS

For the reasons stated above, I find that petitioners are entitled to a Program award on Emily’s behalf. Thus, petitioners’ counsel may initiate efforts toward establishing the appropriate *amount* of the award. I will schedule a status conference shortly to discuss that topic.

George L. Hastings, Jr.
Special Master

to seizures” would be significant in a causal sense, especially if that person went on, as Emily did, to experience a severe seizure disorder.

⁸Of course, my conclusion that Emily’s neurologic disorder probably was worsened by her MMR inoculation should not be interpreted as a conclusion that the MMR inoculation is a particularly dangerous vaccination. To the contrary, given the huge number of MMR inoculations that have been administered world-wide and the very small number of seizures or neurologic disorders reported after such inoculations, it is clear that any risk of neurologic injury from such inoculations is an extremely small one, confined to very rare instances. It remains clear that MMR vaccination is a generally safe procedure, and that the risks resulting from *failure to receive* such vaccinations far exceeds any very slight risk involved in *receiving* them.