

OFFICE OF THE SPECIAL MASTERS
No. 90-2770V
(Filed on June 22, 1998)

MACK and OLLIE FAYE BRADBARY, *
Guardians of AMANDA BRADBARY, *

Petitioners, * **TO BE PUBLISHED**

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

T. Michael Flinn, Carrollton, GA, for petitioners.

Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Statement of the Case

In a decision dated November 17, 1995, the undersigned ruled that petitioners had proved a prima facie case of significant aggravation of Amanda's tuberous sclerosis (TS) because her seizures: (1) began in Table time of her second DPT vaccination, and (2) resumed within Table time of her MMR vaccination. This decision was subject, however, to respondent's proof that a factor unrelated to the vaccines, i.e., TS, was the cause-in-fact of Amanda's seizure disorder and current condition.

The court held an Omnibus hearing on October 8-11, 1996 and June 3-4, 1997 on the issue of TS as a factor unrelated. The court issued a decision on September 15, 1997, holding that, absent symptoms of a vaccine reaction such as high-pitched screaming, inconsolable crying, anorexia, high fever, insomnia, altered affect, or excessive irritability, vaccinees with TS whose seizure began within Table time of a

DPT vaccination would not prevail because respondent had successfully proven that TS was the cause-in-fact of their seizures. See Barnes et al., 1997 WL 620115, at *32-33 (Fed. Cl. Spec. Mstr. Sept. 15, 1997).

On September 22, 1997, the undersigned issued an Order in this case directing the parties to produce more evidence in order to determine: (1) the significance of Amanda's post-vaccination symptoms,⁽¹⁾ and (2) whether respondent had a factor unrelated defense to rebut the statutory presumption that MMR significantly aggravated Amanda's TS by an increase in her seizures.

Facts

Amanda received her second DPT vaccination on July 16, 1982. Med. recs. at Ex. 4-1. She saw her pediatrician, Dr. Mary Miles, on July 21, 1982, five days later. Med. recs. at Ex. 3-5. Dr. Miles' notes from this visit reflect that Amanda had been experiencing episodes during which she acted startled and scared. Med. recs. at Ex. 3-8. These episodes occurred more frequently in the evening and were followed by an hour of inconsolable crying. Id. Mrs. Bradbary did not think Amanda was in pain. Id. She told Dr. Miles that Amanda received her DPT vaccination approximately ten days previously.⁽²⁾ Id. Mrs. Bradbary further noted that Amanda had not have any significant illnesses, i.e., colds, earaches, fever, since birth.⁽³⁾ Med. recs. at 5-15. On examination, Amanda was very bright and alert but strange with Dr. Miles. Med. recs. at 3-5. She had good motor control and no abnormal reflexes. Id. Dr. Miles ordered an EEG because Amanda's history was suggestive of seizures. Id. An EEG performed on July 23, 1982 showed bilateral seizure activity. Med. recs. at Ex. 5-15.

A letter written by Dr. Miles, dated September 2, 1982, states that Amanda's "startling" episodes had increased in frequency during the few days prior to her July 21, 1982 office visit. Med. recs. at Ex. 3-5. Dr. Miles notes that the onset of these "little spells" occurred about three days after Amanda's DPT vaccination. Id. Amanda's EEG showed significantly abnormal bilateral seizure activity. Id. Dr. Miles diagnosed myoclonic seizures, possibly secondary to DPT. Id.

From August 3 to 7, 1982, Amanda was hospitalized at Henrietta Eggleston Hospital for Children. Med. recs. at Ex. 5-2. A history given notes that Amanda had a slight fever the day after her second DPT. Med. recs. at Ex. 5-14. There was no local tenderness at the vaccine site. Id.

The medical record from this hospitalization further reflects that the Bradbarys first noticed Amanda's infantile spasms the day after her second DPT. Id. These spasms presented as sudden brief jerking of her arms. Id. Her arms extended at the elbows and out to the side of her head. Id. She also had head flexion and stiffening of her legs with flexion at the hips and extension at the knees. Id. She had two episodes of spasms during that day. Id. Each episode consisted of two to three spasms separated by about ten seconds. Id.

These episodes primarily occurred in the evening during the first week after their onset. Id. Throughout the second week, however, the episodes began to occur in the mornings. Id. These episodes generally consisted of three to four spasms. Id. The record notes that Amanda's spasms had since increased in frequency and number, occurring at any time during the day and even when Amanda was asleep. Id. After the spasms, Amanda was drowsy. Id. Although the spasms initially appeared to be related to noise, this no longer seemed plausible because they now occurred when Amanda was asleep in a quiet environment. Id.

The record continues to note that Amanda, who formerly was a very good baby, became extremely irritable, having crying spells throughout the day which were unrelated to her spasms. Id. She no longer

slept through the night. Id.

By June 3, 1983, Amanda had not had any infantile spasms in approximately six weeks. Med. recs. at Ex. 7-9. On examination, she was alert and active. Id.

Amanda received an MMR vaccination on Thursday, June 9, 1983. Med. recs. at Ex. 4-1.

On June 13, 1983, Mrs. Bradbary called Dr. Sandra Deckman. Med. recs. at Ex. 7-10. Mrs. Bradbary stated that, prior to the MMR, Amanda had occasional trembling spells during which she appeared scared. ⁽⁴⁾ Id. After the MMR, however, the spells increased. Id. Mrs. Bradbary stated that Amanda had five spells during the morning of June 13, 1983. Id. Mrs. Bradbary further noted that when she would talk to Amanda, the spells would go away. Id.

A medical record dated August 12, 1983 contains a history from Mrs. Bradbary that Amanda's seizures were exacerbated after the MMR vaccination. Med. recs. at Ex. 7-11. Until August 4, 1983, Amanda was having nine to ten episodes per day; however, she had not had any seizures during the week prior to this visit. Id.

An MRI scan performed when Amanda was thirteen years old shows that she has 19 areas of cortical tubers involving her brain. R. Ex. Q. Dr. Zimmerman, who reviewed the scans, commented that the MRI examination was incomplete, believing that numerous images were missing from the three sheets provided. Id.

Medical Expert Reports

Petitioners did not submit a medical expert report in support of their allegation of significant aggravation, preferring to rely on the statutory presumption. They did, however, file an affidavit from Dr. Mary Miles stating that DPT contributed to Amanda's seizures based on the temporal relationship between her DPT and her seizures. Med. recs. at Ex. 3-158 to 3-159.

Respondent submitted two reports from Dr. Mary Anne Guggenheim, a pediatric neurologist. R. Exs. T & Z.

In Dr. Guggenheim's first report, she opines that "Amanda's neurodevelopmental problems are all consistent with tuberous sclerosis, and that her condition today would be the same if she had never received the two immunizations in question." R. Ex. T, p. 1.

In summarizing Amanda's course, Dr. Guggenheim notes that, within a few days of ACTH treatment, Amanda was free of clinical seizure activity until late September when her seizures returned. R. Ex. T, p. 2. By February, her seizures had diminished in frequency. ⁽⁵⁾ Id. In mid-April, her seizures had completely disappeared. Id. Amanda did not have any seizure activity until early June when Mrs. Bradbary noted in her diary that Amanda was having "quivering spells." ⁽⁶⁾ Id.

Dr. Guggenheim refers to these "quivering spells" as a variant of tonic seizures which eventually emerged into more typical complex partial seizures. Id. Dr. Guggenheim found no consistent relationship between Amanda's seizure frequency, type, and dose of medication, or other factors. Id. She further noted that all EEGs subsequent to her initial EEG have been normal. Id.

Dr. Guggenheim's opinion set forth numerous medical facts which led to her conclusions. She noted that infantile spasms are the most common type of initial seizure in a person with TS. R. Ex. T, p. 3. These seizures occur between three and eight months of age. Id. Typically, when infantile spasms disappear

after one year of age, other types of seizures will subsequently develop which may or may not be controlled by anti-convulsants. Id. Dr. Guggenheim further noted:

"The only relationship between MMR immunizations and childhood seizures that has been established is the development of fever, commonly seven to twelve days following immunization and the occurrence of a febrile seizure."

Id.

Applying these facts to the instant case, Dr. Guggenheim stated that Amanda's initial seizures were infantile spasms. R. Ex. T, p. 3. She opined that the course of Amanda's infantile spasms was quite typical in that her infantile spasms disappeared during her second year of life, being replaced by a different type of seizure. Id. The new type of seizure that she experienced began prior to her MMR during the first week of June 1983. Id. Finally, Dr. Guggenheim noted that Amanda has nineteen cortical tubers which "statistically correlates with a high degree of probability that her particular TS brain abnormalities would result in seizures and retardation." Id.

To answer the undersigned's questions about Amanda's post-DPT symptoms, Dr. Guggenheim provided a supplemental report. R. Ex. Z. In this report, Dr. Guggenheim opined that Amanda's post- DPT symptomatology did not evidence a severe inflammatory reaction to DPT. R. Ex. Z, p. 2. Dr. Guggenheim concluded that Amanda had a slight fever the day after her DPT "without any local or other generalized evidence of a severe inflammatory reaction." Id.

Although Amanda became more irritable, had increased crying for no apparent reason, and was hard to comfort during the two weeks after her vaccination, her development remained normal. Id. In Dr. Guggenheim's opinion, these symptoms can be attributed to the course of the infantile spasms themselves rather than Amanda's vaccination. Id. She stated that:

Babies who develop infantile spasms often are increasingly irritable as the spasms become more frequent and complex. . . Over the initial onset of the infantile spasms, their general demeanor will often change from a calm happy infant to one who is fussy and irritable. They also may become more drowsy and depart from their unusual sleep patterns.

Id.

Dr. Guggenheim further noted that Amanda's slight fever the day after DPT was not unusual. Id. Amanda did not exhibit any symptoms indicative of acute encephalopathy. Id. Her increased irritability was part of the natural history of her infantile spasms. Id.

Discussion **Reaction to DPT**

The Vaccine Act affords petitioners 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.⁽⁷⁾ If any of the various injuries in this Table occur 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.⁽⁸⁾

Petitioners rely upon the on-Table onset of Amanda's seizures post-DPT as proof that DPT caused her

seizures. The plain language of the statute clearly affords petitioners this presumption. However, respondent may rebut this presumption by showing that TS was the cause-in-fact of Amanda's onset of seizures. As this court discussed at length in its Omnibus TS Decision, when the primary malady is the onset of a seizure disorder, and the vaccinee manifests few if any symptoms that a doctor would ascribe to the DPT vaccine, respondent will have met its burden of showing that TS is the factor unrelated to the DPT vaccine that caused in fact the vaccinee's seizures. Barnes, supra, at *32-33. This still would not answer the issue of whether or not the seizures were a significant aggravation of the TS, but if respondent proves that the TS caused the seizures, that question is moot.

Dr. Guggenheim was the only doctor to interpret Amanda's post-DPT symptoms in light of the question of whether or not TS was the cause-in-fact of Amanda's seizure disorder. Dr. Guggenheim opined that Amanda's slight fever post-vaccination was due to the vaccine. However, all her other symptoms, i.e., the infantile spasms, crying, fretfulness, change in demeanor over weeks, were a consequence of her TS.

Without medical evidence to rebut Dr. Guggenheim's analysis in light of the evidentiary material produced both in the Omnibus TS hearing and in the instant case, petitioners cannot prevail on a claim that DPT significantly aggravated Amanda's TS.

Significant Aggravation Post-MMR

Congress defined "significant aggravation" as "any change for the worse in a preexisting condition which results in **markedly greater disability, pain, or illness accompanied by substantial deterioration of health** [emphasis added]." 42 U.S.C. § 300aa-33(4). Thus, in order for this court to hold that MMR significantly aggravated Amanda's seizure disorder, it must find that Amanda experienced greater disability, pain, or illness accompanied by a substantial deterioration of health within Table time of the vaccination.

Legislative history provides insight into Congress' interpretation of "significant aggravation:"

The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16, reprinted in U.S.C.C.A.N. 6344, 6356-57. Apparently, Congress did not intend compensation for a slight increase in seizure frequency, i.e., from once per month to once every three and a half weeks. Rather, Congress intended compensation for a serious deterioration or a marked increase in seizure frequency, i.e., from once per month to once per day.

The Act indicates that onset of an on-Table significant aggravation post-MMR must occur within fifteen days of vaccination. 42 U.S.C. § 300aa-14(a)(II).

Mrs. Bradbary's diary reflects that the onset of Amanda's unusual quivering occurred before her MMR vaccination. The medical records show that the quivering varied over time and eventually disappeared temporarily. Dr. Guggenheim analyzed this data and concluded that it was the normal course of TS for infantile spasms to disappear after one year, and then subsequently resume as another type of seizure. This is what happened to Amanda.

Although Mrs. Bradbary gave a history that Amanda's seizures were exacerbated by the MMR, this is

difficult to square with the fact that her diary records the recurrence of Amanda's new type of seizure prior to the administration of the MMR vaccine. Moreover, the diminution of Amanda's quivering spells over the few days after Mrs. Bradbary took Amanda to the doctor suggest that this is hardly a significant aggravation of TS. There does not seem to be any medical relationship between the MMR and the quivering spells which began before the vaccination and continued for a time after it, with a waxing and waning course. Respondent has rebutted the presumption of causation.

Without submission of medical evidence to impeach respondent's evidence, petitioners will not prevail on the issue of whether MMR significantly aggravated Amanda's TS.

Conclusion

The court will hold a telephone status conference in the next few weeks to determine if petitioners intend to submit expert reports that will impeach respondent's evidence. If

petitioners do not intend to submit such reports, the court will dismiss this case.

IT IS SO ORDERED.

DATED: _____ Laura D. Millman

Special Master

1. The medical records indicate that Amanda had a slight fever post-DPT. Med. recs. at Ex. 5-2. Mrs. Bradbary's affidavit indicates Amanda cried excessively and was very fretful. Ex. 17-2.
2. This statement is erroneous because Amanda actually received her vaccination five days before the visit.
3. Mrs. Bradbary did note, however, that Amanda had a slight fever on July 17, 1982. Med. recs. at Ex. 5-15.
4. These spells, which generally lasted for a few seconds, did not involve any jerking. Med. recs. at Ex. 7-10.
5. This diminution was unrelated to anti-convulsants.
6. Mrs. Bradbary's diary entry notes: "June 1, 1983 thru June 8, 1993. Amanda has had no seizures for this week's time, but she has had several spells where she seemed real nervous and quivers all over." Med. recs. at Ex. 15-44.

In an entry dated June 9, 1983, Mrs. Bradbary mentions that Amanda received her MMR vaccination on June 9, 1983. Med. recs. at Ex. 15-45. She states that Amanda "has been quivering quite a bit since [the MMR vaccination]." Id.

On June 10, 1983, Mrs. Bradbary notes that Amanda had another quivering spell. Id. She recorded several spells of quivering for June 11 through June 14, 1983 as well.

Mrs. Bradbary brought Amanda to see Dr. Goddard on June 15, 1983 because of her eyes. Id. Dr. Goddard told her that there was nerve damage to the muscle which controls eye movement. Id.

On June 16, 1983, Mrs. Bradbary noted that Amanda's quivering spells were slowing down. Med. recs. at Ex. 15-46. An entry from June 17, 1983 reflects that Amanda was not having as many quivering spells. Id. On June 18, 1983, Mrs. Bradbary stated that Amanda "very fretful" but was also teething. Id. On June 19, 1983, she noted that Amanda seemed to feel better. Id. An entry from June 20, 1983, reflects that Amanda was enjoying pulling up and was not having quivering spells. Id.

On June 21, 1983, Mrs. Bradbary noted that Amanda was having one to two quivering spells per day. Id. From June 22 to 30, 1983, Amanda was having one quivering spell a day. Id. However, she was still able to pull herself up and transfer objects from hand to hand. Med. recs. at Ex. 15-46 to 15-47.

7. 42 U.S.C. § 300aa-14(a).

8. 42 U.S.C § 13(a)(1)(B).