In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 06-0753V
Filed: September 25, 2012
(Not to be published)

TARA MILLER and BRUCE MILLER, as parents and next friends of William R. Miller, a minor, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES Respondent.	Petitioners' Motion for a Ruling on the Record; Insufficient Proof of Causation; Vaccine Act Entitlement; Denial Without Hearing

DECISION[1]

HASTINGS, *Special Master*

This is an action seeking an award under the National Vaccine Injury Compensation Program ("the Program")[2] on account of an injury to the Petitioners' son, William R. Miller. For the reasons stated below, I conclude that the Petitioners are not entitled to such an award.

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[1]Because this document contains a reasoned explanation for my action in this case, I intend to post this order on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, as provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this entire document will be available to the public. *Id.*

[2] The applicable statutory provisions governing the National Vaccine Injury Compensation Program are found in 42 U.S.C. § 300-10 *et seq*. (2006 ed.). Hereinafter, for ease of citation, all "U.S.C." references will be to 42 U.S.C. (2006 ed.).

I
THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program ("Program"), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table" ("Table"), originally established by statute at §300aa-14(a) and later modified, occurred within the applicable time period after vaccination, as prescribed in the Table, then the injury may be *presumed* to qualify for compensation. §300aa-13(a)(1); §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."

As relevant here, one vaccination listed in the Vaccine Table is the "MMR" inoculation (*i.e.*, measles, mumps, and rubella), and one Table Injury listed for that vaccination is "encephalopathy (or encephalitis)." 42 C.F.R. § 100.3 (2011 ed.).[3] The Table further provides that in order for the vaccine recipient to qualify for an award, such injury must have first manifested within a period of 5 to 15 days following the vaccination.

Another vaccination listed in the Table is the DTaP (diphtheria, tetanus, acellular pertussis) inoculation, and one Table Injury listed for that vaccination is "encephalopathy (or encephalitis)." The Table further provides that in order for the vaccine recipient to qualify for an award, the first symptoms of such an injury must have occurred during the 72-hour period following administration of the vaccine.

Alternatively, if no Table Injury can be shown, the petitioner may gain an award by instead showing that the vaccine recipient's injury was *actually caused* by the vaccination in question. 42 U.S.C. §300aa-13(a)(1); §300aa-11(c)(1)(C)(ii).

II
BACKGROUND

A. Facts

William was born on July 19, 2002. (Ex. 1 at 1.) During the first fifteen months of his life, he received the recommended pediatric immunizations, and routine well-child examinations in which no developmental abnormalities were noted. (Ex. 5 at 4-27; Ex. 6 at 1-2.) However, William did receive treatments for several instances of otitis media and upper respiratory infections. (Ex. 5 at 13-24.)

During a well-child examination on November 10, 2003, William's pediatrician, Dr. Weining Hu, noted no abnormalities of growth or development. At that time, William received his fourth DTaP and his first MMR vaccinations. (Ex. 5 at 28; Ex. 6 at 1.) Eight days later, on

[3] The original Table was set forth at 42 U.S.C. § 300aa-14(a), and periodically revised in the following years. The 2011 edition of the Table incorporates the relevant parts of the administrative revision that occurred in 1997. That revision is applicable to Program cases that were filed after March 24, 1997, and thus is applicable in this case. *See* 62 Fed. Reg. 7685, 7688-90 (1997); 42 U.S.C. § 100.3(c)(1). Hereinafter, for ease of reference, all "C.F.R." references will be to 42 C.F.R. (2011 ed.)

November 18, 2003, he developed a fever that his mother treated with Motrin. After several hours, he suffered a seizure lasting approximately three minutes. (Ex. 7 at 2.) The ambulance technicians who responded to Tara Miller's emergency telephone call noted that, when they arrived, William "was responsive but still postictal," and his axillary temperature was 101.8ºF. (*Id.*) Dr. Stephen Jameson, who later examined William at the St. Cloud Hospital emergency department, noted that he appeared "perfectly fine," but registered a rectal temperature of 102.9ºF. His diagnoses were "[a]cute seizure" and "[a]cute febrile illness - likely viral etiology." (Ex. 4 at 68-9.) William was discharged from the hospital the following morning with no fever or any sign of further seizure activity. Dr. Jameson recorded that at the time of discharge, William was acting playful, walking about the room, and smiling. (*Id.*)

On November 19, Tara Miller contacted Dr. Hu to report that William was "doing well," and to request further instructions. (Ex. 5, at 28.) When Dr. Hu examined William on November 20, 2003, she noted that he had been afebrile for more than 36 hours, with no evidence of seizures, and he was active and playful. She administered an influenza vaccination. (Ex. 5 at 30-31.) No further irregularities were noted over the next three weeks, but on December 12, 2003, William suffered two one-minute episodes of unresponsiveness at home. He was taken by ambulance to the emergency department at St. Cloud Hospital, where Dr. Michael Severson recorded that William was afebrile and had "no history of fever today." (Ex. 4 at 85-6.) Two more episodes of altered mental status occurred while he was in the emergency department, so he was admitted to the hospital for further evaluation and treatment with Dilantin. He was discharged the following day with a prescription for Dilantin, twice daily. (*Id*. at 83.)

William suffered a recurrence on December 31, 2003, involving three episodes of staring and a one-minute generalized tonic-clonic seizure followed by significant lethargy. (Ex. 4 at 133-45.) He had another brief episode of staring while hospitalized, but his electroencephalogram ("EEG") produced a normal result. (Ex. 4 at 133). William's Dilantin dosage was increased and he was discharged on January 1, 2004, with a diagnosis of seizure disorder. (*Id.*) He returned to St. Cloud Hospital on January 3, 2004, because of a febrile seizure that lasted "a couple of minutes." His temperature was 104ºF. Once again, the Dilantin dosage was adjusted and William was discharged. (Ex. 4 at 203-04.)

Dr. Jhablall Balmakund, a pediatric neurologist, examined William on January 8 and February 6, 2004. Another EEG and a magnetic resonance imaging test were performed, along with screening with a Denver Developmental Scale. Dr. Balmakund changed William's anti-seizure medication to Tegretol. In addition to seizures, Dr. Balmakund diagnosed possible pervasive developmental disorder and attention deficit/hyperactive disorder. (Ex. 8 at 1-5.) William continued to suffer frequent seizures in the coming months, and on August 10, 2004, he received diagnoses of intractable epilepsy and developmental delay from Dr. Michael Frost, a specialist in epilepsy. (Ex. 10 at 29-31.) A neuropsychological evaluation performed on March 18, 2005, resulted in diagnoses of autistic disorder, global developmental delays, mixed expressive-receptive language disorder, and seizure disorder. (Ex.12 at 6.) Another neuropsychological examination, performed on August 7, 2006, placed William within the "Severely Autistic" range. (Ex. 10, pp. 49-52.)

B. Procedural History

On November 6, 2006, the Petitioners filed a petition for compensation in the National Vaccine Injury Compensation Program on behalf of their son William. That petition alleged that

William "suffered a 'table injury' known as encephalitis," due to the administration of DTaP and MMR vaccinations that were administered to him on November 10, 2003. (Petition, page 1). In the alternative, they plead that William's injury was caused-in-fact by the vaccinations that he received on that day. (Pet. at ¶ 15).

Petitioners filed extensive medical records and affidavits along with their petition. (Exs. 1-17.) On November 13, 2006, Petitioners filed an additional exhibit, the affidavit and report of Dr. Leon Charash. (Ex. 16b.) By oral motion, Petitioners made a request that their case be transferred to the Omnibus Autism Proceeding ("OAP"), and this case was then transferred to the OAP and reassigned to me, on February 28, 2007.

After reviewing the medical records, respondent filed a "Statement Regarding Jurisdiction and Appropriateness of Proceeding" within the OAP, in combination with respondent's "Rule 4(c) Report," on May 12, 2009. In that document, respondent acknowledged that this case was timely filed and assigned appropriately to the OAP, but contended that the evidence in the record was insufficient to prove that William had suffered a vaccine-related injury.

On January 28, 2011, I issued on Order requiring Petitioners to indicate whether they wished to proceed with this claim. In response to that Order, petitioners filed a "Motion for a Ruling on the Record," on March 14, 2011. Their Motion placed specific emphasis (see page 3) on the affidavits of the Petitioners (Exs. 14 and 15), and the written opinion of their expert, Dr. Leon Charash. (Ex. 1b.) On July 19, 2011, I issued an Order allowing respondent the opportunity to present the opinion of respondent's expert. Respondent's response, including an expert report by Dr. Catherine M. Shaer (Ex. A), was filed on September 9, 2011.

C. Issues for decision

The petition ("Pet.") in this case alleges that William suffered the Table Injury known as "encephalitis," due to the administration of DTaP and MMR vaccinations that he received on November 10, 2003. (Pet. at 1.) In the alternative, Petitioners plead that William's injury was caused-in-fact by the vaccinations that he received. (Pet. at ¶ 15.) Thus, the issues to be decided are whether William suffered the Table Injury of encephalitis, and/or had injuries that were actually caused by either his DTaP or his MMR vaccination.

III
DISCUSSION

In order to qualify for an award under the Program, Petitioners must prove either: 1) that William suffered a Table Injury--*i.e.*, an injury falling within the Vaccine Injury Table--corresponding to one of his vaccinations, or 2) that he suffered an injury that was actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Petitioners offer both rationales, contending that either one or the other is applicable.

A. Table Injury issue

In order to establish the Table Injury known as "encephalopathy (or encephalitis)," the Petitioners would need to show that William manifested the first signs or symptoms of an

encephalopathy within 72 hours of his DTaP vaccination, or within 5 to 15 days following his MMR vaccination. 42 C.F.R. § 100.3(a)(II)(B) and (III)(B). Such a claim must be substantiated by medical records or a medical opinion, and cannot be based merely on the claims of a petitioner alone. 42 U.S.C. § 300aa-13(a)(1).

Here, Petitioners alleged in their petition that William suffered the Table Injury of "encephalitis," due to the administration of DTaP and MMR vaccinations on November 10, 2003. (Pet. at 1.) In support of this allegation, Petitioners offer the affidavit of Dr. Leon Charash, a pediatric neurologist who reviewed William's medical records. Dr. Charash appears to have narrowed the scope of the allegation to just the MMR. He stated:

> The Table describing vaccine injuries indicates that MMR can produce an encephalopathy. Encephalopathy of course is defined as brain damage. Seizures and continuing seizure activity is a manifestation of an encephalopathy. With reasonable certainty, this child did experience that. William has obviously been left with a seizure disorder and disturbances in affect which have led to "autism" or "autistic-like" syndrome… It is my opinion that these flow from his post vaccinal reaction.

Ex. 16(b) at 4. Thus, Petitioners' expert has asserted that William suffered a Table Injury, an "encephalopathy" that was caused by the MMR vaccination.

A Table Injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. The Qualifications and Aids to Interpretation ["QAI"] section of the Table[4] adds, in essence, definitions for the terms used in the Table. One of the conditions specified for compensation after receipt of a pertussis-containing vaccine is "encephalopathy (or encephalitis)," if suffered within 72 hours after administration of the vaccine. Likewise, if an "encephalopathy (or encephalitis)" occurs within 5 to 15 days after the administration of an MMR vaccination, that injury would be compensable. The definition of such an encephalopathy is set forth in the QAI section.

> (2) *Encephalopathy.* For purposes of [the Vaccine Injury Table], a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.
>
> (i) An *acute encephalopathy* is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
>
> (A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.
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> * * * * *

[4] The Vaccine Injury Table must be interpreted by reference to the QAI's definition of key terms. *Althen v. HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed.Cir. 2003).

(D) 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 (*see* paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(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).

(E) 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. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3.[5]

In William's case, it is clear that no "encephalopathy," within the bounds of the above definition, occurred within 72 hours after his DTaP vaccination on November 10, 2003. There is no indication in the medical records of any type of altered mental status for the first seven days after the vaccine was administered. Tara Miller states in her affidavit that due to the advice from the vaccine administrator, she had concentrated on looking for potential problems during this time period. (Ex. 15 at 2.) She acknowledges that "[i]n the days following the vaccination, William showed few symptoms of any problems, but I did notice that he became more irritable during that week." (*Id*.) However, paragraph 2(E) of the Table above makes clear that "irritability" does *not* justify a diagnosis of encephalopathy. Therefore, according to the applicable regulation, the DTaP vaccination cannot be implicated presumptively as the cause of William's subsequent condition.

The allegation with regard to the MMR is more complicated, since William suffered his first seizure on the eighth day following his vaccination. The Vaccine Injury Table indicates that an encephalopathy that occurs within 5 to 15 days after an MMR vaccination may be presumed to have been caused by that vaccination. Furthermore, petitioners' expert Dr. Charash opined that the MMR actually *did* cause an encephalopathy, eight days after William received the vaccine. Dr. Charash' affidavit states that "seizures and continuing seizure activity is a manifestation of an encephalopathy." (Ex. 16(b) at 4.) Yet the applicable regulation is unequivocal in stating that "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E). Thus, the occurrence of William's first seizure, eight days after his

[5] The 2011 edition incorporates the administrative revision of the Table that was promulgated in 1997, which is applicable to Program cases that were filed after March 24, 1997, and thus is applicable here. *See* 62 Fed. Reg. 7685, 7688 (1997)

MMR vaccination, *cannot* be construed as evidence of an encephalopathy unless some *other* evidence of an encephalopathy exists.

The pertinent regulation identifies the type of supportive evidence that would be required, as follows: "children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their **significantly decreased level of consciousness persists beyond 24 hours** and cannot be attributed to a postictal state (seizure) or medication." 42 C.F.R. §100.3(b)(2)(i)(A)(emphasis added). It must be noted that on November 19, 2003, when William was discharged from the hospital on the day after his seizure, Dr. Jameson noted that he was acting playful, walking about the room, and smiling. (Ex. 4 at 68-9.) And Dr. Jameson did not record any evidence of a decreased level of consciousness at that time. Later, on that same day, Tara Miller reported to Dr. Hu that William was "doing well." (Ex. 5 at 28.) Dr. Hu examined William on the next day, November 20, 2003, and noted that he had been afebrile for more than 36 hours, showed no sign of seizures, and was active and playful. (Ex. 5 at 30.) According to these notes William did *not* have a decreased level of consciousness during the day after his seizure. He was examined twice by qualified medical personnel within thirty-six hours of the seizure event, and neither doctor noted any altered mental status comparable to what is described in the statutory definition of an acute encephalopathy.

It is significant that petitioner's expert, Dr. Charash, in his affidavit, explicitly utilizes a definition of "encephalopathy" that is *different* from the definition of an "encephalopathy" as set forth in the Qualifications and Aids to Interpretation of the Vaccine Injury Table. He states that "encephalopathy of course is defined as brain damage." (Ex. 16(b) at 4.) He does not mention the more specific definition of "encephalopathy" provided in the controlling regulation. Petitioners elected to request a ruling on the record without a hearing or any further testimony from Dr. Charash. Further, in weighing the facts of this case, I am also required to consider the opinion of respondent's expert, Dr. Catherine Shaer, who examined the same medical records upon which Dr. Charash relied. On September 9, 2011, respondent filed the Declaration of Dr. Shaer, which states that—

> the record evidence fails to establish that William experienced either an acute or a chronic encephalopathy following [his first] seizure. Specifically, there is no evidence that William experienced a significantly decreased level of consciousness for 24 hours following his seizure on November 18, 2003, and there is no evidence that William experienced a persistent change in neurologic status following his seizure that lasted for at least six months.

(Ex. A at ¶10.) Thus, Dr. Shaer concludes that William did *not* suffer a Table Injury.[6]

When I analyze the available medical records and compare them to the Table Injury definition set forth above, it seems clear that the opinion of respondent's witness, Dr. Shaer, is a more reliable interpretation of William's symptoms. I conclude that William did not experience

[6] While the Table includes the Table Injury of "encephalopathy (or encephalitis)," the Table provides a definition only of "encephalopathy," not of "encephalitis". In this case, however, that lack of a separate definition of "encephalitis" is not important because Dr. Charash's letter alleges only an "encephalopathy," not "encephalitis."

an acute encephalopathy, as defined in the applicable regulations, in the days following his vaccination of November 18, 2003. William did not have a Table Injury.

B. Causation-In-Fact

The legal standard to establish a *prima facie* case of actual causation of a injury by a vaccine requires that petitioners must present "1) a medical theory causally connecting the vaccination and the injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of a proximal temporal relationship between vaccination and injury." *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed.Cir. 2005). Petitioner's expert, Dr. Charash, has made no effort to present such a theory or to explain cause and effect. His affidavit offers only a conclusion, with no explanation. His affidavit does not satisfy Petitioners' burden of proving causation-in-fact.[7]

IV
CONCLUSION

It is, of course, tragic that William suffers from significant neurological problems. He and his family are certainly deserving of sympathy for those difficulties. However, under the law I can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or competent medical opinion to be vaccine-caused. No such proof exists in the record before me. Accordingly, it is clear from the record in this case that Petitioners have not demonstrated either that William suffered a Table Injury or that his condition was "actually caused" by a vaccination. Therefore, I have no choice but to hereby DENY this claim. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[7] Moreover, the causation opinion of Dr. Charash was contradicted by the opinion of Dr. Shaer, and Petitioners have chosen *not* to present Dr. Charash for oral argument.