

OFFICE OF SPECIAL MASTERS

Not for Publication

June 30, 2005

No. 02-554V

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TAYLOR MARIE CAMPBELL, a minor, by \*  
her parents and natural guardians, LEE and \*  
MANDY CAMPBELL, \*

Petitioners, \*

v. \*

SECRETARY OF THE DEPARTMENT OF \*  
HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Clifford J. Shoemaker, Vienna, VA, for petitioners.  
Julia W. McInerney, Washington, DC, for respondent.

**MILLMAN, Special Master**

**DECISION**<sup>1</sup>

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioners filed a petition in this case on May 28, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that acellular DPT, administered to Taylor Marie Campbell (hereinafter, “Taylor”) on Thursday, May 27, 1999,<sup>2</sup> caused her seizure disorder beginning on Monday, May 31, 1999. Taylor had a fever two days after vaccination, on Saturday, May 29, 1999, but no fever during her first seizure on Monday, May 31, 1999.<sup>3</sup>

The undersigned did not hold a hearing in this case, which is within her discretion. Section 300aa-12(d)(3)(B)(I). Petitioners submitted expert medical reports from Dr. Carlo Tornatore, an adult neurologist. Respondent filed an expert medical report from Dr. Bennett L. Lavenstein, a pediatric neurologist.

### **FACTS**

Taylor was born on March 26, 1999. She had her two-month immunizations, including acellular DPT, on Thursday, May 27, 1999. Med. recs. at Ex. 9, p. 4.

Taylor’s mother, Mrs. Mandy Campbell, brought Taylor to her pediatrician, Dr. Robert J. Benak, of the Dothan Pediatric Clinic, on Tuesday, June 1, 1999, complaining that Taylor had jerking the day before, on Monday, May 31, 1999, and that morning (Tuesday, June 1, 1999). Med. recs. at Ex. 9, p. 5. Mrs. Campbell described the jerking as “all over.” Taylor was alert and looking at her mother while she was jerking, which lasted 10 to 15 minutes. Taylor did not have any change in mental status during the entire episode. Mrs. Campbell said, “She has been eating well with no fever except that she did have fever **about** two days ago [emphasis added].” Med. recs. at Ex. 9, p. 5.

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<sup>2</sup> The petition states, incorrectly, that Taylor received her vaccination on May 29, 1999.

<sup>3</sup> This case was transferred to the undersigned on December 22, 2004.

Dr. Benak doubted that Taylor was seizing because she did not have any change in mental status and was acting very normally, according to Mrs. Campbell. Med. recs. at Ex. 9, p. 5. He asked Mrs. Campbell to videotape an episode for him. (This videotape was submitted as petitioners' exhibit 11.)

In a history she gave to the triage nurse (possibly nurse Singh) at Flowers Hospital Emergency Department on Thursday, June 3, 1999, at 7:20 a.m., when Taylor's grandmother took Taylor to the hospital for a seizure, Mrs. Campbell clarified that Taylor's fever occurred on Saturday (May 29, 1999). Med. recs. at Ex. 3, p. 217. She told the triage nurse that Taylor did well on Sunday. She had shaking episodes on Monday morning and Tuesday morning. *Id.* She also stated that Taylor had had her two-month immunizations on Thursday. *Id.* Mrs. Campbell said Taylor had stiffening and eyes rolling back on Monday morning, May 31, 1999, as well as on Tuesday morning, June 1, 1999. *Id.*

Also, on June 3, 1999, at 9:30 a.m., Mrs. Campbell told Dr. James C. Wiley, who recorded the information in the progress notes, that Taylor had a temperature of 101° on Saturday. Med. recs. at Ex. 3, p. 220. Taylor had a brief stiffening spell on Monday with a second episode at 4:00 a.m. Tuesday. *Id.* She saw Dr. Benak and seemed fine. She did well over the next 48 hours until that day's episode. *Id.* She has a first cousin once removed with epilepsy. *Id.*

On admission to Southeast Alabama Medical Center, Mrs. Campbell told Dr. Wiley, who accompanied Taylor on the transfer from Flowers Hospital to Southeast on June 3, 1999, that Taylor's two-month immunizations preceded her 101° fever by 48 hours. Med. recs. at Ex. 4, pp.

72, 74. In addition, Taylor had mild upper respiratory symptoms over the prior week. Med. recs. at Ex. 4, p. 72.

Dr. William G. Watson, in a consultation dated June 3, 1999, at Southeast Alabama Medical Center, notes that Taylor had a mild fever two days after she received DPT vaccine, but no major fever. Med. recs. at Ex. 4, p. 75. His impression was neonatal seizures of undetermined etiology. *Id.*

On June 4, 1999, the Dothan Pediatric Clinic filled out a VAERS (Vaccine Adverse Event Reporting System) report for Taylor, stating that her adverse event occurred on May 31, 1999 and that she had received her immunizations on May 27, 1999, at 10:30 a.m. Med. recs. at Ex. 10, p. 1.

On June 8, 1999, Taylor returned to Dr. Benak to have her urine checked. She had been recently hospitalized for a new onset of seizure disorder, and she had *Klebsiella pneumoniae*, 50,000 colonies, from a bagged urine. Med. recs. at Ex. 9, p. 7.

Mrs. Campbell told Dr. Leon S. Dure, a pediatric neurologist at the University of Alabama, on August 10, 1999, that Taylor did not have any obvious fever at the time of her first seizure. Med. recs. at Ex. 1, p. 8; same record at Ex. 15, p. 1. Mrs. Campbell told Dr. Dure that Dr. Benak had advised her to videotape the event, which she did. *Id.*

#### **Other Submitted Material**

Mrs. Campbell filed an affidavit, dated January 27, 2003. P. Ex. 7. Mrs. Campbell states that Taylor had a low grade fever and was fussy on the day after she received her May 27<sup>th</sup> vaccinations, i.e., on Friday, May 28<sup>th</sup>. On Sunday, May 30, 1999, at around 5:00 a.m., she woke up and Taylor was making a noise like hiccups, rapid without pausing. She picked Taylor up and

noticed she was jerking slightly and her eyes were twitching. This lasted a couple of minutes. On Monday, May 31, 1999, this happened again, but lasted longer. She called the doctor and took Taylor to see him. Dr. Benak was not sure what had happened and asked her to videotape the event if it happened again. Two days later, Mrs. Campbell took Taylor to her mother's house and went to work. When she got there, there was a message that Taylor had been taken to Flowers Hospital because she had a seizure. She went to the hospital immediately. Taylor seized at Flowers and was transferred to Southeast Alabama Medical Center. Taylor had her last seizure on June 10, 2000. *Id.*

Mr. Campbell, Taylor's father, filed an affidavit, dated January 27, 2003. P. Ex. 8. He does not refer specifically to date of seizure onset or to fever. In the petition, petitioners state, at paragraph 9, that Lee Campbell first noticed a change in Taylor's behavior, including seizures, on May 31, 1999.

Mrs. Campbell filed a supplemental affidavit, dated July 27, 2004. P. Ex. 16. She again states that Taylor had a low grade fever and was fussy on the day after her May 27<sup>th</sup> vaccinations, i.e., on Friday, May 28, 1999. She states that Taylor slept the majority of the day and continued to be lethargic and generally not as alert or as responsive as prior to her vaccinations. This "condition" continued until early Sunday morning, May 30, 1999, when she was awakened by the sound of Taylor having a Tourette's-like syndrome with teeth chattering (Taylor was two months old), rapid eye-blinking, and involuntary movements of her extremities. Although this was the first time Mr. and Mrs. Campbell had seen this, they were concerned that Taylor may have had several similar episodes during the previous nights because they discovered later that most of her seizures occurred late in the evening or in the early morning. *Id.*

Petitioners filed a medical expert report from Dr. Carlo Tornatore, an adult neurologist, dated August 5, 2003. P. Ex. 12. He states that Taylor had a fever approximately 48 hours following vaccination followed thereafter by seizures. (The last page of the unpaginated exhibit 12.) He states that fever is a well-known sequela of vaccination in that time frame. He also states that there is a clear temporal relationship between the vaccination and the fever and seizures. Furthermore, he states that there is a well-known biological mechanism associating acellular pertussis vaccine and convulsive disorders, citing references below in his report which he does not actually give. *Id.*

Petitioners filed a supplemental report from Dr. Tornatore, dated June 3, 2004, with three articles. P. Ex. 13. He states at page 4 of his supplemental report that Taylor “developed a febrile syndrome concurrent with the onset of her convulsions.”

Petitioners filed an additional article, “Neurological adverse events associated with vaccination,” by S. Piyasirisilp and T. Hemachudha, 15 *Current Opinion in Neurology* 333-38 (2000), which states, at p. 335, “that DTP vaccination was significantly associated with febrile seizures only on the day of vaccination.... Neither DTP nor MMR was associated with an increased risk for nonfebrile seizures.”

Respondent filed an expert report from Dr. Bennett L. Lavenstein, a pediatric neurologist, as Exhibit A. He states that the onset of Taylor’s seizures was on May 31, 1999 when Taylor, appearing alert and without any change in mental status, began jerking-like movements, lasting 10-15 minutes. This occurred without fever. Dr. Lavenstein states, at page 3 of his report, that Taylor was not encephalopathic within 72 hours of receiving vaccination. She did not have a

decreased level of consciousness or any events lasting more than 24 hours. Dr. Lavenstein does not associate afebrile seizures with vaccination. *Id.*

## DISCUSSION

Petitioners do not allege a Table injury. Therefore, they must prove their allegations by causation in fact. To satisfy their burden of proving causation in fact, petitioners must offer "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." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioners must not only show that but for the vaccine, Taylor would not have had seizures, but also that the vaccine was a substantial factor in bringing about her seizures. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

For the purpose of clarity, the undersigned breaks down the events as follows:

<u>Thursday</u>	<u>Saturday</u>	<u>Monday</u>	<u>Tuesday</u>	<u>Thursday</u>
5/27/99	5/29/99	5/31/99	6/1/99	6/3/99
DPaT	fever	seizure	seizure	seizure

The issue then is whether or not Taylor had a febrile seizure on Monday, May 31, 1999 (an affirmative would mean that petitioners prevail) or an afebrile seizure on that date (an

affirmative would mean that petitioners would not prevail). As stated in one of the articles that petitioners submitted (P. Ex. 17), “Neurological adverse events associated with vaccination,” by S. Piyasirisilp and T. Hemachudha, 15 *Curr Opin Neurol* 333-38, at 335 (2002):

DTP vaccination was significantly associated with febrile seizure only on the day of vaccination. ... Neither DTP nor MMR was associated with an increased risk for nonfebrile seizures.”

Dr. Carlo Tornatore, petitioners’ expert neurologist, in his supplemental report, dated June 3, 2004 (P. Ex. 13), states that Taylor developed a febrile syndrome concurrent with the onset of her convulsions. “Concurrent” means “[h]appening at the same time as something else.”<sup>4</sup> Clearly, as Mrs. Campbell told numerous medical recorders in the contemporaneous histories and even two months later, Taylor’s first seizure did not occur with fever.

Dr. Bennett L. Lavenstein, respondent’s expert pediatric neurologist, in his report dated October 20, 2004 (respondent’s Ex. A), states that Taylor’s afebrile seizures are not related to her vaccination and she did not have encephalopathic signs. Because Taylor’s mental status did not change while she was seizing, her pediatrician Dr. Benak even doubted that she had had seizures when he saw her June 1, 1999, which was why he requested Mrs. Campbell to videotape the next episode, if it occurred.

The medical records, replete with histories that Mrs. Campbell gave, establish that Taylor’s initial seizure occurred on Monday, May 31, 1999, and that she did not have a fever at that time. Dr. Tornatore’s statement about “concurrence” of fever and seizures is erroneous.

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<sup>4</sup> [www.dictionary.com](http://www.dictionary.com).



Mrs. Campbell told three different people on June 3, 1999 (the triage nurse, Dr. Wiley, and Dr. Watson) that Taylor had a fever on Saturday. She informed the triage nurse that Taylor had a fever on Saturday, but had been fine on Sunday. She specifically told Dr. Wiley that Taylor's fever on Saturday was 101°. She must have informed Dr. Watson of the degree of temperature on Saturday in order for him to conclude that it was a mild, not a major, temperature.

The only earlier information she gave about the timing of Taylor's fever was on June 1, 1999, when she told Dr. Benak that Taylor's fever had been about two days earlier.

The undersigned recognizes how traumatic the initial events of Taylor's seizing were, having watched the videotape that Mrs. Campbell made after Dr. Benak on June 1, 1999 requested she do so because he doubted Taylor was seizing since her mental status did not change during the event. In that videotape, while Taylor is seizing, Mrs. Campbell, holding Taylor in her arms, is weeping and saying, over and over, "Taylor, I love you." Clearly, when she visited Dr. Benak on June 1, 1999, having witnessed these terrible events that morning, June 1, 1999, at 4:00 a.m., and earlier on Monday, May 31, 1999, she was not likely to forget them or when they occurred. That she was less specific about the timing of Taylor's fever when she saw Dr. Benak on June 1, 1999 is not surprising.

Once Taylor's grandmother brought Taylor to the hospital on June 3, 1999 because she was seizing once more, and Mrs. Campbell joined them at the hospital, she was precise in her history, consistent with what she told Dr. Benak two days before, that the first seizures occurred on Monday, May 31<sup>st</sup>, followed by more seizures on Tuesday, June 1<sup>st</sup>. She also told a nurse and two doctors (Drs. Wiley and Watson) that Taylor had had a fever of 101° on Saturday, May 29, 1999, but had been fine on Sunday, May 30<sup>th</sup>. Moreover, she was clear that Taylor had not had a

fever when she first seized on Monday, May 31<sup>st</sup>, as she informed Dr. Dure two months later.

Weighing the lack of specificity on June 1, 1999 about the day of fever (“about” two days earlier) with the specificity to three different medical personnel on June 3, 1999 about the day of fever (it was Saturday, when she had 101°, but she was fine on Sunday), the undersigned finds that it is more likely than not that Taylor’s fever occurred on Saturday, not on Sunday.

However, in Mrs. Campbell’s first affidavit, written four years after the events at issue in this case, she states that Taylor had a fever the day after her vaccinations, and that she had fever again on Sunday with seizures on Sunday. This is not credible.

In Mrs. Campbell’s supplemental affidavit, written five years after the events at issue in this case, she states that not only did Taylor have a fever the day after her vaccinations, but that she slept the rest of the day and was lethargic and not in her usual mental state until Sunday when she had more fever and had her first seizures. Mrs. Campbell even mentions teeth chattering, although Taylor was just two months old. (In the videotape, Taylor’s gums are not chattering.) This supplemental affidavit is also not credible.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff’d, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records

are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

This has been a traumatic time in Mrs. Campbell's life and, although Taylor now appears to be seizure-free, the Campbells have had a difficult experience. Probably the trauma explains the discrepancy between what Mrs. Campbell told Dr. Benak, the Flowers triage nurse, Dr. Wiley, Dr. Watson, and Dr. Dure, and what she is now telling this court in her two affidavits. Her earliest histories reflect that Taylor's fever occurred 48 hours after her vaccinations, i.e., on Saturday, May 29, 1999, that Taylor was fine on Sunday, that her first seizures occurred on Monday, May 31, 1999 and were not in the context of fever, and that her second seizures occurred early on Tuesday, June 1, 1999, after which she went to see Dr. Benak. Mrs. Campbell's first affidavit recounts some of these events just one day off, starting them on Sunday. That would have made her visit to Dr. Benak on Monday and Taylor's trip to Flowers Hospital on Wednesday. But the medical records do not reflect these dates.

Her supplemental affidavit not only repeats symptoms that do not appear anywhere in the medical records (fever on Friday, May 28, 1999), but amplifies those symptoms with encephalopathic symptomatology that directly contradicts the medical records. (The fact that Taylor's mental status never changed during her seizures is what caused Dr. Benak to doubt that

she indeed had had seizures, yet Mrs. Campbell's supplemental affidavit is replete with Taylor's mental status change.)

The undersigned holds that Taylor's fever occurred on Saturday, May 29, 1999, 48 hours after her vaccinations, and 48 hours before her first seizures on Monday, May 31, 1999. Therefore, Taylor had an onset of afebrile seizures on Monday, May 31, 1999, four days after vaccination.

The undersigned has never accepted that either whole cell or acellular DPT causes afebrile seizures. See Nanez v. Secretary of HHS, No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003); Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, \*11 (Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002); Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The Institute of Medicine (IOM) also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of studies of febrile and afebrile seizures, and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.

Petitioners have not presented a credible prima facie case that DPaT caused Taylor's seizures.

## CONCLUSION

Petitioners' petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.<sup>5</sup>

**IT IS SO ORDERED.**

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DATE

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Laura D. Millman  
Special Master

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<sup>5</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.