

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS  
99-209V  
December 12, 2006  
Not for Publication**

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TRACI PEARL,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

Respondent.

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Hepatitis B vaccine; causation  
in fact; decision on the record

Clifford Shoemaker, Esq., Shoemaker & Associates, Vienna, VA, for petitioner.  
Catharine Reeves, Esq., U.S. Department of Justice, Washington DC, for respondent.

**VOWELL, Special Master**

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

On April 7, 1999, Mr. Roy Pearl timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> [the “Vaccine Act” or “Program”] on behalf of his minor daughter, Traci Pearl [“Traci”],<sup>3</sup> alleging that the hepatitis B vaccinations she received on April 15, 1992, May 27, 1992,

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in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). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

<sup>2</sup> Hereinafter, for ease of citation, all “§” references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

<sup>3</sup> On September 5, 2006, I granted a motion to recaption this case, as Traci had reached the age of majority.

and February 10, 1993 caused “adverse reactions.” Petition, ¶ 2.<sup>4</sup> Simultaneously, petitioner requested a stay of the proceedings to obtain medical records and affidavits, as none of the statutorily required supporting documentation accompanied the petition.<sup>5</sup> On December 22, 1999, at petitioner’s request, proceedings were suspended for 180 days. A status conference in this and numerous other cases involving hepatitis B vaccinations was held on January 21, 2000, to discuss petitioner’s motion to designate a master file for all hepatitis B vaccine cases filed by petitioner’s counsel of record. The motion to designate a master file was denied. Order, dated February 14, 2000. Petitioner filed status reports on February 15, May 16, August 21, and December 12, 2000; and on March 13, 2001, but filed no medical records or other exhibits.

On August 8, 2001, petitioner was authorized to issue subpoenas. That same month, noting that no medical records had been filed in the two and one third years since the petition in this case had been filed, the assigned special master ordered petitioner to file a single medical record by January 18, 2002 or risk dismissal of the case for failure to prosecute. Order, dated August 23, 2001. Nine exhibits containing medical records were filed on December 19, 2001.

After review of Petitioner’s Exhibits 1-9, respondent filed a status report requesting that the petition be amended to allege a specific injury; that petitioner file an affidavit and all medical records generated after October 28, 1998; and that petitioner file an expert report supporting her claim. Respondent’s Status Report, dated March 28, 2002. Petitioner thereafter requested that all action on her case be stayed, and on February 24, 2003, that request was granted. The case remained stayed until it was reassigned to me in February 2006.

On March 27, 2006, I held a recorded joint status conference in numerous cases involving the hepatitis B vaccine, including this one. At that conference, petitioner’s counsel represented that he was having difficulty locating either Traci or her father, who remained the petitioner of record, although Traci had reached the age of majority. Petitioner’s counsel indicated that he wished to transfer this case to another attorney, but would not be able to do so until he located his clients. I vacated all previously granted stays, and ordered counsel to file a status report by May 26, 2006, either indicating that he had located his clients or detailing the efforts he had made to do so. See Order, dated April 3, 2006 (summarizing the events of the March 27 status conference).

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<sup>4</sup> The petition contains two paragraphs numbered “2”. This statement appears in the second of those two numbered paragraphs.

<sup>5</sup> Section 300aa–11(c) of the Vaccine Act requires the petition to be accompanied by certain documentary evidence, including records pertaining to the vaccination and subsequent treatment. See *also*, Vaccine Rule 2(e), RCFC, Appendix B.

In an order dated June 22, 2006, I summarized the events that transpired in this case after the March status conference: Petitioner's counsel filed his May status report one day late, requesting additional time to locate his clients. It was not responsive to my order of April 3, 2006, in that it failed to detail the steps counsel had taken to locate his clients. Being disinclined to grant petitioner's counsel's request for additional time without further explanation, I held another joint recorded status conference on June 9, 2006. Based on the representations made at that status conference, I ordered petitioner's counsel to file a status report by July 26, 2006 indicating what specific efforts he had made to locate his client. I further indicated that I would entertain a request from either party to rule on the record, should counsel be unable to contact his clients by that date. I reminded counsel that late responses to court orders were not acceptable and that requests for extensions of time must be timely filed and contain an explication of counsel's efforts to comply with the deadline.

On July 31, 2006, petitioner's counsel once again filed an untimely request for an enlargement of time, requesting an additional 60 days to locate his clients and detailing his previous efforts to locate them. See Motion for Enlargement of Time, dated July 31, 2006. On August 8, 2006, I ordered petitioner to show cause by September 6, 2006 why this case should not be dismissed for failure to prosecute. In that order, I noted that the July status report was duplicative of the information adduced at the June 9, 2006 status conference regarding efforts to locate Traci and Mr. Pearl.

On September 6, 2006, petitioner's counsel filed a response to the show cause order, indicating that he had contacted Traci Pearl and that she no longer desired to pursue her claim. He requested an additional 30 days to file a statement to that effect and a Motion for Judgment on the Record. I granted that request, giving petitioner until October 13, 2006 to file a motion for judgment on the record. Order, dated September 15, 2006. On October 12, 2006, petitioner's counsel requested an additional 30 days to obtain authorization from his client to file a motion for judgment on the record. In view of the repeated requests for enlargements of time in this case, I conducted a status conference to ascertain the problem in obtaining Traci's authorization. At the status conference, I noted that the last substantive filings in this case were made in December 2001. While the case was stayed for a substantial period of time, all stays were lifted in March 2006. Deadlines established by the court have come and gone, with no substantive action by petitioner. I denied the motion for enlargement and indicated my intention to rule on the record. See Order, dated October 23, 2006. Petitioner has made no further filings.

While a dismissal for failure to comply with court orders might also be appropriate in this case,<sup>6</sup> I have elected to rule on the record as it now stands. Having

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<sup>6</sup> See *Sapharas v. Sec'y, HHS*, 35 Fed. Cl. 503 (1996) (upholding dismissal of a petition for compensation for failure to comply with court order and failure to substantiate the claim); and *Tsekouras v. Sec'y, HHS*, 26 Cl. Ct. 439 (1992), *aff'd*, 991 F.2d 810 (Fed. Cir. 1993) (dismissal for failure to prosecute

considered the entire record, I conclude that petitioner has failed to demonstrate her entitlement to compensation.

In order to prevail under the Program, petitioner must prove either a “Table Injury”<sup>7</sup> or that a vaccine listed on the Table was the cause in fact of an injury. Petitioner did not suffer a Table Injury. While Petitioner’s Exhibit [“Pet. Ex.”] 1, p. 1, establishes that she received the three hepatitis B vaccinations alleged in the petition, no evidence submitted links her vaccinations to any illness, disability, injury, or condition. See § 300aa-11(c)(1)(C)(i).

### **I. Medical History**

Traci was born prematurely with a ventricular septal defect that rapidly progressed to congestive heart disease. She was hospitalized briefly when she was two months old and treated with cardiac medication. Pet. Ex. 1, p. 133. During a visit to a pediatric cardiologist when she was 10 months old, the cardiologist suggested the possibility of metabolic disease. *Id.*, p. 116. By 27 months of age, her cardiac disease appeared stable, but she showed poor growth, a condition that her doctor suggested might have a genetic basis. *Id.*, p. 123. Traci was seen regularly by pediatric cardiologists, who noted that she was asymptomatic, that her cardiac defect appeared to be healing, and that she continued to be small for her age. See, e.g., *id.*, pp. 124-31.

Throughout her first eight years, Traci had frequent upper respiratory and ear infections. *Id.*, pp. 58-83. She had chickenpox when she was 3 ½ years old. *Id.*, p. 60. Her childhood medical records contain a gap from November 1990 (*id.*, p. 52) to Oct 4, 1997 (*id.*, p. 51) when they resume again with the same physician, Dr. Peter Shulman. Other medical records indicate that she was seen by a number of physicians during the gap in the pediatric records, but none appeared to be acting as her primary care provider. See, e.g., Pet. Ex. 1, pp. 172-77; Pet. Ex. 2, pp. 1-15; Pet. Ex. 7, pp. 8-10.

In November 1993, Traci was referred to a rheumatologist for arthralgias. Pet. Ex. 1, pp. 174-78. By history, she had developed red and blue lesions on her arms in May 1991, when she was 8 ½ years old. The lesions disappeared without treatment after a few weeks.

In April 1992, Traci had her first hepatitis B vaccination. The second vaccination occurred in May 1992 and the third in February 1993. Pet. Ex. 1, p. 1. In September 1993, some seven months after her last hepatitis B vaccination, Traci again

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and for ignoring court orders to substantiate the petition).

<sup>7</sup> 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 hepatitis B vaccine is listed on the Table; however petitioner’s medical condition is not an injury specified for compensation for that vaccine.

experienced skin lesions. *Id.*, p. 178. These lesions were painful, a symptom not noted in connection with the May 1991 lesions. Several health care providers suggested that these new lesions might be self-inflicted. See, e.g., Pet. Ex. 9, p. 168, 177-78. A skin biopsy of the lesions found no evidence of inflammatory process. Pet. Ex. 1, p. 2.

In November 1993, Traci also complained of muscle weakness, arthralgias and puffiness in her ankles, and arthralgias in her knees, shoulders, elbows, wrists, and fingers. *Id.*, pp. 178-80. An electromyogram ["EMG"] showed abnormal fibrillation consistent with a diffuse myopathy with denervation signs.<sup>8</sup> *Id.*, p. 181. The records do not reflect subsequent treatment, but by history, the skin rash and weakness improved after a few months and Traci was active in sports until a knee injury in January 1995. *Id.*, pp. 165, 38. She had reconstructive knee surgery in July 1995. *Id.*, pp. 11-13.

In April 1996, Traci's parents took her to see Dr. Virgilio Salanga, a rheumatologist who was treating Traci's mother for systemic lupus erythematosus ["SLE"].<sup>9</sup> The medical history recorded by Dr. Salanga reflected that early in 1996, Traci developed problems with her left knee as well as her right one. She also developed muscle weakness in both legs, which had spread to her shoulder muscles as well. An electromyogram performed on March 29, 1996, demonstrated diffuse myopathy, consistent with inflammatory myopathy. Pet. Ex. 1, pp. 37-42.

Serologic tests were largely normal, with the exception of a slightly elevated anticardiolipin IgG antibody and a positive antinuclear ["ANA"] antibody. Doctor Salanga's clinical impression and plan for treatment included ruling out inflammatory muscle disease, SLE or other autoimmune disorder, and secondary fibromyalgia/myospasm. He requested additional serological testing and a muscle biopsy. *Id.*, pp. 41-42. The muscle biopsy was normal, ruling out a dystrophinopathy (a form of muscular dystrophy). *Id.*, p. 161.

Traci was seen for several other medical problems in 1996, notably eye pain and abdominal pain and vomiting, and she was tested for allergies. Although medical

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<sup>8</sup> An electromyogram is also known as an electromyograph. An electromyogram is used to evaluate patients with muscle weakness. The test monitors the electrical activity of a muscle. *Mosby's Manual of Diagnostic and Laboratory Tests* at 571 (3d ed. 2006). "Fibrillation" is a spontaneous muscle movement that may indicate an underlying nerve or muscle disease. *Id.* "Myopathy" refers to muscle disease. *Dorland's Illustrated Medical Dictionary* ["Dorland's"] at 1215 (30<sup>th</sup> ed. 2003). "Denervation" refers to the removal or absence of a nerve. *Id.* at 488.

<sup>9</sup> Commonly known as "lupus," systemic lupus erythematosus is a chronic inflammatory disease. It is characterized by severe vasculitis, renal problems, and skin and nervous system lesions. Its cause is unknown, but both immune system disorders and viral infections have been suggested as possible causes, and lupus-like reactions to certain drugs have been noted. Diagnosis is based on objective physical examination and laboratory tests for antinuclear antibody in the cerebrospinal fluid and a positive lupus erythematosus cell reaction, as well as on subjective findings. *Mosby's Medical Dictionary* at 1813 (7<sup>th</sup> ed. 2006).

histories reported that she was diagnosed with fibromyalgia while in Texas for treatment in July 1996 (Pet. Ex. 6, pp. 6-7) , there were no medical records filed from that hospital. A rheumatologist she saw after returning from Texas questioned the fibromyalgia diagnosis because of her abnormal EMG tests, noting that such test results were unusual in a patient with fibromyalgia. *Id.*, pp. 7-8.

Allergy testing in August 1996, revealed multiple reactions to environmental allergens and foods, with the most significant reaction to dust mites. *Id.*, p. 5.

The ophthalmologist who examined her for eye pain noted a malar butterfly rash on her face. Pet. Ex. 1, p. 162. A malar rash is a symptom of SLE. *Mosby's Medical Dictionary* at 1813. He recommended an admission to Miami Children's Hospital for neurology and rheumatology consultations. When doctors at Miami Children's Hospital were unable to find a cause for her problems, Traci's father took her to Boston, MA.

During her hospitalization in Boston, the medical history recorded that her abdominal pain began in July 1996,<sup>10</sup> and worsened gradually, resulting in a 20 pound weight loss. By the time of her hospitalization in Boston, she required tube feeding. She was diagnosed with esophagitis, gastritis, and a duodenal ulcer after numerous tests. As the discharge summary indicated:

Adolescent Medicine and Psychiatry felt that there was a strong psychiatric component to her presentation and though she did not meet the criteria for Anorexia Nervosa could have an Eating Disorder, NOS.<sup>11</sup> Rheumatology felt that she probable [sic] did not have fibromyalgia but could have an underlying vasculitis and noted a livedo reticularis rash which might be suggestive of PAN.<sup>12</sup> Dermatology was then consulted and concluded that the rash was not impressive, not consistent with PAN. A team meeting among all the consult service occurred and consensus was that there was medical pathology (some sort of inflammatory GI process) causing her pain but that her pain response was markedly out of proportion to the severity of her disease, that her pain response was attributed primarily to psychiatry.

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<sup>10</sup> Other records attributed the beginning of her abdominal symptoms to medications prescribed for treatment of her fibromyalgia. Pet. Ex. 6, p. 6.

<sup>11</sup> "NOS" is a common medical abbreviation for "Not Otherwise Specified." Neil M. Davis, *Medical Abbreviations* at 252 (2005).

<sup>12</sup> Probably referring to polyarteritis nodosa, a form of systemic vasculitis. *Dorland's* at 1478.

Pet. Ex. 2, p. 1; see *also* Discharge Summary at Pet. Ex. 2, p. 26. She was discharged on Omeprazole, a drug used to treat heartburn or dyspepsia.<sup>13</sup>

In November 1997, Traci was again seen for reflux and abdominal pain, By history, she had been well since April 1997, but began vomiting after meals again in early November. Pet. Ex. 1, p. 147. The gastrointestinal problems persisted, and in April 1998, Traci was hospitalized and underwent a Nissen fundoplication.<sup>14</sup> Pet. Ex. 8, p. 124. The medical records filed in this case end in October 1998, with Traci continuing to have muscle pain and gastric problems. Pet. Ex. 6, p. 3.

The only mention of a relationship between the hepatitis B vaccinations and Traci's medical condition is found at Pet. Ex. 8, p. 26, and indicates that Traci's father believed her medical condition to be related to her vaccinations six years earlier.

## II. Discussion

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion. See § 300aa-13(a)(1). Petitioner has failed to proffer medical records or an expert opinion causally linking her medical condition to her vaccinations.

To satisfy her burden of proving causation in fact, petitioner must "show by preponderant evidence that the vaccination brought about her injury by providing: (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 proximate temporal relationship between vaccination and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See *also, Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). She must show "that the vaccination was the reason for the injury. A medical or scientific explanation must support this logical sequence of cause and effect." *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." *Grant*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Hasler v. U.S.*, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), *cert. denied*, 469 U.S. 817 (1984).

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<sup>13</sup> *Dorland's* at 1307.

<sup>14</sup> This surgical procedure involves wrapping part of the stomach completely around the lower end of the esophagus. *Dorland's* at 743.

While petitioner clearly had numerous medical problems in 1996 -1998, there is no evidence to indicate that the hepatitis B vaccinations were the cause of those problems. Her childhood medical history suggests an unusual number of common infections, although nothing in it connects those upper respiratory and ear infections to any vaccine trigger. Her initial skin lesions in 1991 predated the first hepatitis B vaccine she received in April 1992. The arthralgias she developed in 1993 occurred six to seven months after her final hepatitis B vaccination. There is no evidence in this record to suggest that arthralgias can be caused by the hepatitis B vaccine or that this time period is suggestive of a temporal connection between vaccination and disease. The temporal connection between vaccination and her fibromyalgia and gastrointestinal symptoms in 1996-98 is even more attenuated.

While close calls regarding causation should be resolved in favor of the petitioner, *Althen*, 418 F.3d at 1280, in this case petitioner has completely failed to meet her burden to establish vaccination causation for her injury.

### **III. CONCLUSION**

A special master can only authorize compensation when a medical condition either falls within one of the “Table Case” categories or when some evidence, such as a competent medical opinion, causally connects the vaccine with the injury. No such proof exists in the record before me. Therefore, the petition for compensation is DENIED. 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 with this decision.<sup>15</sup>

**IT IS SO ORDERED.**

**December 12, 2006**

           Date

**s/Denise K. Vowell**

**Denise K. Vowell**

Special Master

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<sup>15</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.