

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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DAVID WIED,

Petitioner,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

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No. 01-505V  
Special Master Christian J. Moran

Filed: December 11, 2006  
Posted: March 23, 2007\*

Judgment on the record; hepatitis B;  
failure to establish causation; denial of  
compensation.

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*Altom M. Maglio, Maglio, Christopher & Toale*, Sarasota, Florida for petitioner  
*Althea Walker Davis, United States Dep't of Justice*, Washington, D.C. for respondent

UNPUBLISHED DECISION<sup>1</sup>

The petition alleges that David Wied’s receipt of the hepatitis B vaccine caused injuries to his peripheral nervous system and his central nervous system. Petition, filed August 29, 2001, ¶ 6. The petition seeks compensation pursuant to the National Vaccine Injury Compensation Program (“the Program”). 42 U.S.C. §§ 300aa-1 et seq.

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\* After this decision was filed, Mr. Wied submitted a motion to redact the decision. After additional briefing, Mr. Wied filed a motion to withdraw this motion on March 13, 2007. Consequently, the decision is being posted without any redactions.

<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 Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of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 to move to delete such information before 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.

On November 8, 2006, Mr. Wied filed a Motion for a Ruling on the Record. This motion is GRANTED. The Court finds that the information on the record does not show entitlement to an award under the Program. Petitioner's claim for compensation is hereby DENIED.

## **I. FACTS**

A summary of the information submitted in this case shows that Mr. Wied<sup>2</sup> received two doses of the hepatitis B vaccine in 1998. Around that time, Mr. Wied experienced joint and muscle pain. He also experienced headaches and problems with his vision. In response to these ailments, he was treated by various doctors over the next five years. The list of his treating physicians includes his pediatrician, two rheumatologists, an ophthalmologist, two neurologists, and two doctors specializing in immune and environmental disorders. Although most treating doctors failed to identify the cause of Mr. Wied's problems, the two specialists in immune disorders concluded that Mr. Wied's problems were caused by the hepatitis B vaccine. For the reasons explained in the analysis section, which follows the more detailed explication of the facts below, the statements by these two doctors are not sufficient to meet Mr. Wied's burden of proof.

Mr. Wied was born on December 31, 1987. Exhibit 13 (labor and delivery records from Lutheran General Hospital) at 43; exhibit 1 (affidavit of Sherry Wied) ¶ 3. His medical history for the next ten years is not relevant for adjudicating his claim. He had some illnesses typical of childhood. See, generally, exhibit 11 (records of North Arlington Pediatrics) and exhibit 7 (records of Associates in Head, Neck & Ear Surgery). Respondent, however, has not argued that these conditions affect his claim for compensation. See Respondent's Report, filed July 11, 2006.

As relevant to this case, Mr. Wied received his first dose of the hepatitis B vaccine from his pediatrician, Dr. Dobkin, at his office in Illinois on September 3, 1998. Exhibit 11 at 13, 25; exhibit 1 ¶ 3. Mr. Wied was ten years old. During this visit, Mr. Wied and/or his mother complained to Dr. Dobkin that he was experiencing pain in his eyes and aches in his knees and ankles when he played soccer. Exhibit 11 at 25.

On September 24, 1998, Mr. Wied's mother called his pediatrician about a concern that he might have arthralgia.<sup>3</sup> Exhibit 11 at 25. In Ms. Wied's affidavit, which was drafted approximately three years later, she stated that her son was having joint and muscle pain, extreme fatigue, nausea, and abdominal cramping, all around this time. Exhibit 1 ¶ 3. In response to Ms. Wied's telephone call, Dr. Dobkin provided names of rheumatologists.

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<sup>2</sup> As noted below, while this lawsuit was pending, Mr. Wied reached the age of majority. Thus, this opinion typically refers to him as "Mr. Wied." The medical records, which are from seven to eight years ago, generally refer to him as "David."

<sup>3</sup> Arthralgia is defined as "pain in a joint." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 30<sup>th</sup> Ed., p.149.

On October 5, 1998, Mr. Wied saw a rheumatologist, Dr. Michael Miller, for complaints of generalized arthralgia that was worsened in his knees and ankles over the past year. Dr. Miller assessed Mr. Wied with generalized arthralgia possibly related to hyperextensibility. Laboratory tests were ordered to evaluate his condition further. Exhibit 5 at 13-14.

On October 7, 1998, Mr. Wied returned to his pediatrician. Dr. Dobkin provided the second dose of the hepatitis B vaccination. Exhibit 11 at 13, 24. Dr. Dobkin also evaluated Mr. Wied based upon his complaints that he was experiencing pain in his legs for the last six to eight months as well as three episodes of diffuse achiness with low-grade fever. Dr. Dobkin assessed Mr. Wied with arthralgia. Exhibit 11 at 24.

On December 23, 1998, Mr. Wied saw a practitioner at Simpson Eye Associates. Mr. Wied stated that his distance vision was not clear, and that he had headaches, joint pain, and sensitivity to light. The practitioner noted that Dr. Miller evaluated him for arthritis. The practitioner's impression included ankylosing spondylitis, fibromyalgia, and possible intermittent uveitis. Exhibit 4 at 17-18.

In January 1999, Mr. Wied consulted another rheumatologist, Dr. Charles Spencer. Dr. Spencer reported that Mr. Wied had been absent from school since September due to multiple pains, severe fatigue, poor sleeping, photophobia, nausea, and severe headaches. In Dr. Spencer's opinion, Mr. Wied was suffering from fibromyalgia, not chronic arthritic disease. Dr. Spencer prescribed medications to improve his sleeping. Exhibit 6 at 29-30.

By the end of January, Mr. Wied's mother told his pediatrician, Dr. Dobkin, that she was concerned that the hepatitis B vaccine was linked to David's symptoms. She indicated that she did not want other vaccinations given. Exhibit 11 at 22. Apparently, Ms. Wied saw an episode of 20/20, the ABC television show, that caused her to suspect a connection between the hepatitis B vaccine and her son's condition. Exhibit 14 at 6.

Mr. Wied next returned to Simpson Eye Associates. Dr. Patricia Davis noted that Mr. Wied was seeing white spots and was wearing sunglasses indoors because his vision was painful. Her impression was that Mr. Wied suffered from fibromyalgia and photophobia that was possibly caused by intermittent uveitis, instead of a demyelinating process. She recommended that he see a neurologist. Exhibit 4 at 15-16.

Mr. Wied saw a pediatric neurologist, Dr. James Tongard, on February 15, 1999. Dr. Tongard noted that Mr. Wied was being evaluated for a possible demyelinating disease. The symptoms that Dr. Tongard reported were consistent with those reported to other doctors: extreme sensitivity to light, headaches, fatigue, episodes of tachycardia, sensitivity to tastes and smells, and aching all over his body concentrated in his muscles and joints. Dr. Tongard referred Mr. Wied to a pediatric ophthalmologist and recommended an MRI scan of the brain. Exhibit 24 at 21-23. Although a pediatric ophthalmologist examined Mr. Wied, he could not find any cause for the photophobia. Exhibit 16 at 8.

On February 26, 1999, Mr. Wied returned to Dr. Spencer's office for a follow-up. Dr. Spencer still believed that he was suffering from mild to moderate fibromyalgia. Dr. Spencer altered his medication and recommended continued treatment by Dr. Tonsgard, the neurologist. Dr. Spencer noted that Ms. Wied was concerned that the hepatitis B vaccine contributed to David's problems. However, Dr. Spencer did not report whether he agreed with Ms. Wied's concern. Exhibit 6 at 32, 34.

On March 8, 1999, Mr. Wied began seeing Andrew Campbell, M.D., medical director of the Center for Immune, Environmental, and Toxic Disorders, near Houston, Texas. The initial materials, which appear to be completed by Ms. Wied, raised concerns about the hepatitis B vaccination. Exhibit 15 at 572, 578. Dr. Campbell took a history and ordered numerous tests. Exhibit 15 at 578, 580. Dr. Campbell diagnosed at least nine conditions, including a hepatitis B vaccine reaction. Exhibit 15 at 456, 580. He also recommended that Mr. Wied begin intravenous immunoglobulin ("IVIG") treatments, and that he take vitamin B complex, Claritin, and magnesium and return in June for a follow-up. Exhibit 15 at 456-57, 582.

On April 16, 1999, Mr. Wied again saw Dr. Spencer. His condition did not differ in any significant respect. Dr. Spencer continued to believe that he suffered from fibromyalgia. Dr. Spencer again noted that Ms. Wied "remains concerned that the Hepatitis B shot started David's problems." Although Dr. Spencer notes that he discussed these concerns, Dr. Spencer's report does not memorialize Dr. Spencer's independent assessment. Exhibit 6 at 35.

On June 26, 1999, Mr. Wied saw Dr. Burton Waisbren, Director of the Waisbren Clinic in Milwaukee, Wisconsin. Dr. Waisbren obtained a history consistent with the chronology given above. Dr. Waisbren also conducted a physical examination and ordered many blood tests. Exhibit 3 at 15-27. Dr. Waisbren opined that Mr. Wied suffered from "Multiple-Antigen-Mediated-Autoimmunity (the MAMA Syndrome)." Id. at 16. He recommended intramuscular treatment with gamma globulin, an anti-viral program, and prednisone. He also stated that "based on exclusion of other disease and my experience I feel that this boy is suffering from post vaccinal acquired autoimmunity." Id.

Pediatric neurologist Nishant Shah evaluated Mr. Wied on July 19, 1999. The history that Dr. Shah received indicated that Mr. Wied had a reaction to both hepatitis B vaccinations. To determine whether Mr. Wied suffered from a demyelinating condition, Dr. Shah recommended a nerve conduction study. Dr. Shah also recommended an EEG to look for evidence of an encephalopathy. Exhibit 6 at 39-42. Dr. Shah concluded that Mr. Wied's "clinical presentation was consistent with several systemic symptoms starting shortly after the first dose of hepatitis B vaccine and being exacerbated after the second dose of hepatitis B vaccine." Id. at 40.

Mr. Wied continued to receive treatment from various doctors. In particular, he saw Dr. Shah twice in 2000. Exhibit 6 at 47-50. Mr. Wied also received IVIG, as prescribed by Dr. Campbell, from 1999 until at least 2003. Exhibit 10, exhibit 15, exhibit 26. The evidence of

medical treatment stops in 2003. Information about Mr. Wied's current condition was not submitted.

## **II. PROCEDURAL HISTORY**

Ms. Sherry Wied, Mr. Wied's mother, filed this petition on August 29, 2001, when he was a minor. (In June 2006, when Mr. Wied reached the age of majority, the caption of the case was changed to indicate that he was prosecuting the case. This change does not affect the merits of the case.) The first set of medical records were filed in March 2002. Ms. Wied filed other medical records periodically. Mostly recently, two exhibits of medical records were filed in July 2004.

For various reasons the case did not progress for approximately two years. By order dated March 29, 2006, Ms. Wied was required to file an expert report or a status report by July 26, 2006.

Respondent filed its report, pursuant to Vaccine Rule 4, on July 11, 2006. Respondent asserted that the petition should be denied. Respondent argued that the existing record did not demonstrate "a reputable medical or scientific theory casually connecting the vaccine to any alleged injury." Respondent's Report at 13.

Mr. Wied did not file an expert report on July 26, 2006. However, he did request additional time to submit an expert report. This request was granted and a new deadline of November 6, 2006, was set. Rather than submit an expert report on that date, Mr. Wied filed a single sentence motion seeking a ruling on the record "to dismiss this matter." Petitioner's Motion for Ruling on Record, filed November 8, 2006, at 1. Respondent filed a response.

## **III. ANALYSIS**

To receive compensation condition under the Program, Mr. Wied must prove either: (1) that he suffered a "Table Injury"—that is, 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); Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Mr. Wied does not claim that he suffered a table injury. Thus, he must prove causation in fact.

A petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A).

The records are sufficiently developed that a decision made be made as to whether Mr. Wied is entitled to a Program award. See 42 U.S. C. § 300aa-12(d)(3)(B)(v); Vaccine Rule 8(b).

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] 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 of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

The records do not support a judgment in favor of Mr. Wied because he has failed to establish any of the three prongs required by Althen.

By medical records or by medical opinion, Mr. Wied has failed to establish the first prong of Althen – “a medical theory causally connecting the vaccination and the injury.” As mentioned, Mr. Wied has not presented the opinion of an independently retained expert. Thus, he must rely upon the opinions of treating doctors contained in the medical records.

The doctor's reports do not contain a “medical theory.” An independent review of the exhibits indicates that some association between the hepatitis B vaccine and Mr. Wied's various illnesses were made by four physicians: Dr. Waisbren, Dr. Campbell, Dr. Shah, and Dr. Spencer.

The two strongest statements come from Dr. Waisbren and Dr. Campbell. Dr. Waisbren stated that Mr. Wied suffered from “post vaccinal acquired autoimmunity..” Exhibit 3 at 16. Dr. Campbell diagnosed a hepatitis B vaccine reaction. Exhibit 15 at 456, 580. However, these statements do not satisfy Mr. Wied's burden of proof.

Dr. Waisbren's and Dr. Campbell's statements do not express a “medical theory.” The statements are conclusions that lack a theory explaining how the hepatitis B vaccine caused Mr. Wied's condition. Without any reasoning explaining how Dr. Waisbren and Dr. Campbell came to their conclusions, assessing the accuracy of their statement is very difficult, if not impossible. See Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, \*1377 n.6 (Fed. Cir.1994) (“An expert opinion is no better than the soundness of the reasons supporting it.”). In addition, Mr. Wied did not submit a curriculum vitae for Dr. Waisbren or for Dr. Campbell. Thus, no evidence – other than their title of “doctor” — indicates their expertise and ability to

reach a conclusion that a vaccine caused an injury. Mr. Wied has also not demonstrated that Dr. Waisbren or Dr. Campbell are reliable. See Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1306 (Fed. Cir. 1999) (affirming special master’s use of factors from Daubert v. Merrill Dow Pharm. Inc., 509 U.S. 579, 591-92 (1993), to evaluate reliability of expert testimony). For these reasons, Dr. Waisbren’s and Dr. Campbell’s conclusions are entitled to very little weight. Although, by itself, the lack of an express theory suffices to find that Mr. Wied failed to meet his burden of proof, another reason buttresses this conclusion.

Besides Dr. Waisbren’s and Dr. Campbell’s statements, other statements from treating physicians do not assist Mr. Wied in meeting his burden of proof. While Dr. Shah associates the hepatitis B vaccination with the onset of Mr. Wied’s condition, Dr. Shah fails to state that the vaccination caused Mr. Wied’s problem and he does not offer a causal theory. Exhibit 6 at 40.

The final treating physician to note a possible connection between the hepatitis B vaccinations and Mr. Wied’s illnesses is Dr. Spencer. Dr. Spencer, however, does not offer a theory based upon his training as a rheumatologist. Instead, Dr. Spencer’s reports merely memorialize concerns raised by Mr. Wied’s mother. Exhibit 6 at 32, 34, 35. A finding that a vaccine caused a medical problem cannot be based upon the statements of a petitioner who lacks expertise. 42 U.S.C. § 300aa-13(a)(1). Given that no evidence suggests that Mr. Wied’s mother is an expert on medical causation, her statements as reflected in Dr. Spencer’s reports cannot be given any weight.

Furthermore, Mr. Wied has failed to establish the second prong of Althen – a logical sequence of cause and effect. The points regarding the first prong of Althen, discussed above, also explain why Mr. Wied fails to meet the second prong. Neither Dr. Waisbren, nor Dr. Campbell, nor Dr. Shah, nor Dr. Spencer explain the sequence of events starting with vaccination and culminating in Mr. Wied’s symptoms or illnesses.

Finally, Mr. Wied failed to establish the third prong of Althen – an appropriate temporal relationship between vaccination and the onset of his illness. Because proof for the first two prongs was lacking, it follows that the record does not contain any information about what is an appropriate interval.

#### **IV. CONCLUSION**

For these reasons, petitioner’s claim for compensation is hereby DENIED. In the absence of a motion for review, the Clerk of the Court shall enter judgment dismissing the petition.

IT IS SO ORDERED.

S/ Christian J. Moran

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Christian J. Moran  
Special Master