

In the United States of Federal Claims

OFFICE OF SPECIAL MASTERS

TIMOTHY WOODY and CARMEN *
VERDUGO WOODY, as the parents and *
natural guardians of V.W., an infant, *

No. 13-366V
Special Master Christian J. Moran

Petitioners, *

Filed: October 23, 2014

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Decision on the record;
insufficient proof of causation;
Diphtheria-Tetanus-Acellular-
Pertussis (“DTaP”) vaccine;
encephalopathy.

Respondent. *

Mark T. Sadaka, Englewood, NJ, for petitioners;
Ryan D. Pyles, United States Dep’t of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION BASED UPON WRITTEN RECORD¹

Timothy Woody and Carmen Verdugo Woody alleged that a diphtheria-tetanus-acellular pertussis (DTaP) vaccine harmed their son, V.W. They sought compensation through the Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa—10 through 34 (2006). After collecting medical records but without submitting an expert opinion, the petitioners sought a ruling based upon

¹ The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa—12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

the written record. The material does not support a finding of entitlement. Thus, the Clerk's Office is instructed to issue a judgment denying compensation.

Background

V.W. was born in February 2009. "He had no significant health issues throughout his first 3 years of life, and received routine immunizations." Pet'rs' Mot. at 2. Later testing showed he responded to these vaccinations in an appropriate manner. Exhibit 2 at 9-15. When V.W. was three years old, he saw his pediatrician for a checkup. The doctor's checklist indicates "vaccine reaction none." V.W.'s mother requested a "split vaccine schedule." Exhibit 8 at 5-6. During this April 6, 2012 visit, V.W. received his fourth dose of the DTaP vaccine.

V.W.'s health in the next few days is disputed. According to his mother's affidavit, in the days immediately following this vaccination, he was fussy and slept excessively. Exhibit 13 at 3.

This account seems improbable. Ms. Verdugo Woody brought V.W. back to the pediatrician's office on April 9, 2012, to check the result of a tuberculin test. The doctor's office did not record any complaints and noted that V.W. had a normal temperature. Exhibit 8 at 1. The absence of any complaints in V.W.'s medical records suggests that he was well, creating a contradiction with Ms. Verdugo Woody's affidavit. But, resolving this factual discrepancy is not necessary because the assertions of Ms. Verdugo Woody are not material, as explained below.

On April 19, 2012, Ms. Verdugo Woody returned to the pediatrician's office again. Dr. Machado's notes indicate that Ms. Verdugo Woody's chief complaint was "side effects from vaccines." Exhibit 8 at 2. This notation suggests that the pediatrician's office could be receptive to a parent's concern about vaccination, contrary to the petitioners' argument that the pediatrician's staff was dismissive about a similar complaint on April 9, 2012. In any event, Dr. Machado examined V.W. and concluded that he "appeared normal with regular energy, activity, no apparent lethargy, or weakness." Id. at 3.

The next day, Ms. Verdugo Woody brought V.W. to an emergency room. She again reported a vaccine reaction. Exhibit 5 at 7. The doctor found him normal but recommended follow-up with a neurologist.

The neurologist received a similar history – vaccine reaction – and reached a similar assessment – V.W. was normal. Exhibit 2 at 25-28. A review of the medical records shows that over the next few months, this pattern repeated. Ms. Verdugo Woody reported a history of vaccine reaction, including sleepiness, but several doctors found nothing wrong. E.g. exhibit 2 at 16-17 (report of Dr. Sanchez-Vegas).

In light of the doctors' finding that V.W. was normal, the Secretary raised a question about the condition for which the petitioners were seeking compensation. A related issue is how the petitioners could establish the requirement of a severe injury. Of the three options in 42 U.S.C. § 300aa—11(c)(1)(D), the only one available is an injury lasting more than six months. In response to a question asked in a status conference, the petitioners indicated that V.W. experienced excessive sleepiness.²

The petitioners pursued their claim that the vaccinations caused excessive sleepiness by filing a petition on May 30, 2013. The petition did not explicitly identify V.W.'s injury as excessive sleepiness. Instead, the petition alleged V.W. suffered an encephalopathy that either the April 6, 2012 DTaP vaccination caused or the DTaP vaccination significantly aggravated. Although the petitioners pleaded in the alternative, they appear not to be pursuing significant aggravation since their pending motion does not refer to that theory of recovery. However, the petitioners have argued for compensation based upon V.W. suffering an injury listed on the Vaccine Injury Table.

Shortly after the submission of the petition, the petitioners filed some medical records. They did not file a complete set of records from the pediatrician's office due to the pediatric practice's lack of response. See Pet'rs' Mot. at 8 n.2. Petitioners obtained them in response to a subpoena and filed them as exhibit 8. Ms. Verdugo Woody submitted her affidavit as exhibit 13.

² Petitioners argue V.W. "was diagnosed with post-vaccine encephalopathy." Pet'rs' Mot. at 2. However, the cited medical record does not actually say this. Instead, Ms. Verdugo Woody told Dr. Kalika that Victor was "diagnosed as a post-vaccine encephalopathy." Exhibit 12 at 3. The petitioners have not identified any record showing that a doctor diagnosed a post-vaccine encephalopathy. Thus, the history given to Dr. Kalika is not supported.

The Secretary filed her report, pursuant to Vaccine Rule 4, on February 19, 2014. She noted the discrepancy between Ms. Verdugo Woody's affidavit and the documents created contemporaneously with the events described in the affidavit. Resp't's Rep't at 2 n.1, 9. The Secretary maintained that the petitioners did not establish entitlement to compensation based upon either an on-Table claim or an off-Table claim. Id. at 5, 9.

In a status conference, the parties considered whether to have a hearing to determine V.W.'s condition in the days following DTaP. The petitioners' attorney was given an opportunity to counsel the family and to propose a course of action.

The petitioners did not request a hearing. The petitioners proposed a resolution based upon written submissions. Pet'rs' Status Rep't, filed April 17, 2014. Petitioners submitted the pending motion for a ruling on the record and the Secretary opposed the substantive relief requested.

Analysis

In establishing the Vaccine Program, Congress instructed the Court of Federal Claims to promulgate rules, including a rule for "the opportunity for parties to submit . . . evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings." 42 U.S.C. § 300aa—12(d)(2)(D). In accord with this statutory directive, "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d).

To receive compensation, the petitioners must establish that the vaccination caused V.W. some harm. The Vaccine Act creates two avenues to establish causation. First, the petitioners could show that V.W. suffered an injury listed on the vaccine injury Table, in which case causation is presumed. Second, for injuries not listed on the Table, petitioners can establish causation-in-fact. W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355 (Fed. Cir. 2013). For off-Table injuries, the Federal Circuit spelled out that the petitioners' burden is to 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 proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The burden of proof is preponderance of the evidence. Id.

Here, petitioners invoke both methods. The evidence, however, does not show entitlement for either an on-Table or off-Table claim.

The Vaccine Injury Table associates a vaccine containing pertussis antigen with an encephalopathy occurring within 72 hours of vaccination. 42 C.F.R. § 100.3(a) ¶ II. The Qualifications and Aids to Interpretation define “acute encephalopathy” for a child of V.W.’s age as

one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

42 C.F.R. § 100.3(b)(2)(i)(B). The Qualifications and Aids to Interpretation further define “acute encephalopathy” by excluding some symptoms as demonstrating the required mental state. The list of excluded symptoms includes both sleepiness and fussiness. 42 C.F.R. § 100.3(b)(2)(i)(E).

Ms. Verdugo’s Woody’s affidavit asserts sleepiness and fussiness. Whether V.W. actually suffered the symptoms is genuinely disputed. The Secretary points to the visit on April 19, 2012. The records from this visit do not reflect a decreased level of consciousness. If this dispute were over a material fact, then the special master could order a hearing. See Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775 (2006). A hearing for Ms. Verdugo Woody to testify is not needed.³ Pursuant to Qualifications and Aids to Interpretation, sleepiness does not

³ The petitioners also did not request a hearing.

count as evidence of an acute encephalopathy. In other words, sleepiness is not a material fact.

Petitioners' argument for an on-Table claim is based exclusively on Ms. Verdugo Woody's affidavit. Pet'rs' Mot. at 8-9. The petitioners do not specifically identify any way V.W. manifested symptoms of an "acute encephalopathy" as defined in the Table. Thus, petitioners have not shown that V.W. satisfies the definition for an on-Table injury. Petitioners, therefore, must pursue a claim based upon an off-Table injury.

When deciding an off-Table claim, special masters must base their decisions upon medical records or medical opinion. 42 U.S.C. § 300aa—13. The petitioners did not submit an opinion from a doctor retained for this litigation. Therefore, petitioners must rely upon medical records.

The medical records do not satisfy petitioners' burden. They consistently show Ms. Verdugo Woody saying that V.W. suffered a vaccine reaction but the doctors not agreeing with this complaint. In the three months after vaccination, V.W. saw several doctors. At best, some doctors recommended that V.W. not receive additional doses of the pertussis vaccine. But, even these doctors did not find anything objectively wrong with V.W. Under these circumstances, the recommendation against additional pertussis vaccinations does not establish, on a more likely than not basis, that a vaccine harmed V.W. See Vig v. Sec'y of Health & Human Servs., 01-0198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) (finding that withholding pertussis vaccine did not demonstrate causation).

The doctors' statements do not fulfill the Althen criteria. Petitioners' motion did not make any argument connecting any Althen prong to specific evidence in V.W.'s case. Consequently, the petitioners have not established that they are entitled to compensation for an off-Table injury.

Conclusion

The petitioners have not established that V.W. suffered either an on-Table injury or an off-Table injury caused-in-fact by the DTaP vaccine. Consequently, they are not entitled to compensation.

The Clerk's Office is instructed to issue judgment in accord with this decision.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master