

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-783V

June 5, 2008

VACHE and NAIRA KARAPETIAN, *
Legal Representatives of a Minor Child, *
THOMAS KARAPETIAN, *

Petitioners, *

v. *

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

Respondent. *

Second supplemental report
of expert doctor required to
explain how DPaT causes
infantile spasms and deafness

ORDER¹

Petitioners filed a petition on November 21, 2006 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that their son Thomas Karapetian (hereinafter,

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order 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.

“Thomas”) had a Table encephalopathy after receiving acellular DPT vaccine and that acellular DPT vaccine caused in fact Thomas’s infantile spasms, developmental delay, and deafness.

Petitioners filed an expert report and supplemental report from Dr. Perry Lubens stating that Thomas had a Table encephalopathy and that acellular DPT caused Thomas’s infantile spasms and deafness. However, Dr. Lubens omits discussion in his reports that, in order for petitioners to satisfy the regulatory interpretation of a Table encephalopathy in 42 C.F.R. §100.3(b)(2)(A), the vaccinee must have a significantly decreased level of consciousness beyond 24 hours which cannot be attributed to a seizure, and in 42 C.F. R. §100.3(b)(2)(E), “Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy.” Thomas’s appearing dazed while he was having infantile spasms is not indicative of a Table encephalopathy because the regulatory definition excludes seizures from the definition of a Table encephalopathy.

In addition, Dr. Lubens’s reports do not satisfy the Federal Circuit criteria for proving causation in fact because he does not discuss a biologically plausible medical theory explaining how acellular DPT causes infantile spasms and deafness. To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence "(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. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]” the logical sequence being supported by

“reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

Without more, "evidence showing an absence of other causes does not meet petitioners' 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. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioners must show not only that but for acellular DPT vaccine, Thomas would not have had infantile spasms and deafness, but also that the vaccine was a substantial factor in bringing about Thomas's infantile spasms and deafness. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The undersigned ORDERS petitioners to file a second supplemental report from Dr. Lubens in which he is to discuss the basis for his opinion that acellular DPT caused Thomas's infantile spasms, keeping in mind that his own diagnosis of Thomas's infantile spasms is that they were cryptogenic (*i.e.*, cause unknown). Dr. Lubens's consultation with Thomas on December 9, 2003 notes:

For the last two weeks, Thomas has been having flurries of extensor spasms. Between the episodes though he is fine. There hasn't been any change in his behavior. ... He is visually aware. ... He seems to have no abnormal motor patterns or abnormal behaviors. ... He is visually alert. ... He reaches out and back for the toy. No abnormal movements or postures were seen. ...
Impression: Thomas has cryptogenic infantile spasms.

Med. recs. at Ex. 5, pp. 9-10.

Dr. Lubens is also to discuss in his second supplemental report the basis for his opinion that acellular DPT caused Thomas's deafness.

Respondent filed an expert report from Dr. Mary A. Guggenheim (Ex. A) with a medical article (Ex. C) discussing early childhood deafness. Respondent subsequently submitted another medical article on deafness (Ex. D). Petitioners are to provide Dr. Guggenheim's expert report and the articles on deafness to Dr. Lubens so that he may respond to her expert report and discuss the deafness articles in his second supplemental report.

Dr. Lubens is to keep in mind that if petitioners do not prove a causal nexus between acellular DPT and Thomas's deafness, Thomas's infantile spasms, which did not last longer than six months, will be insufficient for them to receive damages even if they were to prove either a Table encephalopathy or causation in fact because the Vaccine Act requires that the vaccine injury or its sequelae last longer than six months. 42 U.S.C. §300aa-11(c)(1)(D)(i).

In addition, on March 20, 2008, the undersigned ordered petitioners to file supplemental affidavits by July 1, 2008. On May 8, 2008, petitioners moved for a two-week extension of time which the undersigned granted on May 12, 2008. On May 27, 2008, petitioners filed Mr. Karapetian's supplemental affidavit. As of the date of this Order, the undersigned has not yet received Mrs. Karapetian's supplemental affidavit which is now two weeks late and petitioners have not asked for an extension of time within which to file it. The undersigned ORDERS that petitioners file Mrs. Karapetian's supplemental affidavit which answers the following:

Petitioner Naira Karapetian filed an affidavit, dated November 20, 2006, as Ex. 14 accompanying the petition in this case. In her affidavit, Mrs. Karapetian states that, on the day of vaccination or the next day, Thomas had a confused look on his face (¶ 9), seemed to be staring blankly at things (¶ 10), no longer recognized her, was irritable, cried more than usual, and generally acted oddly (¶ 11).

The undersigned orders petitioner Mrs. Karapetian to file a supplemental affidavit explaining if the characteristics she describes in paragraphs 9-11 of her affidavit occurred while Thomas was having infantile spasms or, instead, occurred between his infantile spasms.

If Mrs. Karapetian states in her supplemental affidavit that the characteristics she describes in paragraphs 9-11 of her affidavit occurred between Thomas's infantile spasms, then Mrs. Karapetian shall explain why she and her husband told Dr. Perry Lubens on December 9, 2003 that Thomas was fine between his infantile spasms. (P. Ex. 5, p. 9.)

In addition, if Mrs. Karapetian states in her supplemental affidavit that the characteristics she describes in paragraphs 9-11 of her affidavit occurred between Thomas's infantile spasms, then Mrs. Karapetian shall explain why she and her husband told Dr. Lubens on December 9, 2003 that there had not been any change in Thomas's behavior. (P. Ex. 5, p. 9.)

Mrs. Karapetian shall explain why she and her husband told medical personnel that Thomas was attentive if the characteristics she describes in paragraphs 9-11 of her affidavit occurred between Thomas's infantile spasms. (P. Ex. 6, p. 31.)

Mrs. Karapetian shall explain why she and her husband told the nurse that Thomas had normal activities of daily living if the characteristics she describes in paragraphs 9-11 of her affidavit occurred between Thomas's infantile spasms. (P. Ex. 6, p. 33.)

Mrs. Karapetian shall explain why, if the characteristics she describes in paragraphs 9-11 of her affidavit occurred between Thomas's infantile spasms, her and her husband's only complaint to the doctor was that Thomas was constipated for four days. (P. Ex. 7, p. 18.)

The deadline for petitioners to file Dr. Lubens's second supplemental report responding to the questions the undersigned has raised in this Order and to Dr. Guggenheim's expert report and articles is **August 1, 2008**.

Petitioners shall file Mrs. Karapetian's second affidavit immediately if they have not already done so.

The telephonic status conference set for **Tuesday, July 1, 2008, at 3:00 p.m. (EDT)**, is cancelled. A new telephonic status conference shall be set when the undersigned receives the second supplemental affidavit of Mrs. Karapetian and the second supplemental report of Dr. Lubens.

The undersigned makes note that Mr. Karapetian's second supplemental affidavit does not answer any of the questions the undersigned ordered him to answer and he denies knowledge of the histories given in the medical records. The undersigned takes his denial to mean that Mr. Karapetian was not present when these medical histories were given.

In contemplating the likelihood of their prevailing in this case on the issue of whether DPT causes infantile spasms, petitioners should be aware that the following decisions issued in the Vaccine Program have held that DPT vaccine does not cause infantile spasms: Thompson v. Secretary of HHS, No. 99-436V, 2003 WL 21439672 (Fed. Cl. Spec. Mstr. May 23, 2003); Perez v. Secretary of HHS, No. 00-328V, 2003 WL 431593 (Fed. Cl. Spec. Mstr. Jan. 14, 2003); Raj v. Secretary of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. Spec. Mstr. June 14, 2001); Grady v. Secretary of HHS, No. 95-173V, 2000 WL 1772473 (Fed. Cl. Spec. Mstr. Nov. 16, 2000); Jenkins v. Secretary of HHS, No. 90-3717V, 1999 WL 476255 (Fed. Cl. Spec. Mstr. June 23, 1999); Hoag v. Secretary of HHS, No. 94-67V, 1998 WL 408783 (Fed. Cl. Spec. Mstr. Apr. 22,

1998), aff'd, 42 Fed. Cl. 238 (Fed. Cl. Oct. 15, 1998); Jackson v. Secretary of HHS, No. 90-1903V, 1995 WL 120210 (Fed. Cl. Spec. Mstr. Mar. 3, 1995); Woodcock v. Secretary of HHS, No. 90-1030V, 1992 WL 92169 (Ct. Cl. Spec. Mstr. Apr. 10, 1992); Shelley v. Secretary of HHS, No. 90-604V, 1991 WL 239693 (Cl. Ct. Spec. Mstr. Oct. 29, 1991).

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master