In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-694V
June 6, 2014
Not to be Published

WAHEED AHMED and NERMEEN HASSN, as Legal Representatives of NADA AHMED,	*	
Petitioners,	*	Influenza vaccine; haemophilus B influenza vaccine; hepatitis A vaccine; acute disseminated encephalomyelitis; leukodystrophy; no expert report; petitioners' motion for judgment on administrative record; dismissal
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mindy M. Roth, Glen Rock, NJ, for petitioners.
Julia W. McInerny, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On September 18, 2013, petitioners filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that influenza, haemophilus B influenza, and hepatitis A vaccines administered on October 1, 2010 to their daughter Nada Ahmed

[1] Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends 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). 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 constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

("Nada") caused her to suffer from acute disseminated encephalomyelitis ("ADEM"). Pet. ¶¶ 5, 6.

The medical records show that Nada was diagnosed with atypical ADEM, whose onset was one day after her vaccinations. Her initial diagnosis of ADEM was followed by degenerative white matter brain disease that was diagnosed as leukodystrophy, whose etiology is unknown.

On December 19, 2013, during the first telephonic status conference with the parties, the undersigned discussed the issue of sequelae in this case. Nada's ADEM did not last long enough to satisfy the Vaccine Act's requirement that a vaccine injury last more than six months. 42 U.S.C. § 300aa-10(c)(1)(D)(i). Furthermore, there was no proof in the record that Nada's ADEM and leukodystrophy are related.

On December 19, 2013, the undersigned issued an Order reiterating the substance of the status conference:

> The complicated part of this case concerns sequelae. After Nada's brain MRIs showed that her lesions were no longer active, she proceeded to have a white matter brain injury (leukodystrophy), whose cause is still unknown. This white matter brain injury is progressive and causing brain atrophy. Nada's parents are first cousins, and she has consequently long continuous regions of homozygosity, in which there are many genes with about 33 autosomal recessive genes that are associated with white matter changes and spasticity. Med. recs. Ex. 7, at 1661 (Dr. Susan S. Brooks' report of March 7, 2013). No doctor, whether pediatric neurologist or geneticist, has given a cause for Nada's leukodystrophy, even though all of them are aware Nada had ADEM. This suggests to the undersigned that none of Nada's treating doctors thinks her ADEM caused her leukodystrophy.

Order, Dec. 19, 2013, ECF No. 9.

Over the next few months, petitioners filed additional medical records but no expert medical report supporting that either Nada's ADEM lasted more than six months or, when her ADEM lesions were no longer active, her subsequent leukodystrophy was due either to her ADEM or to her vaccinations.

On April 10, 2014, petitioners filed a Motion for Judgment on the Administrative Record. Petitioners state in their Motion that Nada had a reaction, i.e., ADEM, to her vaccinations. Mot. J., Apr. 10, 2014, ECF No. 14. They do not discuss in their Motion the statutory requirement that her reaction last more than six months.

On April 16, 2014, the undersigned issued an Order stating that 42 U.S.C. § 300aa-11(c)(1)(D)(i) requires that a vaccine injury last more than six months, but "[n]o doctor who has treated Nada and voiced an opinion in the medical records has stated that her leukodystrophy is a sequela of her ADEM, and petitioners have not filed an expert medical report saying her leukodystrophy is a sequela of her ADEM." Order, Apr. 16, 2014, ECF No. 16. The undersigned ordered respondent to file a response to petitioners' Motion for Judgment on the Administrative Record by June 2, 2014.

On June 2, 2014, respondent filed her Rule 4(c) Report and Response to Petitioners' Motion for Judgment on the Record. Resp't's Resp, June 2, 2014, ECF No. 19. Respondent states petitioners have not made a prima facie case of causation in fact. They have not proved that: her vaccinations caused her ADEM, her ADEM lasted more than six months, her ADEM caused her leukodystrophy, or, if she never had ADEM but only leukodystrophy, the vaccines caused the leukodystrophy. Resp't's Resp. at 8–9.

On June 4, 2014, the undersigned held a telephonic status conference with the parties and asked petitioners' counsel if she wanted to file a reply to respondent's Rule 4(c) Report and Response to Petitioners' Motion for Judgment on the Record. Petitioners' counsel stated she would not file a reply.

The undersigned **GRANTS** petitioners' Motion for Judgment on the Administrative Record and **DISMISSES** this case.

FACTS

Nada was born on October 8, 2009.

On October 1, 2010, she received influenza, haemophilus B influenza, and hepatitis A vaccines. Med. recs. Ex. 9, at 1755, 1764, 1765.

One day post-vaccination, Nada was lethargic, irritable, weak in all four extremities, and had loss of milestones. Med. recs. Ex. 5, at 164. Her parents brought her to JFK Emergency Department. Id.

From October 10–12, 2010, Nada was at JFK Medical Center, where she was diagnosed with ADEM and truncal ataxia. Med. recs. Ex. 11, at 1878. A neurology consultation on October 10, 2010 states that Nada's brain MRI showed bilateral periventricular white matter disease, but her lumbar puncture was negative. Id. at 1895. Another MRI on October 12, 2012 showed brain lesions consistent with but "somewhat atypical" for ADEM. Med. recs. Ex. 5, at 212. A geneticist consulting on Nada's case noted that "parental consanguity makes a rare recessive disorder possible," and POLG disorders (mitochondrial recessive disorders) can mimic ADEM. Id. at 287.

Nada's MRI on February 22, 2011, showed "dramatic worsening of the previous abnormalities in the white matter." Med. recs. Ex. 7, at 1615. Dr. Vikram Bhise, a pediatric neurologist, suspected leukodystrophy, with a differential diagnosis of infantile metachromatic leukodystrophy or vanishing white matter disease. Id. at 1618.

On June 27, 2011, an MRI showed white matter enhancement indicating a "demyelinating process, leukodystrophy or metabolic process" was more likely than a "demyelinating disease such as [ADEM] or multiple sclerosis." Id. at 1634. Dr. Bhise found these new results "very unusual," and he conferred with a colleague at Johns Hopkins, who suspected a mitochondrial disease. Id. at 1638.

An August 5, 2011 MRI showed significant, continued increase in white matter signal abnormalities, leading Dr. Bhise to diagnose "an unusual leukodystrophy." Id. at 1640, 1643.

On March 7, 2013, Nada saw Dr. Susan S. Brooks, a pediatric geneticist, who noted that Nada had ADEM followed by leukodystrophy. Med. recs. Ex. 7, at 1661. She had a four-month-old sister who died from a mitochondrial DNA depletion syndrome caused by a homozygous RRM2B mutation. Id. Nada is a heterozygous carrier of the mutation, as are her parents, who are first cousins. Id. Nada has long continuous regions of homozygosity. Id. There are many genes in these regions, with about 33 autosomal recessive genes that are associated with white matter changes and spasticity. Id. Nada's third brain MRI showed the same white matter involvement but also mild diffuse atrophy and two ring enhancing lesions. Id. Her MRIs showed increased diffuse atrophy. Id. Dr. Brooks' diagnosis was leukodystrophy of unclear etiology, unexplained white matter disease, and progressive white matter changes. Id. at 1665.

DISCUSSION

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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 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[.]"

Althen, 418 F.3d at 1278.

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. Id. at 1148.

Although petitioners allege Nada's vaccinations caused her ADEM, the medical records do not prove their allegation, and petitioners have not filed an expert medical report in support of their allegations that Nada suffered from ADEM or that the vaccine caused it. The Vaccine Act does not permit the undersigned to rule for petitioners based on their claims alone, "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1) (2006). Moreover, petitioners have not proved that Nada's ADEM lasted more than six months, as the Vaccine Act requires, or that her subsequent leukodystrophy was caused by either her ADEM or her vaccinations.

Petitioners have not satisfied the first prong of Althen in that they have not presented through medical records or an expert medical opinion a theory explaining how Nada's vaccinations could cause ADEM and/or leukodystrophy. Petitioners have not satisfied the second prong of Althen that there is a logical sequence of cause and effect showing that these vaccines did cause Nada's ADEM and/or leukodystrophy. Petitioners have not satisfied the third prong of Althen that one day is a medically appropriate time interval to show causation of ADEM and/or leukodystrophy from any or all of her vaccinations. Thus, petitioners have not made a prima facie case of causation.

The undersigned **GRANTS** petitioners' Motion for Judgment on the Administrative Record. This case is **DISMISSED**.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.[2]

IT IS SO ORDERED.

June 6, 2014
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

[2] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.