

OFFICE OF SPECIAL MASTERS

No. 06-487V

August 3, 2006

ANGELENA GONZALES and JOSEPH GONZALES, as next friends to TOMAS RUSSELL GONZALES,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Death from Epstein-Barr virus with onset 24 days after MMR; how will petitioners prevail?

ORDER TO SHOW CAUSE¹

Petitioners filed a petition² dated June 29, 2006, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., on behalf of their son Tomas Russell Gonzales

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.

² The undersigned notes that the caption does not accurately reflect that Mr. and Mrs. Gonzales are the legal representatives of Tomas' estate. They must prove representative authority under their state law to bring this petition. Section 300aa-11(b)(1)(A).

(hereinafter, "Tomas"), alleging that acellular DPT, inactivated polio vaccine, and MMR vaccine administered on June 10, 2004 caused Tomas' death on July 9, 2004 from Epstein-Barr virus (EBV). The onset of Tomas' symptoms, by his parents' history, was July 4, 2004, 24 days after vaccination. The vaccinations have nothing to do with EBV.

Petitioners allege in their petition that Tomas had a Table encephalopathy within the Table time limits, which for MMR run from 5-15 days after vaccination. Twenty-four days is nine days after that time limitation expires.

Petitioners are ORDERED TO SHOW CAUSE on August 11, 2006, at the 2:00 p.m. (EDT) status conference, to explain why this case should not be dismissed.

FACTS

Tomas was born on May 24, 1996. He probably had a seizure in 2001 when he hit his head in a store. Med. recs. at Ex. 6, pp. 52, 55. On July 7, 2004, Mr. Gonzales brought Tomas to the University of New Mexico Hospital as a transfer from Shiprock Hospital. He stated that Tomas did not look right starting on July 4, 2004 and did not seem himself. He had a fever and swelling on his neck. Med. recs. at Ex. 7, p. 1. He had a seizure which lasted two minutes. He had no history of diarrhea or runny nose. *Id.* Tomas had fevers and a viral illness since July 4, 2004 and was seen by a primary care physician who started him on Amoxicillin. He acted funny, did not want to play, and was tired for the next two days. He had a temperature of 102 degrees on July 6, 2004 and was taken to a pediatrician. He was given Tylenol and had swollen neck glands. That night, he had stiffening all over for two minutes. Med. recs. at Ex. 7, p. 7. Mrs. Gonzales reported nightly sightings of a bat for the last month in Shiprock, a "mangy" cat around the house, and several dogs in the area. Med. recs. at Ex. 7, p. 8. Tomas had decreased oral

intake for one day and a reduction of activity for two days. Med. recs. at Ex. 7, p. 9. Tomas had been generally healthy up until this time. Med. recs. at Ex. 7, p. 10. His sister had had a “slight” pneumonia for several days. *Id.*

The death certificate attributes the cause of death to EBV with cerebral edema. Med. recs. at Ex. 8, p. 1. The autopsy showed brain edema and herniation. Med. recs. at Ex. 8, p. 3. Dr. Patricia J. McFeeley’s diagnosis was EBV infection, history of seven days fever and malaise, history of stiffening episodes, marked cerebral edema with tonsillar tenting and uncal herniation, chronic inflammation of portal triads (hepatitis), splenomegaly, and positive EBV IgG and IgM antibodies. Med. recs. at Ex. 8, p. 6. She stated that Tomas’ antibodies to EBV together with his enlarged spleen were characteristic of a viral infection. The lack of evidence of a specific viral infection in his brain suggested an immunotoxic effect of the viral infection. *Id.*

DISCUSSION

This is a causation in fact case because the onset of Tomas’ encephalopathy occurred after the Table time limit of 15 days post-MMR vaccination. To satisfy their burden of proving causation in fact, petitioners must offer "(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[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 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 the MMR vaccine, Tomas would not have had EBV which caused his death, but also that the vaccine was a substantial factor in bringing about his EBV and death. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

According to Tomas’ parents, he became ill on July 4, 2004 with fever. This is 24 days post-vaccination. Considering that the official cause of death was EBV-induced brain edema, the undersigned does not expect petitioners to find an expert medical opinion to state that MMR caused Tomas to contract EBV over three weeks later. Petitioners are ORDERED TO SHOW CAUSE at the August 11th status conference why this case should not be dismissed.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master