

OFFICE OF SPECIAL MASTERS

No. 03-551V

August 11, 2006

NATASHA CARLES, by her Mother and Next Friend, JACKELINE NOVIKOV-CARLES,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

Hepatitis B vaccine followed almost immediately by GBS; a week prior to her vaccination, she had a URI and stuffy nose; causation?

ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated March 10, 2003, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated November 12, 2003, on behalf of her daughter Natasha Carles (hereinafter, "Natasha"), alleging that hepatitis B vaccine administered on March 24, 2000, caused Natasha Guillain-Barre Syndrome (GBS) almost

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.

immediately. According to the amended petition, ¶ 3, the next morning, Natasha had a sudden weakness in her feet and legs. A tingling sensation in her toes developed over the weekend, and as days passed, this sensation spread to her hands, arms, mouth and legs.

Petitioner is ORDERED TO SHOW CAUSE by September 29, 2006 why this case should not be dismissed.

FACTS

Natasha was born on May 26, 1988.

On March 24, 2000, Natasha went to Dr. Nadia Ghattas for a check-up. Med. recs. at Ex. 1, p. 6. She complained about frequent headaches. On physical examination, Natasha had nasal congestion. Dr. Ghattas' impression was headache and allergic rhinitis. *Id.* She prescribed nasonix nasal spray, one spray to each nostril. Med. recs. at Ex. 1, p. 7. On that date, Natasha received hepatitis B vaccine. *Id.*

On April 3, 2000, Natasha returned to Dr. Ghattas, complaining of pain in her knees and weakness, backache, and muscle soreness. She fell on the steps once in school. *Id.* On physical examination, Dr. Ghattas noted unsteady walking, marked muscle weakness of thighs and legs, more marked on the left side, with a normal sensory examination. Natasha needed help to get off the examining table. Dr. Ghattas referred her to a neurologist. *Id.*

On April 5, 2000, Dr. Marilyn A. Kubichek, a pediatric neurologist, saw Natasha. Her father accompanied Natasha. Med. recs. at Ex. 1, p. 13. Natasha noticed muscle soreness starting about one and one-half weeks earlier in her lower extremities which got worse. A week ago, the soreness was intolerable. She needed assistance to walk down stairs. *Id.* On examination, her upper extremities strength was 4/5 bilaterally. Her lower extremities strength

was 3-/5 bilaterally. Sensory examination showed decreased sensation in a stocking/glove distribution. Her deep tendon reflexes (DTRs) were absent. Her gait was wide based. Med. recs. at Ex. 1, p. 14. Dr. Kubichek wanted to rule out GBS. *Id.*

On April 5, 2000, Natasha was admitted to St. Barnabas Medical Center. Med. recs. at Ex. 2, p. 4. Natasha had been complaining of pain in her hips and lower extremities for a period of about two weeks. Prior to her March 24, 2000 visit to the doctor, her parents considered her recent physical activity (basketball) as the contributing factor and did not seek help for Natasha at that time. *Id.*

They gave a history that Natasha had a stuffy nose and URI symptoms a week prior to her hepatitis B vaccination. Med. recs. at Ex. 2, p. 5.

Medical histories that Natasha's parents gave to the hospital treaters indicate that Natasha's weakness began before she received hepatitis B vaccine. On April 5, 2000, they stated that Natasha had a history of weakness on March 22nd of her lower extremities which they attributed to physical activity. She received a hepatitis B vaccination on March 24th. She had progressive worsening of her weakness. Med. recs. at Ex. 2, p. 20. Also on April 5, 2000, they told other hospital personnel that Natasha was in her usual healthy state until a month previously when she had soreness of her upper legs which her mother attributed to basketball practice. On March 24th, Natasha received her first hepatitis B vaccine and, since then, had complained of first lower leg weakness and now full leg weakness. This was different than the previous soreness which had improved. Med. recs. at Ex. 2, p. 17.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner 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).

Petitioner must show not only that but for the vaccine, Natasha would not have had GBS, but also that the vaccine was a substantial factor in bringing about her GBS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and did so in that case. The onset interval after hepatitis B vaccination was three weeks. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, Natasha's onset of GBS was within 24 hours, a period too close in time to vaccination to cause demyelination. Moreover, she had an upper respiratory infection for a week prior to her vaccination, and a URI itself can cause GBS. One week's time between URI and onset of GBS symptoms fits within a medically appropriate time frame for causation. (There are some histories of headaches, leg weakness and soreness that antecede the vaccination which raise the possibility that onset of Natasha's GBS occurred before vaccination.)

Petitioner must file an expert report stating that hepatitis B vaccine was a substantial factor in causing Natasha's GBS by **September 29, 2006** or this case will be dismissed.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 29, 2006**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master