

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-26V

September 29, 2009

To be Published

MICHAEL PATRICK RILEY, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Richard R. Buley, Missoula, MT, for petitioner.

Michael P. Milmo, Washington, DC, for respondent.

Entitlement: influenza vaccine; eight days later, Guillain-Barré syndrome; respondent asks for ruling on the record

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

Petitioner filed a petition on January 15, 2008, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that influenza vaccine administered on

¹ 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.

November 6, 2006 caused him Guillain-Barré syndrome (GBS) whose onset was eight days later..

Petitioner was admitted to Community Medical Center in Missoula, MT, on November 20, 2006. He was discharged on January 25, 2007 with a diagnosis of GBS secondary to influenza vaccine. Med. recs. at Ex. 5, p. 131. Dr. T. Shull Lemire wrote the discharge summary.

Petitioner filed an expert report from a treating physician, Dr. Denise Allen. Med. recs. at Ex. 10, p. 604.

Petitioner also filed on April 6, 2009 an expert report from another treating physician, Dr. T. Shull Lemire.

Respondent filed a Rule 4(c) Report and Request for Ruling on the Record on September 25, 2009, denying that compensation was appropriate, but choosing not to expend further resources to defend the case. Respondent did not file an expert report.

Dr. Allen's Expert Report

Dr. Allen, a rehabilitation specialist, has been petitioner's treating doctor since January 4, 2007. Med. recs. at Ex. 10, p. 605. She states that petitioner's GBS was almost certainly caused by his influenza vaccination of November 6, 2006. *Id.* She states that she has treated a number of people with GBS which is an inflammatory disorder in which the body's immune system attacks the nerves outside the brain and spinal cord. *Id.* She continues, "It is well known and documented in the literature that Guillain-Barre Syndrome may occur within days or weeks of an influenza infection or an influenza vaccination." *Id.* Dr. Allen calls petitioner's GBS a classic presentation with occurrence after an influenza vaccination with a total absence of any other

factor known to trigger GBS. *Id.* Therefore, her opinion is that the influenza vaccination on November 6, 2006 caused petitioner's GBS. *Id.*

Dr. Lemire's Expert Report

Dr. Lemire states that, based on the facts of petitioner's case and a review of the literature, petitioner's GBS was caused by his influenza vaccination. Filing of April 6, 2009, p. 1. He describes GBS as an acute, immune-mediated demyelinating polyneuropathy. *Id.* He recounts various medical articles in support of causation of GBS from flu vaccine. *Id.*

Dr. Lemire recounts a number of causes of GBS, such as recent infectious illnesses, including influenza, Epstein-Barre virus, HIV viruses, and bacterial infections. *Id.* Petitioner received flu vaccine on November 6, 2006, and came to the hospital with diffuse numbness and lower extremity weakness 10 days later. *Id.* at pp. 1-2. A spinal fluid study showed no bacteria or other disease process. There was no evidence that petitioner had been sick at all before his GBS because he had no complaints of nausea, vomiting, diarrhea, or other symptoms of possible viral infection. *Id.* at p. 2.

Before petitioner received flu vaccine, he was given an informed consent form asking if he were sick with an acute infection, including fever, or if he had any immunosuppressive diseases, to which petitioner answered no. *Id.*

In light of a complete absence of any triggering mechanism other than the influenza vaccine, and petitioner's GBS following the specific pattern one would expect to see in GBS following influenza vaccination, Dr. Lemire opines that the influenza vaccine he received on November 6, 2006 caused petitioner's GBS. *Id.*

DISCUSSION

This is a causation in fact case. To satisfy his 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, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148

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

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal “compensation program” under which awards are to be “made to vaccine-injured persons quickly, easily, and with certainty and generosity.” House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.

The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

Dr. Allen and Dr. Lemire, both treating physicians who submitted expert reports, state that GBS has frequently been causally associated with influenza vaccine in the medical literature. They also note that GBS is an autoimmune or immune-mediated disease. They emphasize that petitioner had no causes, such as bacterial or viral infection, for GBS except for influenza vaccine which was administered within an appropriate time period before his onset of GBS to signify causation.

The Federal Circuit in Capizzano emphasized the importance of the special masters’ heeding the opinions of petitioner’s four treating doctors in that case since “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” 440 F.3d at 1326. See also Andreu

v. Secretary of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009). Here, there are two treating doctors opining that the vaccination caused petitioner's injury.

Respondent has not filed an expert opinion and has chosen not to expend further resources to contest entitlement.

Petitioner has proved causation in fact. The parties are now in damages and have both filed life care plans. Their sole issue in dispute is whether petitioner's pre-vaccination shoulder degeneration is the cause of his current shoulder problems or GBS has exacerbated his pre-vaccination shoulder problems. Each side has submitted medical expert reports describing that petitioner's shoulder problem is or is not exacerbated by his GBS.

CONCLUSION

Petitioner is entitled to reasonable compensation. The next telephonic status conference on October 5, 2009 at 12:30 p.m. (EDT) will focus on resolving the issue of damages.

IT IS SO ORDERED.

September 29, 2009
DATE

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