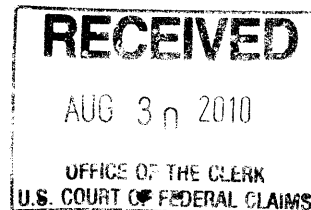


In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No.99-202V

August 30, 2010



LISA A. LIPPA,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Respondent.

Lisa A. Lipa, Mechanicsville, VA, for petitioner (pro se).

Glenn A. MacLeod, Washington, DC, for respondent.

Onset of neurologic symptoms
four months after hepatitis B
vaccination; petitioner requests
dismissal

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition dated July 28, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine caused an unspecified adverse reaction. This ultimately turned out to be multiple sclerosis (MS).

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.

A record from Henderson County Health Department shows that petitioner received her first hepatitis B vaccination on November 10, 1995 and her second hepatitis B vaccination on December 8, 1995. P's Ex. C.

Four months after her second hepatitis B vaccination, on April 12, 1996, petitioner saw her physician, Dr. Zenida Maddela, about a feeling of pins and needles in her left foot which had started the previous Sunday, putting onset at April 7, 1996. P's Ex. B, p. 5.

On April 20, 1996, petitioner saw Dr. Pedro Dominguez at Community Methodist Hospital for a consultation. Dr. Dominguez stated petitioner had no significant problems until she developed numbness in her left foot during Easter, two to three weeks previously. She did not have any headaches or any other symptoms. R. Ex. N, p. 29.

On April 25, 1996, petitioner saw Dr. Steven P. Kuric, a neurologist, and denied that she had had any recent illness or infection prior to her onset after Easter 1996 of numbness in her left foot. She also denied any prior headaches. R. Ex. N, p. 1.

On October 22, 1997, petitioner saw Dr. Paul L. Moots, a neurologist, and stated that before the onset of numbness in her left foot in April 1996, she did not have any prior focal neurologic symptoms, including those involving vision, balance, dysarthria, weakness, or numbness. She denied any prior infections or febrile illnesses. R. Ex. O, pp. 6-7.

This case's sole issue is whether hepatitis B vaccination can cause MS when there is a four-month gap between vaccination and onset. The undersigned has previously held that hepatitis B vaccine can cause MS if it occurs within one month. See, e.g., Werderitsh v. Sec'y of HHS, No. 99-310V, 1999 WL 1672884 (Fed. Cl. Spec. Mstr. 1999) (one-month onset of MS after second hepatitis B vaccination). Recently that time interval has been extended to two

months in demyelinating cases. See, e.g., Jane Doe/64 v. Sec'y of HHS, No. [redacted], 2009 WL 180078 (Fed. Cl. Spec. Mstr. January 21, 2009) (two-month onset of variant of MS called Devic's Disease after second hepatitis B vaccination). But the undersigned has never held that hepatitis B vaccine can cause demyelination four months post-vaccination.

During a status conference held on August 30, 2010, petitioner asked to dismiss this case. The undersigned grants her request.

DISCUSSION

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 1317, 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. Id. at 1148.

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

Here, petitioner's onset of MS was four months after her second hepatitis B vaccination. Under the Federal Circuit's rulings in Knudsen, Althen, and Capizzano, petitioner must prove a biologically plausible medical theory connecting causally the vaccination and the illness, a logical sequence of cause and effect, and a medically appropriate time frame between vaccination and onset. It is the time interval that is the problem in this case.

Petitioner's motion to dismiss is granted. Petitioner has failed to make a prima facie case and this petition must be 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 in accordance herewith.²

IT IS SO ORDERED.

Aug. 30, 2010
DATE

Laura D. Millman
Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.