

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 01-308V

December 15, 2009

To be Published

ERIC BIENIUS,

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Petitioner,

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v.

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Entitlement: hepatitis B vaccine;

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CIDP not uremic neuropathy in

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the context of kidney disease

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

*

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Respondent.

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Clifford J. Shoemaker, Vienna, VA, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

Petitioner filed a petition dated May 21, 2001 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccines administered on April 17, 1998, May 18, 1998, and June 17, 1998 caused him Guillain-Barré syndrome (GBS). This diagnosis was later changed to chronic inflammatory demyelinating polyneuropathy (CIDP).

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.

According to petitioner's Ex. 35, p. 264, his onset of CIDP occurred after his second hepatitis B vaccination and was aggravated after his third hepatitis B vaccination.

On May 21, 2001, this case was assigned to chief special master Gary J. Golkiewicz.

On November 15, 2001, petitioner filed medical records.

On May 28, 2002., petitioner filed the expert report of Dr. Carlo Tornatore.

On July 24, 2002, this case was reassigned to former special master E. Lavon French.

On February 12, 2003, respondent filed her Rule 4(b) Report.

On November 25, 2003, the case was reassigned to chief special master Gary J.

Golkiewicz.

On January 15, 2004, petitioner filed an intent to participate in Omnibus proceedings on whether hepatitis B vaccine could cause demyelinating illnesses.

On January 23, 2004, the case was reassigned to former special master (now Judge) Margaret M. Sweeney.

From October 13-15, 2004, former special master Sweeney held the Omnibus hearing on hepatitis B vaccine and demyelinating illnesses.

In December 2005, former special master Sweeney became a judge on the US Court of Federal Claims.

On January 10, 2006, this case was assigned to the undersigned together with 64 other cases that comprised the Omnibus hepatitis B vaccine-demyelinating injury cases, dealing with transverse myelitis (TM), GBS, CIDP, and multiple sclerosis (MS).

In the four Omnibus paradigm decisions the undersigned issued² the undersigned ruled that hepatitis B vaccine can cause TM, GBS, CIDP, and MS and did so in those cases.

On December 9, 2009, in a telephonic status conference, respondent's counsel stated that respondent will no longer defend this case and asked for a ruling on the record, based on petitioner's expert Dr. William Wilmer's supplemental report which addressed respondent's expert Dr. Bernard Kaplan's concerns.

Experts

Dr. William Wilmer

Attached to the petition as Ex. 10 is an Affidavit dated May 18, 2001 from petitioner's treating nephrologist (kidney specialist), Dr. William Wilmer, opining that petitioner's GBS was due to hepatitis B vaccine.

In the medical records at Ex. 44, p. 138, is a letter Dr. Wilmer wrote dated May 1, 2001, stating that petitioner's GBS/CIDP was associated with his hepatitis B vaccinations, occurring abruptly after his second vaccination and then severely worsening after his third vaccination.

In the medical records at Ex. 47, p. 1, is a letter Dr. Wilmer wrote dated February 18, 2005, stating that he attributes petitioner's debilitating complication to hepatitis B vaccination.

² Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused TM; onset was 12 or 13 days after first vaccination with recovery; onset of TM was one week after second vaccination); Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused GBS and CIDP; onset was 21 days after second vaccination); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS; onset was one month after second vaccination); Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused GBS and death; onset of GBS was eight days after fourth vaccination).

On November 9, 2009, in response to respondent's expert Dr. Kaplan's opinion that petitioner's neuropathy was due to end-stage renal disease, petitioner filed Ex. 64, a supplemental report from Dr. Wilmer, distinguishing on page 1 between uremic neuropathy which is predominantly sensory and petitioner's CIDP which was predominantly motor. In addition, weakness is not typical of uremia. On page 2, Dr. Wilmer states that petitioner did not have an identifiable infection at the time, and despite dialysis, which restored his energy level and appetite, and ameliorated other uremic symptoms, his condition worsened neurologically.

Dr. John R. Warmolts

On page 176 of medical records filed on November 15, 2001 (refiled on December 17, 2008 as Ex. 44, p. 141) is a letter from a treating neurologist Dr. John R. Warmolts to a nephrologist Dr. Donald Middendorf recounting that it was of note that petitioner received two hepatitis B vaccinations and pneumonia vaccine six weeks before he had the onset of weakness. Petitioner had congenital absence of the left kidney and was on peritoneal dialysis following the recent development of renal failure. On page 177, Dr. Warmolts states it is speculatively possible that petitioner's GBS was due to his recent vaccinations. He did not relate it to renal disease. He advised petitioner to forego any future flu or hepatitis vaccinations.

Dr. Carlo Tornatore

On March 28, 2002, refiled as Ex. 12 on March 28, 2008, petitioner filed the expert report of Dr. Carlo Tornatore, a neurologist, stating that within 10 days of his second hepatitis B vaccination, petitioner had onset of weakness in his lower extremities, later diagnosed as GBS. Dr. Tornatore opined that hepatitis B vaccine caused petitioner's GBS.

Dr. Vinay Chaudhry

On February 12, 2003, respondent filed as Ex. A the expert report of Dr. Vinay Chaudry, a neurologist, stating that petitioner did not have GBS but instead CIDP or a subacute inflammatory demyelinating polyneuropathy or acute uremic neuropathy related to renal failure, not to the vaccinations. Among the articles attached to Dr. Chaudry's expert report is an article entitled "Accelerated Neuropathy of Renal Failure" by Dr. A.H. Ropper, 50 Arch Neur 536-39 (1993). Ex. B, No. 2.

Dr. Bernard S. Kaplan

On July 30, 2009, respondent filed as Ex. D the expert report of Dr. Bernard S. Kaplan, a pediatric nephrologist, who stated at page 5 that petitioner's neuropathy was related to his chronic kidney disease and resembled but was not identical to GBS. Respondent's Exs. G, H, and I are articles discussing neuropathy associated with end-stage renal disease.

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 CIDP, but also that the vaccine was a substantial factor in bringing about his CIDP. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner’s treating doctors 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, we have two treating physicians, Drs. Wilmer (nephrologist) and Warmolts (neurology), opining in the medical records that petitioner’s hepatitis B vaccinations caused his CIDP. We even have positive rechallenge because, after becoming ill a week following his second hepatitis B vaccination, petitioner became significantly worse a week after his third hepatitis B vaccination. This is in addition to the expert report of Dr. Tornatore. The

undersigned need not reiterate the numerous decisions in which petitioners have satisfied the three Althen prongs in hepatitis B vaccine-CIDP cases.

Respondent recognizes the strength of petitioner's proof and expressed the intent to end its defense on the issue of entitlement. Petitioner has prevailed on entitlement.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement. The next telephonic status conference is set for Wednesday, January 27, 2010, at noon (EST), to proceed in resolving the issue of damages.

IT IS SO ORDERED.

December 15, 2009
DATE

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