

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. [redacted]V

January 16, 2009

Reissued redacted on January 21, 2009

To Be Published

JANE DOE/29, Personal Representative *
of the Estate of DECEDENT, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

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

Linda S. Renzi, Washington, DC, for respondent.

Entitlement; Hep B vaccine;
two months later, Devic's Disease
(a variant of MS) then death

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

The original petitioner filed a petition on April 3, 2000, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations

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. Petitioner moved to redact her name and that of decedent. The undersigned grants petitioner's motion and reissues this ruling on entitlement in redacted form.

administered on April 20, 1998 and May 20, 1998 caused her unspecified injury. She later alleged multiple sclerosis (MS). Petitioner died on May 21, 2008. The cause of death was reported as “Complications of demyelinating disorder (probable Devic’s Disease).” P. Ex. 32, p. 12. The case continues with the personal representative of decedent’s estate as petitioner.

On December 8, 2008, respondent filed a Rule 4(c) Report and Request for Ruling on the Record. Respondent determined not to expend further resources defending this case and asked the undersigned to rule on the existing record.

FACTS

Decedent was born on December 4, 1961.

On April 20, 1998, she received her first hepatitis B vaccination. Med. recs. at Ex. 8, p. 3.

On May 20, 1998, decedent received her second hepatitis B vaccination. *Id.*

On July 26, 1998, two months after her second hepatitis B vaccination, decedent noted retro-orbital pressure in her left eye followed by decreased visual function. Med. recs. at Ex. 1, p. 51. Initial pressure sensation improved with antihistamines. *Id.*

On July 27, 1998, she noted a curtain over the superior visual field in her left eye which gradually progressed. She saw Dr. Linda Angell on July 30, 1998 on an emergency basis. She told Dr. Angell she had a gray spot field of vision with sudden onset. Med. recs. at Ex. 6, p. 24. She had no history of headache, dizziness, or previous blurred vision, diplopia, numbness or weakness, of even a transient nature. Med. recs. at Ex. 1, p. 51.

On July 28, 1998, decedent saw Dr. James Rawlinson with a field defect in the lateral aspect of her left eye. She had had two previous episodes where both eyes were affected which

lasted a day or two. She recalled no headache afterwards. She had mild discomfort in her eyes. Med. recs. at Ex. 8, p. 95.

On August 4, 1998, decedent saw Dr. Eric R. Eggenberger for a neuro-ophthalmologic evaluation and he diagnosed her left eye with retrobulbar optic neuropathy, most logically optic neuritis. *Id.*

On September 8, 1998, decedent saw Dr. Rawlinson with leg pain and weakness. Med. recs. at Ex. 8, p. 96. She had a two-week history of intermittent weakness in her left leg. On one occasion, it gave out and she started to fall but caught herself. Recently, she had some mild discomfort in her right calf. *Id.*

On September 18, 1998, decedent saw Dr. Rawlinson with leg pain and vision problems. She had complete resolution of her visual disturbances after taking IV steroids followed by a Prednisone taper. Med. recs. at Ex. 8, p. 97. The pain in her left calf resolved on the Prednisone. She had been off Prednisone for two weeks and began experiencing visual disturbances similar to her prior experience which seemed to be primarily a field defect and her vision seemed darker in the lateral aspect of her left eye. She also had some mild discomfort above the eye and some nasal congestion, but no purulent drainage and no sore throat or ear pain. Decedent questioned if her multiple sclerosis symptoms were due to her receiving hepatitis B vaccine on April 20, 1998 and May 20, 1998. She became symptomatic for the first time on July 14, 1998. *Id.*

On January 25, 1999, decedent had an MRI scan of her brain which was negative. Med. recs. at Ex. 1, p. 65. There was an abnormal signal in the upper cervical spinal cord which was improved when compared to a previous MRI of December 31, 1998. *Id.* Dr. David I. Kaufman diagnosed neurologic syndrome involving decedent's optic nerves and spinal cord. The cause

could be Devic's syndrome (neuromyelitis optica) secondary to MS. However, sarcoid or other etiologies could not be eliminated. *Id.* Decedent also had a right lumbosacral radiculopathy most likely corresponding to a right L5-S1 nerve root abnormality. A mildly axonal primary motor peripheral polyneuropathy might be possible. *Id.*

On June 25, 1999, decedent saw Dr. Daniel L. Murman, a neurologist. Med. recs. at Ex. 1, p. 69. She had been hospitalized in April for significant worsening of her myelitis resulting in quadriparesis and sensory loss below the cervical region. On June 15, 1999, decedent developed blurring of her right eye. *Id.*

Other Submitted Material

Petitioner filed exhibit 17, neurologist Dr. Carlo Tornatore's expert report, dated October 9, 2007. He states that it is biologically plausible for hepatitis B to cause demyelination because vaccines are composed of organic compounds of viral or bacterial origin, whether recombinant or otherwise, whose purpose is to initiate an immune response in the recipient. Ex. 17, p. 6. But if any of the vaccine antigens shares a homology with the recipient's antigens, the host's immune response will attack both the vaccine antigens and the host's antigens, resulting in an autoimmune response. Ex. 17, pp. 6-7. This concept is also known as molecular mimicry and is well-established in immunology. Dr. Tornatore refers to three filed articles (P. Exs. 19-21). Ex. 17, p. 7. He concludes that hepatitis B vaccine caused decedent's MS.

Petitioner filed a supplemental report from Dr. Tornatore, dated November 25, 2007. P. Ex. 22. He thought that the decedent's onset of demyelinating optic neuritis might have occurred approximately 18 days after her hepatitis B vaccination, although the medical records reflected a two-month interval. *Id.*

Petitioner's exhibit 20 is an article entitled "A study of molecular mimicry and immunological cross-reactivity between hepatitis B surface antigen and myelin mimics" by D-P Bogdanos, et al., 12 *Clin & Develop Immunol* 3:217-24 (2005). The authors begin their article with the statement: "Molecular mimicry based on amino acid similarities shared by viral and self antigens has long been proposed as a pathogenic mechanism for autoimmune disease" *Id.* at 217. They conducted tests involving hepatitis B vaccinees to see if there were cross-reactivity between hepatitis B vaccine surface antigen and myelin mimics in normal subjects and found there was such reactivity for a limited time period without the subjects having clinical symptoms.

Respondent did not file an expert report.

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. *Id.* at 1148.

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

Here, the decedent's onset of Devic's disease (a variant of MS) was two months after her second vaccination. In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. However, the onset interval after vaccination in Werderitsh was one month. Dr. Roland Martin, respondent's expert, testified in Werderitsh that an appropriate temporal interval for an immune reaction would be a few days to three to four weeks. Werderitsh was one of the four paradigm cases in the Omnibus hepatitis B vaccine-demyelinating illnesses proceeding involving multiple sclerosis, transverse myelitis, Guillain-Barré syndrome, and chronic inflammatory demyelinating polyneuropathy.

But in Pecorella v. Secretary of HHS, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008), this one-month limit on the appropriate time interval between vaccination and illness became extended to two months. In Pecorella, petitioner alleged causation of transverse myelitis two months after she received hepatitis B vaccine. Respondent, as in the instant action, preferred not to expend any more resources in defending the case and asked for a

ruling on the record. The undersigned had previously ruled in another paradigm cases in the Omnibus hepatitis B vaccine-demyelinating illnesses proceeding, Stevens v. Secretary of HHS, No. 99594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), that hepatitis B vaccine could cause transverse myelitis and did in that case. In Pecorella, the undersigned ruled for petitioner.

Since the Pecorella decision, the undersigned has accepted that the medically appropriate time frame for causation in the hepatitis B vaccine-demyelinating illnesses cases is now up to two months after vaccination.

In the instant action, decedent's onset of Devic's Disease, a variant of MS, is either 18 days (her and petitioner's recollection of onset, but not reflected in the medical records) or two months (reflected in the medical records) after vaccination. If onset is 18 days, decedent fits within the old accepted time frame of three to 30 days between vaccination and onset. If the onset is two months, decedent fits within the new accepted time frame of two months set in Pecorella.

Petitioner's expert neurologist, Dr. Carlo Tornatore, discussed in his reports the concept of molecular mimicry as the biologically plausible medical theory underlying the first prong of causation. There is a logical sequence of cause and effect in petitioner's having received the vaccination and then experiencing optic neuritis, the first symptom of her Devic's Disease, a variant of MS. As discussed, the onset after vaccination is appropriate to prove causation, whether the onset is 18 days or two months after vaccination.

Petitioner has prevailed on the issue of entitlement. The medical records during decedent's final hospitalization reflect that she died from demyelinating disease. Not only did decedent have a vaccine injury, but also her death was vaccine-related.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement and will have a telephonic status conference soon with the parties to discuss further proceedings.

IT IS SO ORDERED.

January 16, 2009
DATE

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