

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-408V

May 28, 2008

To be Published

LORI BARILLARO, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

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

Althea W. Davis, Washington, DC, for respondent.

Entitlement; hepatitis B vaccine followed 3 weeks later by optic neuritis and ultimately MS

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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.

Petitioner filed a petition on June 28, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that hepatitis B vaccine caused her optic neuritis three weeks later and, ultimately, multiple sclerosis (MS).

On June 28, 1999, this case was initially assigned to special master John Edwards. On August 3, 1999, the chief special master assigned the case to himself. On April 5, 2001, the chief special master assigned the case to the undersigned. On December 5, 2002, the chief special master again assigned the case to himself. On May 7, 2003, the chief special master assigned the case to former special master Margaret M. Sweeney. From October 13-15, 2004, former special master Sweeney took testimony in the Omnibus proceedings on hepatitis B vaccine and demyelinating illnesses. On January 11, 2006, the chief special master again assigned this case to the undersigned.

On July 26, 2006, the undersigned issued an opinion in Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), one of the four paradigm cases in the Omnibus proceeding, holding that hepatitis B vaccine can and did cause petitioner's MS which began one month after her second hepatitis B vaccination. 2006 WL 1672884, at *2. The time interval between her vaccination and the onset of her MS was medically appropriate. 2006 WL 1672884, at *26.

On November 9, 2006, in the instant action, during a telephonic status conference, respondent's counsel stated respondent wanted to attempt a litigative risk settlement in this case. After 10 telephonic status conferences, respondent asked during the March 3, 2008 status conference that the undersigned issue a ruling on entitlement on the record. The undersigned

responded that petitioner would have to file an expert medical report in order to prove causation in fact.

On May 27, 2008, petitioner filed Dr. Carlo Tornatore's expert report and curriculum vitae (Ex. 55).

FACTS

Petitioner was born on August 16, 1955.

On February 3, 1998, petitioner received hepatitis B vaccine.

On February 23, 1998, petitioner saw Dr. Perin Diana, Jr., who diagnosed her with optic neuritis. Med. recs. at Ex. 2, p. 2.

On February 25, 1998, petitioner saw Dr. Gary Dee, who did an MRI of her head with and without contrast. The result twas petitioner had a small right periventricular white matter lesion. Dr. Dee questioned if she had demyelinating disease. Med. recs. at Ex. 12, p. 20.

On February 27, 1998, petitioner saw Dr. Harold E. Trinkoff, a neurologist. She had no other symptoms, including no motor, sensory, gait, or bladder problems. Her neurological examination was normal except for her right eye. He diagnosed petitioner with right retrobulbar neuritis. She did not have symptoms of demyelinating disease or MS. Med. recs. at Ex. 12, p. 18.

On March 5, 1998, petitioner saw Dr. Trinkoff again and he administered a visual evoked potential test. She did not have neurophysiological evidence suggestive of diffuse neurological involvement such as demyelinating disease. MEd. recs. at Ex. 12, p. 17.

On May 14, 1998, petitioner saw Dr. Robert L. Lesser, an ophthalmologist. He diagnosed her with optic neuritis in her right eye without recovery. The history was that, on February 23,

1998, she lost vision in her right eye but did not have pain on movement of the eye. However, her lost vision was preceded by a sharp pain in the back of her head on the right side going up to her forehead. By the next day, she noted she had no useful vision. She recalled receiving a hepatitis B vaccination about a week before the onset of the visual loss with no systemic reaction. Dr. Diana had diagnosed petitioner with optic neuritis on February 23, 1998. Med. recs. at Ex. 1, p. 8.

On June 19, 1998, petitioner saw Dr. Trinkoff with new recent symptoms. For the prior two weeks, her left hand and arm and her face had numbness. She had a low B12 level. He did not detect any motor or sensory deficits and assumed she was having a minor exacerbation of MS. Med. recs. at Ex. 12, p. 15.

On the same day, petitioner had another MRI of her head done. Med. recs. at Ex. 12, p. 14. Dr. Harry Hajedemos interpreted the MRI as showing interval enlargement of the right periventricular signal abnormality consistent with an acute and active demyelinating plaque secondary to MS. *Id.*

On March 23, 1999, Dr. Trinkoff wrote that petitioner had a history of MS symptoms three weeks after receiving hepatitis B vaccine. Med. recs. at Ex. 12, p. 8.

On July 13, 2000, Dr. Trinkoff administered a nerve conduction study of petitioner's leg after she complained of leg numbness lasting for an hour, left greater than right. Med. recs. at Ex. 12, p. 3. She had a normal neurophysiological study of her left lower extremity without evidence of peripheral nerve dysfunction. *Id.* Dr. Trinkoff stated her symptoms were unusual for demyelinating disease given that she would have episodes lasting a few minutes. Leg symptoms were also atypical for demyelinating disease. Med. recs. at Ex. 12, p. 2.

On July 23, 1999, petitioner saw Dr. Arthur M. Siegel, a neurologist. He found her neurologically normal except for her eye. He attributed her optic neuritis to a post-allergic reaction to hepatitis B vaccine. Med. recs. at Ex. 14, p. 1.

On February 23, 2001, Dr. Burton A. Waisbren, Sr., wrote that petitioner had post-hepatitis B MS. Vaccines cause demyelinating disease. The time frame was consistent. Med. recs. at Ex. 33, pp. 62, 72, 73.

On August 6, 2001, petitioners saw Dr. Edward J. Fredericks who felt there was no relationship between her vaccination and MS. Med. recs. at Ex. 26, p. 24.

On August 20, 2001, petitioner saw Dr. John G. Gitzus who stated that a 20-day onset was too short to link MS to hepatitis B and that her first hepatitis B vaccination did not provoke antibodies and there was no molecular mimicry. Med. recs. at Ex. 27, p. 4.

On September 21, 2001, Dr. Trinkoff wrote that he initially believed there was no association between hepatitis B and petitioner's MS, but he changed his mind based on his experience with one patient. Med. recs. at Ex. 32, pp. 12, 19.

Other Submitted Material

Dr. Carlo Tornatore, a neurologist, submitted an expert report. P. Ex. 55. He states that petitioner developed an acute onset of optic neuritis about three weeks after receiving hepatitis B vaccine. She ultimately developed MS. His opinion is that hepatitis B vaccine caused her optic neuritis and MS. Ex. 55, p. 7. The basis of Dr. Tornatore's opinion is that it is biologically plausible for hepatitis B vaccine to cause demyelination because it is composed of antigens that are made of organic compounds of viral origin. If petitioner has antigens sharing a homology with the vaccine's antigens, then petitioner's immune response to the vaccine will also be

directed at her own antigens, leading to an autoimmune response. The concept that viral antigens share homology with host antigens is well established in immunology. Moreover, the temporal relationship of the vaccination and the onset of petitioner's neurological symptoms and a logical sequence of cause and effect form the basis of his opinion.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(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"

Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

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. 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 hepatitis B vaccine, she would not have had optic neuritis and MS, but also that the vaccine was a substantial factor in bringing about her optic neuritis and MS. 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.

The Federal Circuit stated in Althen, 418 F.3d at 1280, that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."

The Federal Circuit in Capizzano emphasized the opinions of petitioner's four treating doctors in that case. 440 F.3d at 1326. In the instant action, there are treating doctors who have opined both for and against causation from the hepatitis B vaccination.

As the Federal Circuit stated in Knudsen, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." The undersigned's task is to determine medical probability based on the evidence before the undersigned in this particular case. Althen, 418 F.3d at 1281 ("judging the merits of individual claims on a case-by-case basis").

The Federal Circuit in Knudsen, 35 F.3d at 549, also stated: "The special masters are not 'diagnosing' vaccine-related injuries."

Dr. Tornatore's theory here that a biologic component in hepatitis B vaccine caused petitioner's immune response to react against not only the vaccine antigen but also against a similar or homologous antigen in her own body, causing autoimmune disease. This theory is biologically plausible and the undersigned accepted that theory in Werderitsh.

The pathological process described in the medical literature that Dr. Tornatore cited and discussed in his report is consistent with petitioner's clinical course, and shows a logical sequence of cause and effect between the vaccination and the onset of her neurological symptomatology.

The timing here of three weeks between petitioner's vaccination and her onset of optic neuritis was appropriate for an immune response.

Petitioner has satisfied the three prongs enunciated by the Federal Circuit in Althen. Petitioner has proved a prima facie case of causation in fact that hepatitis B vaccine caused her

optic neuritis and MS, and that, without the hepatitis B vaccination, she would not have had the injury.

CONCLUSION

Petitioner has prevailed on the issue of entitlement. The undersigned encourages the parties to settle damages in this case. A telephonic status conference will be held today to discuss how the parties are proceeding with damages.

IT IS SO ORDERED.

May 28, 2008
DATE

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