

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-295V

September 8, 2010

To Be Published

NANCY DAVIS, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Ronald C. Homer, Boston, MA, for petitioner.

Ann D. Martin, Washington, DC, for respondent.

Entitlement; tetanus toxoid;
transverse myelitis nine days
later; respondent requests
ruling on the record

MILLMAN, Special Master

RULING ON ENTITLEMENT¹

Petitioner filed a petition dated May 11, 2009, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that tetanus toxoid and diphtheria vaccine (Td)

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.

administered to her on June 28, 2006 caused her to suffer transverse myelitis (TM), the onset of which was nine days later.

On August 20, 2009, respondent file a Rule 4(c) Report, stating that petitioner was not entitled to compensation because she had not filed an expert report in support of her allegation. Rule 4(c) Report, pp. 9-10.

On October 30, 2009, petitioner filed an expert report from the neurologist Dr. Carlo Tornatore (Exhibit 19), together with 19 medical articles (Tabs A through S), and Dr. Tornatore's curriculum vitae (Exhibit 20). Dr. Tornatore states that petitioner had a combined axonal and demyelinating neuropathy which Dr. Tornatore described as a combination of TM and peripheral neuritis called myeloneuritis, which is a variant of acute disseminated encephalomyelitis (ADEM) and TM. Ex. 19, p. 10. He then proceeds to discuss in depth the pathological manifestations of TM plus the medical literature attached to his report. TM when manifesting as an autoimmune disease is due to a variety of humoral and cellular immune derangements resulting in neuronal injury and demyelination. Id. A variety of immune stimuli through molecular mimicry or superantigen-mediated immune activation may trigger the immune system to injure the nervous system. Id. Post-vaccinal TM has been reported in the literature following hepatitis B, rabies, smallpox, typhoid, influenza, tetanus, DTaP, MMR, and rubella vaccinations. Id. at 11. Dr. Tornatore notes that the Johns Hopkins Transverse Myelitis Center evaluates patients with acute myelopathies by determining whether there has been a recent vaccination or systemic illness. Id. Dr. Tornatore then specifically reviews the medical literature including textbook discussions of causation between vaccinations and TM. Id. at 12-

14. The literature which he describes also posits a time frame that is consistent with petitioner's case herein. Id. at 14.

On February 26, 2010, during a telephonic status conference, respondent's counsel advised that her client decided not to get an expert in this case and requested 30 days to file respondent's position.

On March 29, 2010, respondent filed Respondent's Notice of Filing Statement, stating "she does not intend to submit further evidence on this issue." R's Notice, p. 1. Respondent notes that in light of similar cases in which the undersigned has ruled for petitioners, the testimony of respondent's expert would not be useful here, citing: Stevens v. Sec'y of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. 2006) (hepatitis B vaccine caused TM); Camerlin v. Sec'y of HHS, No. 99-615V, 2003WL 22853070 (Fed. Cl. Spec. Mstr. 2003) (HiB vaccine caused ADEM/TM); Herkert v. Sec'y of HHS, No. 97-518V, 2000 WL 141263 (Fed. Cl. Spec. Mstr. 2000) (DTaP vaccine was a substantial factor causing TM); and Johnson v. Sec'y of HHS, No. 99-219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. 2000) (Td vaccine caused ADEM). Respondent also mentions that another special master found that Td vaccine caused TM: Hargrove v. Sec'y of HHS, No. 05-694, 2009 WL 1220986 (Fed. Cl. Spec. Mstr. 2009). Id. at 4. Although not conceding liability, respondent states she "respectfully declines to expend further resources to present her own expert testimony." Id.

FACTS

Petitioner was born on July 29, 1947.

On June 28, 2006, she received Td vaccine. Med. recs. at Ex. 7, p. 1.

On July 10, 2006, petitioner went to Woodland Heights Medical Center where she gave a history to Dr. Stig Peitersen that she had been well until three days prior to admission when the left side of her body became numb. This continued until the next day and, on the following day, the numbness spread to both sides of her body. She had Td about two weeks previously, but no recent illnesses in the prior month. Dr. Peitersen diagnosed petitioner with post-infectious myelitis. Med. recs. at Ex. 9, p. 1.

On September 17, 2007, petitioner saw Dr. Lila Cherry, a neurologist, for an EMG and nerve conduction study. The results were that she had a significant neuropathy which was both axonal and demyelinating of the left and right common peroneal nerves, and a mild demyelinating neuropathy of both tibial and sural nerves. Med. recs. at Ex. 11, pp. 4, 5.

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.

The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors. 440 F.3d at 1326. In that case, there were four treating doctors who ascribed petitioner's rheumatoid arthritis to her hepatitis B vaccination.

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

The undersigned ruled in Johnson v. Sec'y of HHS, No. 99-219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. 2000), that Td vaccine caused ADEM, a disease manifesting demyelinating lesions in both the spinal cord and brain. Onset was two weeks after vaccination. In Johnson, petitioner's treating pediatric neurologist testified on her behalf. Another neurologist noted in petitioner's medical records that Td vaccine probably triggered her ADEM. In the instant action, the onset of TM, a disease manifesting demyelinating lesions in the spinal cord, or myeloneuritis (spinal cord and peripheral demyelination), was nine days after vaccination.

Although respondent does not concede liability in this case, respondent has stated orally and in Respondent's Notice of Filing Statement that respondent will not expend any further resources to defend this case. Respondent has not provided any expert report to counter Dr.

Tornatore's expert report or the 19 articles he supplied. Dr. Tornatore described in his expert report the biologically plausible medical theory explaining how Td vaccine can cause TM or myeloneuritis, that Td vaccine did cause petitioner's TM or myeloneuritis as a logical sequence of cause and effect, and that nine days is an appropriate time frame to show causation in this case.

The undersigned rules that Td vaccine caused petitioner's TM or myeloneuritis.

Petitioner has proven a prima facie case of causation in fact. This case is now in damages.

CONCLUSION

Petitioner is entitled to damages. Both parties have filed life care plans and are continuing to work on settling damages. The next telephonic status conference is set for Monday, October 25, 2010, at 11:00 a.m. (EDT).

IT IS SO ORDERED.

September 8, 2010
DATE

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