

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 01-537V

April 8, 2008

Not to be Published

PAUL SHIRLEY,

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Petitioner,

*

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v.

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Entitlement; hepatitis B
vaccine followed seven
weeks later by CIDP

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SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

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Respondent.

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

Lisa A. Watts, Washington, DC, for respondent

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¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States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 dated September 24, 2001, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated January 3, 2002, alleging that his second hepatitis B vaccine administered on September 27, 2000 caused his Guillain-Barré Syndrome (GBS) whose onset was within hours of vaccination. He was diagnosed with GBS on December 6, 2000, more than ten weeks after receiving hepatitis vaccine. Med. recs. at Ex. 11. According to histories he gave to medical providers, the onset of his neurologic symptoms was seven weeks after vaccination. Petitioner was ultimately diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP).

On April 8, 2008, during a prehearing status conference, respondent's counsel requested that the undersigned rule on the record. The report (Ex. 33) from petitioner's expert Dr. Carlo Tornatore states a biologically plausible medical theory and a logical sequence of cause and effect that are similar to his testimony in other cases involving hepatitis B vaccine and demyelinating diseases, such as CIDP. He also cites an epidemiologic report from Dr. Lawrence Schoenberger finding a causal link between swine influenza vaccine and GBS lasting nine or 10 weeks. Dr. Tornatore states this is an appropriate time frame in which to see an autoimmune response.

The report (Ex. A) from respondent's expert Dr. Gerald F. Winkler rejects any association between hepatitis B vaccine and CIDP based on epidemiologic data, but states that, if an analogy between Schoenberger's epidemiological study of swine flu vaccination and the onset of GBS were applicable to hepatitis B vaccine and CIDP, petitioner's onset here would be "within the range of statistically significant increased incidence." R. Ex. A, p. 12.

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case. Respondent's expert in the Omnibus proceedings, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks.

Based on respondent's request to rule on the record in the instant action, and Dr. Winkler's admission that, were the Schoenberger data transferable to hepatitis B vaccine and CIDP, petitioner's onset interval is appropriate for causation, the undersigned rules that petitioner has made a prima facie case.

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, supra, 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 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).

Based on the prior holdings relating causally hepatitis B vaccine and demyelinating diseases, in particular CIDP, and respondent's expert's agreement that, if biological plausibility and logical sequence of cause and effect were persuasive in this case, the temporal interval between petitioner's vaccination and onset of CIDP is within the range of statistically significant increase incidence, the undersigned rules that petitioner has made a prima facie case of causation in fact.

CONCLUSION

Petitioner is entitled to compensation. This case is now in damages.

IT IS SO ORDERED.

April 8, 2008
DATE

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