

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-1781V

April 11, 2008

REGINA PECORELLA, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Hepatitis B vaccination followed two months later by TM; ultimately diagnosed as MS

ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated December 22, 2004, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on January 9, 2002 caused her injury. ¶ 3. On January 12, 2002, three days after vaccination, petitioner's liver enzymes were slightly elevated, a condition her gynecologist attributed to the

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order 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.

vaccination but of no great concern. ¶ 4. According to petitioner's affidavit, filed with her petition, the onset of her pain was March 16, 2002, over two months after her hepatitis B vaccination. Affidavit, ¶ 6. Petitioner was diagnosed with transverse myelitis (TM) and ultimately with multiple sclerosis (MS).

Petitioner claims that the Hernán article substantiates a long-onset cause of MS from hepatitis B vaccine. ¶ 20. On pages 726-28 of petitioner's medical records, petitioner has attached the Hernán article: "Recombinant hepatitis B vaccine and the risk of multiple sclerosis. A prospective study," 63 *Neurology* 838-42 (2004). Hernán and his associates analyzed 163 MS cases and 1,604 matched controls. *Id.* at 839. They concluded that an increased risk lasted for three years post-hepatitis B vaccination. *Id.* at 840.

In a subsequent article, filed with respondent's expert Dr. Greenberg's report (Ex. A), entitled "Hepatitis B vaccination and multiple sclerosis: the jury is still out," Hernán and co-author S.S. Jick, in 15 *Pharmacoepidemiology & Drug Safety* 653-55 (2006), state that the association between hepatitis B vaccine and MS has not been convincingly demonstrated but an absence of an association has not been established either. *Id.* at 653. (The authors ignore the general principle that one cannot prove a negative.) Hernán and Jick support another author's "conclusion that there is not enough evidence to establish the existence of an increased risk of MS associated with hepatitis B vaccine in adults. However, we also believe that there is not enough evidence to establish the absence of an increased risk of MS associated with hepatitis B vaccine. Only additional, fully prospective data will help us escape from this deadlock." *Id.* at 655.

Since Hernán after his 2004 article reflected that there was not enough evidence to support a causal relationship between hepatitis B vaccine and MS, petitioner herein needs some other basis to substantiate her allegation that hepatitis B vaccine followed two months later by the first symptom of TM, later diagnosed as MS, caused her TM, later diagnosed as MS.

Dr. Harry S. Jacob, in a letter dated December 8, 2004 (p. 27 of petitioner's records), bases his opinion that hepatitis B vaccine caused petitioner's TM and MS with only a broad reference to unspecified medical literature linking hepatitis vaccines and neurological events. He also states there are no other causative factors (which is not affirmative evidence as the Federal Circuit requires). Dr. Jacob does not discuss onset interval between the vaccine and petitioner's first symptom of TM, which is a significant omission since, without a discussion of time frame, petitioner fails to satisfy the third criterion of making a prima facie case of causation in fact.

In the four Omnibus paradigm decisions the undersigned has issued² concerning hepatitis B vaccine and demyelinating diseases, the undersigned has held that the medically appropriate time frame between hepatitis B vaccine and the onset of GBS, CIDP, TM, or MS is between three and 30 days, based on the testimony of petitioners' expert Dr. Vera Byers and respondent's expert Dr. Roland Martin. Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525, at *12, *15 (Fed. Cl. Feb. 24, 2006). In order for the undersigned to expand the time frame to two

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).

months, petitioner must produce evidence to support that expansion or she will fail to make a prima facie case.

Petitioner is ORDERED TO SHOW CAUSE by **May 30, 2008** why this case should not be dismissed.

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

Petitioner has so far failed to produce credible evidence that hepatitis B vaccine causes TM or MS two months after vaccination. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **May 30, 2008**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master