In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 09-31V
September 28, 2009
To be Published

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CYNTHIA LILLEY, Parent of ROBERT LILLEY, a minor,	*	
Petitioner,	*	
v.	*	Entitlement: hepatitis B vaccine; six weeks later, transverse myelitis; respondent asks for ruling on the record
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Ronald C. Homer, Boston, MA, for petitioner.
Ann D. Martin, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on January 15, 2009, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on July 13, 2006 caused her son Robert Lilley (hereinafter, "Robert") to have transverse myelitis (TM).

[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.

. This case follows 65 cases transferred to the undersigned in January 2006 as part of the Omnibus hepatitis B vaccine-demyelinating injury cases, dealing with TM, Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and MS.

In the four Omnibus paradigm decisions the undersigned issued[2] concerning hepatitis B vaccine and demyelinating diseases, the undersigned held that hepatitis B vaccine could cause TM, GBS, CIDP, and MS, and 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. Spec. Mstr. Feb. 24, 2006).

That time frame expanded to eight weeks (two months) in the undersigned's decision in Pecorella v. Secretary of HHS, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008), concerning another recipient of hepatitis B vaccine who contracted TM two months later, when respondent filed a Request for a Ruling on Record, choosing not to expend any further resources in defending that case.

[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 was12 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).

Petitioner in the instant action filed an expert report on July 20, 2009 from Dr. Paul Maertens, a pediatric neurologist, stating that hepatitis B vaccine caused Robert's acute TM. Ex. 16. Attached to Dr. Maertens' report are medical articles filed as Tabs A-J to Ex. 16.

Respondent filed a Rule 4(c) Report and Request for Ruling on the Record on September 25, 2009, denying that compensation was appropriate, but choosing not to expend further resources to defend the case. Respondent did not file an expert report.

Dr. Maertens' Expert Report

Dr. Maertens describes TM as an acute myelopathy characterized by inflammation and demyelination of the spinal cord white matter. Ex. 16, p. 2. Robert had previously been healthy before his hepatitis B vaccination of July 13, 2006. One week before onset of his TM, Robert did not have a history of rash, gastroenteritis, flu-like symptoms or fever, all of which can be causally related to TM, but none of which was present in Robert. *Id.*

Dr. Maertens continues that vaccinations are well known to carry the risk of causing TM. Ex. 16, p. 3. Most hepatitis viruses have been reported to cause rare cases of TM. *Id.* Hepatitis B vaccine has been shown to cause TM. Ex. 16, p. 4. He states that the postulated mechanism for central nervous system damage is molecular mimicry in which autoantibodies develop in response to an infection or immunization. *Id.*

Dr. Maertens concludes that an onset of 42 to 43 days in Robert's case is well within medical expectations of an autoimmune demyelinating disorder. *Id.*

Included among Tabs A-J to Ex. 16 is Tab D, a case report entitled "Transverse myelitis following hepatitis B vaccination" by F. Trevisani, et al., 19 J Hepatol 2:317-18 (1993). This

concerned the plasma-derived hepatitis B vaccine, rather than the recombinant form. Onset of TM was 21 days post-vaccination.

Tab F is a case report entitled "Acute transverse myelitis secondary to hepatitis B vaccination," by C. Iniguez, et al., 31 Rev Neurol 5:430-32 (2000). A 15-year-old girl had onset of TM one week after receiving hepatitis B vaccine.

Tab G is a case report entitled "Inflammatory polyradiculoneuropathy with spinal cord involvement and let[h]al outcome after hepatitis B vaccination" by E. Sindern, et al., 186 J Neurological Sciences 81-85 (2001). The patient experienced an inflammatory polyradiculoneuropathy similar to GBS nine days after his fourth recombinant hepatitis B vaccination. He died from multiorgan failure, septic shock, and adult respiratory distress syndrome 17 weeks after vaccination. *Id.* at 82. The authors considered molecular mimicry as a pathogenic pathway. *Id.* at 85.

Tab H is a report entitled "Clinical Correspondent. Hepatitis B vaccine related-myelitis?" by F. Karaali-Savrun, et al., 8 European J of Neurology 711-15 (2001). The authors describe four cases of people experiencing acute myelitis after receiving recombinant hepatitis B vaccine. The onsets were four weeks for the first two cases, three weeks for the third case, and three months for the fourth case after vaccination. The authors discuss the complication of autoimmune diseases of the nervous system after a number of immunizations. *Id.* at 714. They posit the mechanism of molecular mimicry or reactivation of a dormant virus. *Id.*

Tab I is a case report entitled "Early-onset Acute Transverse Myelitis Following Hepatitis B Vaccination and Respiratory Infection" by L.F. Fonseca, et al., 61 Arq Neuropsiquiatr 2-A:265-268 (2003). A three-year-old boy had onset of TM 10 days after

receiving hepatitis B vaccine. At the time of vaccination, he had mild upper airway respiratory symptoms of rhinorrhea and cough. *Id.* at 266. The authors surmise that the boy had post-infectious or post-vaccinal TM. *Id.* at 267.

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, 956 F.2d 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, Robert would not have had TM, but also that the vaccine was a substantial factor in bringing about his TM. 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 undersigned has already ruled in the Omnibus paradigm case Stevens that hepatitis B vaccine can cause TM. Dr. Maertens stated in his expert report in this case that hepatitis B vaccine did cause Robert's TM. The vaccine caused an autoimmune disease through the process of molecular mimicry whereby in forming antibodies to the antigen in the vaccine, the body then proceeds to attack itself. The onset of Robert's TM six weeks after vaccination falls within the two-month acceptable time limit for causation established in Pecorella. A number of case

reports posit the same biologically plausible theory and timing that Dr. Maertens described in his report.

Petitioner has proved causation in fact.

CONCLUSION

Petitioner is entitled to reasonable compensation. The next telephonic status conference on October 7, 2009 at 11:00 a.m. will focus on resolving the issue of damages.

IT IS SO ORDERED.

September 28, 2009
DATE

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