

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. [redacted] V

Originally Filed: April 13, 2010

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To be Published

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JOHN DOE/64, \*

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;  
less than two months later, MS;  
respondent does not present expert  
and asks for ruling on the record

**MILLMAN, Special Master**

## RULING ON ENTITLEMENT<sup>1</sup>

Petitioner filed a petition dated November 3, 2009 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that his third hepatitis B vaccination administered on November 17, 2008 caused him multiple sclerosis (MS).

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<sup>1</sup> 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 decision is being redacted because of petitioner's April 27, 2010, motion which was granted.

Former special master (now Judge) Margaret M. Sweeney held an Omnibus hearing from October 13-15, 2004 in the 65 hepatitis B vaccine-demyelinating injury cases. Four cases were selected as paradigms to determine if hepatitis B vaccine could (and in those four cases, did) cause transverse myelitis (TM), Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and MS.

In January 2006, the 65 cases comprising the Omnibus proceeding were transferred to the undersigned. In the four paradigm decisions the undersigned issued<sup>2</sup> concerning hepatitis B vaccine and demyelinating diseases, the undersigned held that hepatitis B vaccine could and did cause the diseases, 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. Feb. 24, 2006).

Subsequently, in five cases, the undersigned ruled that a demyelinating illness occurring within eight weeks of hepatitis B vaccination was an appropriate time interval for causation. In three of those cases, respondent indicated that she would no longer expend time or money to defend the case and asked for a ruling on the record. Those three cases are: (1) Pecorella v. Sec'y of HHS, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. September 17, 2008)

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<sup>2</sup> 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).

(hepatitis B vaccine; two months until onset of transverse myelitis); (2) Jane Doe/29 v. Sec'y of HHS, No. [redacted], 2009 WL 180078 (Fed. Cl. Spec. Mstr. January 21, 2009) (hepatitis B vaccine; two months until onset of Devic's disease, a variant of MS); and (3) Lilley v. Sec'y of HHS, No. 09-31V, 2009 WL 3320518 (Fed. Cl. Spec. Mstr. September 28, 2009) (hepatitis B vaccine; six weeks until onset of TM).

In addition, in two cases, relying on the holding in Pecorella, the undersigned held after trial that petitioners prevailed even though onset was beyond 30 days after vaccination: (1) Hawkins v. Sec'y of HHS, No. 99-450V, 2009 WL 711931 (Fed. Cl. Spec. Mstr. February 27, 2009) (two months until onset of acute disseminated encephalomyelitis, another demyelinating disease); and (2) Fisher v. Sec'y of HHS, No. 99-432V, 2009 WL 2365459 (Fed. Cl. Spec. Mstr. July 13, 2009) (hepatitis B vaccine; two months until onset of optic neuritis, another demyelinating disease).

Although the instant action was filed in 2009 after the Omnibus proceeding concluded, the undersigned will apply the holdings the undersigned issued in the Omnibus paradigm cases to it. The paradigm case concerning hepatitis B vaccine and MS was Werderitsh. Since issuing the paradigm decisions, the undersigned has resolved numerous other cases involving the same issues. Moreover, the undersigned will apply the extension of the medically appropriate time interval between vaccination and onset to two months in the instant action since respondent has previously expressed the view in similar cases that, due to limitations on expenses and attorney time, respondent will not hire an expert to contest petitioner's expert's opinion.

## **FACTS**

Petitioner was born on April 22, 1960.

He received his first hepatitis B vaccination on May 21, 2008 and his second hepatitis B vaccination on June 20, 2008. Med. recs. at Ex. 5, p. 91.

On November 17, 2008, petitioner received his third hepatitis B vaccination. Id.

On January 8, 2009, petitioner saw Dr. Charles J. Lancelotta, Jr., a neurosurgeon, complaining of numbness from the umbilicus down. Med. recs. at Ex. 3, p. 4. He was recently exercising on a recumbent bicycle. Whenever he was sitting, he would get numbness in the right buttock area into the upper right leg which would go away when he stopped. The prior Tuesday, which was December 30, 2008, he noticed numbness not only of the right leg after the exercise, but in his entire body below the level of his umbilicus, unassociated with pain or weakness. Id.

From January 8 to 13, 2009, petitioner was hospitalized at Georgetown University Hospital where he was diagnosed with myelitis. Med. recs. at Ex. 8, pp. 5, 6. He came under the care of Dr. Carlo Tornatore, a neurologist, who diagnosed him with MS. Med. recs. at Ex. 13, p. 9. A brain MRI performed on January 10, 2009 showed nonspecific foci of T2 hyperintensity in the right occipital white matter and at the superior margin of the left lateral ventricle, consistent with demyelinating disease. Med. recs. at Ex. 8, p. 20.

On March 23, 2009, petitioner had another brain MRI which showed worsening demyelination since the prior brain MRI of January 10, 2009. He had a larger lesion on the left. The differential diagnosis was worsening demyelination including MS. Med. recs. at Ex. 1, pp. 2, 3. On March 23, 2009, an MRI of petitioner's thoracic spine showed a one centimeter focus of abnormal signal. Med. recs. at Ex. 13, p. 43.

On July 30, 2009, petitioner saw Dr. Tornatore who noted that petitioner had an increase in difficulty with cognition. Med. recs. at Ex. 13, p. 26.

## Expert Report

### Dr. Carlo Tornatore

On February 25, 2010, petitioner filed an expert report from his treating neurologist, Dr. Carlo Tornatore. Ex. 15. Dr. Tornatore's opinion is that petitioner's MS was triggered by his November 2008 hepatitis B vaccination. Ex. 15, p. 1. Dr. Tornatore first saw petitioner on January 22, 2009. Ex. 15, p. 2. Only on April 1, 2009 when petitioner's wife inquired whether petitioner should receive a second dose of hepatitis A vaccine did Dr. Tornatore learn that petitioner had received any recent vaccinations. Id. On further inquiry, Dr. Tornatore learned that petitioner had received hepatitis B vaccine in November 2008, less than eight weeks prior to the onset of his symptoms. Id. Dr. Tornatore states in his expert report, "I counseled him at that time to not receive any further Hepatitis vaccinations since I thought the vaccination was the probable cause of his Multiple Sclerosis." Id.

Explaining the basis for his opinion that petitioner's third hepatitis B vaccination triggered his MS, Dr. Tornatore states:

Is it biologically plausible that the hepatitis vaccine could cause demyelination? Vaccinations are composed of organic compounds of viral or bacterial origin, recombinant or otherwise, which are meant to stimulate an immune response once injected. If the antigens present on the vaccine share any homology with host antigens, then the immune response will be directed at both the injected antigens and host antigens, leading to an autoimmune response. The concept that viral or bacterial antigens share homology with host antigens, also known as molecular mimicry, is a well established concept in immunology (Lahesmaa et al. Clin Exp. Immunol 1991 86(3):399-404). A recent paper examined this specifically with hepatitis B vaccine ("A study of molecular mimicry [sic] and immunologic cross-reactivity between hepatitis B surface antigen and myelin mimics" Clin Dev Immunol 2005 12:217-224).

Ex. 15, p. 3.

Dr. Tornatore concludes his expert report by stating that to a reasonable degree of medical certainty, his opinion is that the November 2008 hepatitis B vaccination resulted in petitioner's development of MS, based on the temporal relationship of the vaccination and the onset of the neurologic symptoms, a plausible biological mechanism as previously described, and a reasonable sequence of cause and effect. Id.

Dr. Tornatore's curriculum vitae was filed as Ex. 16.

#### Respondent's Position

On April 5, 2010, respondent filed her Rule 4(c) Report stating that petitioner had not presented a prima facie case of causation under the Vaccine Act and there is no scientifically reliable evidence that hepatitis B vaccine can cause MS. Rep. at 9. Moreover, respondent stated that petitioner did not show that an appropriate temporal relationship exists. Id. However, respondent refused "at this juncture" to hire an expert. Rep. at 13.

During a telephonic status conference held on April 12, 2010, the undersigned asked respondent's counsel if respondent was asking the undersigned to rule on the record or was going to hire an expert in the future to defend. Respondent's counsel checked with respondent and, in a subsequent status conference held an hour later, stated that respondent had no intention of hiring an expert in the future and requested a ruling on the record.

#### **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, 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, he would not have had MS, but also that the vaccine was a substantial factor in bringing about his 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 in Capizzano emphasized the importance of the special master’s heeding the opinions of petitioner’s four treating doctors in that case, and stressed that special masters similarly heed the opinion of treating doctors in their own cases. 440 F.3d at 1326.

The undersigned has already ruled in the Omnibus paradigm case Werderitsh that hepatitis B vaccine can cause MS. The undersigned has accepted Dr. Tornatore’s theory of molecular mimicry in all of the cases in which he has been petitioner’s expert. Petitioner has satisfied the first Althen criterion that there is a biologically plausible medical theory relating hepatitis B vaccine to MS, i.e., molecular mimicry.

There is a logical sequence of cause and effect that hepatitis B vaccine, which can lead to MS, did lead to petitioner’s MS in this case. Respondent states in her Rule 4(c) Report that “there is no evidence of an apparent alternative cause.” Rep. at 13. Petitioner has satisfied the second Althen criterion of a logical sequence of cause and effect.

Until the Pecorella case, the undersigned relied upon the Omnibus testimony of Dr. Vera Byers for petitioners and Dr. Roland Martin for respondent that the appropriate time interval for causation (if Dr. Martin were to accept causation of demyelinating disease from hepatitis B

vaccine) was from three to 30 days. However, due to respondent's statements in Pecorella, Jane Doe/29, and Lilley (dealing with hepatitis B vaccine followed up to two months later by demyelinating disease) that respondent would not hire an expert and requesting a ruling on the record, and based on the undersigned's subsequent holdings after trial in Hawkins and Fisher that two months between hepatitis B and demyelinating illness was an appropriate interval, in the instant action, the undersigned holds that petitioner satisfies the third Althen criterion, i.e., two months is an appropriate temporal interval between hepatitis B vaccination and onset of MS.

The Federal Circuit in Capizzano has stressed the special masters' heeding the opinions of treating doctors. Here, petitioner's treating neurologist Dr. Tornatore wrote an expert report opining that hepatitis B caused petitioner's MS, listing the biologically plausible medical theory, the logical sequence of cause and effect, and the temporally appropriate interval.

Petitioner has proved causation in fact.

### **CONCLUSION**

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and has set a telephonic status conference for Friday, June 4, 2010, at 10:30 a.m. (EDT), to discuss how the parties are proceeding in resolving damages.

**IT IS SO ORDERED.**

April 13, 2010  
DATE

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