In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 99-611V
September 28, 2007
To be Published

WALTER AUGUSTYNSKI, Petitioner,	*	
v.	*	Entitlement; hepatitis B vaccine; numbness and tingling the next day; prior exposure to vaccine shortened onset of MS
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	

Ronald C. Homer, Sylvia Chin-Caplan, Boston, MA, for petitioner.
Voris F. Johnson, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition dated August 4, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on July 29, 1996 caused him unspecified injury (ultimately, petitioner was diagnosed with multiple

[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.

sclerosis or MS). He had numbness and tingling the day after vaccination, which eventually spread up his legs. Over two months later, he experienced vision loss in his right eye which was diagnosed as optic neuritis. A brain MRI confirmed he has MS.

This case was one of those consolidated in an Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases (see below).

A hearing was held on August 2, 2007. Testifying for petitioner was Dr. Carlo Tornatore. Testifying for respondent was Dr. Arthur Safran.

FACTS

Petitioner was born on April 14, 1957.

On June 24, 1996, he received his first hepatitis B vaccine. Med. recs. at Ex. 6, p. 3.

On July 29, 1996, petitioner received his second hepatitis B vaccine. Med. recs. at Ex. 6, p. 8. This record is not a vaccination record, but a "Resurrection Health Care Report of Employee Incident," dated August 14, 1996. (Petitioner was an employee of Our Lady of the Resurrection Medical Center.) In the Report of Employee Incident, petitioner states that, on the day after he received his second hepatitis B vaccination, he had tingling and numbness in his feet, and stomach pains. On July 31, 1996, the tingling and numbness spread to his knees and his stomach pain continued. On August 1, 1996, this spread to his thighs. By the end of that week, tingling and numbness spread to his hips and his stomach pain continued. *Id.*

On August 7, 1996, petitioner went to the Emergency Department of Our Lady of the Resurrection Medical Center, complaining of a vaccine reaction. Med. recs. at Ex. 1, p. 8. He stated he received hepatitis B vaccine on July 29, 1996, and had the onset of a tingling sensation and numbness on July 30, 2006 of both feet gradually involving his upper legs with an episode of

abdominal pain. He saw his primary care physician the prior Saturday (August 3, 1996). Med. recs. at Ex. 1, p. 9. He was told he had no problems, but since August 3rd, he has continued to have intermittent tingling and numbness bilaterally of the lower extremities extending to include his abdomen. Med. recs. at Ex. 1, p. 11.

On August 20, 1996, petitioner saw Dr. Ralph Cabin, who diagnosed him with post-immunization neuropathy. Med. recs. at Ex. 7, p. 2.

On October 23, 1996, petitioner saw Dr. Andrew A. Berman, a neuro-ophthalmologist. Med. recs. at Ex. 2, p. 1. Petitioner stated he had perfect vision until October 9, 1996, when he could not see well out of his right eye. Petitioner stated he had no antecedent trauma or illness, but had received the first two hepatitis B vaccinations in June and July 1996. The day after his second hepatitis B vaccination on July 29, 1996, he developed lower extremity weakness and paresthesias which a neurologist diagnosed as Guillain-Barré Syndrome (GBS). *Id.* Dr. Berman's impression was that petitioner had retrobulbar optic neuritis in his right eye. Med. recs. at Ex. 2, p. 2.

On October 25, 1996, petitioner had a brain MRI whose result was abnormal, showing multiple tiny high signal lesions in the periventricular white matter, a pattern most likely due to MS. Med. recs. at Ex. 1, pp. 14, 15.

On August 25, 1997, petitioner saw Dr. John A. Vottero. Med. recs. at Ex. 4, p. 1. Petitioner stated that he received the second hepatitis B vaccination on July 29, 1996, and on the next day, he developed bilateral foot numbness progressing in severity and extending to his knees on the second day, and to his thighs on the third day. Although his initial diagnosis was GBS,

that changed to MS after he developed optic neuritis. Dr. Vottero agreed with the MS diagnosis. *Id.*

Other Material Submitted

Petitioner filed an article entitled "A study of molecular mimicry and immunological cross-reactivity between hepatitis B surface antigen and myelin mimics" by D-P Bogdanos, et al., 12 *Clin & Developmental Immunology* 3:217-24 (2005). P. Ex. 14. The authors state that small hepatitis B virus surface antigen shares strong homologies with major myelin antigens such as myelin basic protein (MBP) and myelin oligodendrocyte glycoprotein (MOG). *Id.* at 222. The authors found cross-reactive immunity after vaccination, which decreased over time with most vaccinees maintaining the anti-hepatitis response but losing the response against self. *Id.* at 223. The authors state:

> These findings suggest that upon vaccination, induction of an anti-viral response is initially capable of promoting cross-reactive anti-self immune responses, which decrease over time, possibly as a result of peripheral tolerance mechanisms. This scenario may explain why very rarely adverse post-vaccination autoimmune reactions occur....

Id. (None of the subjects in the study had demyelinating disease before vaccination or developed it after vaccination, even with their temporary anti-self immune response.)

Petitioner filed an article entitled "The initiation of the autoimmune response in multiple sclerosis" by S. Markovic-Plese, C. Pinilla, and R. Martin, 106 *Clin Neur & Neurosurgery* 218-22 (2004). P. Ex. 32. (Dr. Roland Martin was respondent's neuroimmunological expert at the Omnibus proceeding.) The authors review "molecular events involved in the activation of

autoreactive T-cells, an initial event in the development of the autoimmune disease process in MS." *Id.* at 218. They state:

> Current studies support the critical role of CD4+ myelin-specific cells in the initiation of autoimmune responses in MS. However, myelin-reactive cells are part of the normal T-cell repertoire, and are detected at comparable frequencies in the peripheral blood of both MS patients and normal controls. Thus, their presence is not sufficient to trigger pathological autoimmune response. Rather, it is the frequency of activated myelin-reactive cells that is increased in MS patients in comparison to healthy individuals. Peripherally activated autoreactive CD4+ lymphocytes cross the blood brain barrier and initiate chronic inflammatory response in the CNS, as documented in the experimental autoimmune encephalomyelitis (EAE), an animal model of MS.

Id.

They continue:

> [M]olecular mimicry results in the autoimmune disease only when it takes place in the context of local inflammation, presentation of released self antigens, and a sufficient number of autoreactive T-cells.

Id. at 219.

OMNIBUS TESTIMONY

The Omnibus proceeding concerning whether or not hepatitis B vaccine could cause demyelinating diseases such as multiple sclerosis (MS), transverse myelitis (TM), Guillain-Barré syndrome (GBS), and chronic inflammatory demyelinating polyneuropathy (CIDP) went to hearing before former special master (now Judge) Margaret M. Sweeney from October 13-15, 2004. For a general description of the Omnibus hearing, see Stevens v. Secretary of HHS, No. 99594V, 2006 WL 659525, at *1-3 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). The undersigned was assigned the hepatitis B-demyelinating diseases cases in January 2006.

As part of the Omnibus hearing, Dr. Vera Byers, petitioners' expert immunologist, when questioned whether an onset of one day of demyelinating disease after hepatitis B vaccination was consistent with causality, testified:

> [Someone could have onset of] demyelinating symptoms beginning as early as one day. But that can only occur in my opinion in cases where people have had a very strong boost fairly shortly before. So in other words and I think it's probably got to be B-cell mediated because it's difficult to think that the T-cells could be activated, throw all the cytokines out, pull in all the inflammatory cells, and start demyelination within one day. But I think that if you have preformed antibodies that have been built up to a fairly high concentration because you've had repeated recent boosters that you could produce antigenic body complexes which then could produce some neurologic symptoms. But I agree, one day is difficult.

Omnibus tr. at pp. 102-03.

Dr. Roland Martin, one of respondent's expert neurologists, testified in the Omnibus proceeding that MS inflammation is antibody-mediated in some patients. Omnibus tr. at p. 209. In other patients, MS is likely T-cell-mediated. *Id.* If something happened earlier than a day after exposure to an antigen, it must be related to superantigen stimulation. Omnibus tr. at 219-20. He stated vaccines do not contain superantigens. Omnibus tr. at 220. The most recent categorization of MS patients defined four subgroups of MS. In only one of the four subgroups were antibodies involved. Omnibus tr. at 260.

TESTIMONY

Dr. Carlo Tornatore testified for petitioner. Tr. at 4. He is an associate professor in neurology at Georgetown and director of its MS center. Tr. at 6. He sees 1,500 MS patients at least twice a year. Tr. at 9. He testified in the Omnibus proceeding on hepatitis B vaccine and demyelinating diseases that there did seem to be a plausible mechanism whereby hepatitis B

surface antigen activated the immune response enabling T-cells to cross into the brain, causing demyelination and MS. Tr. at 9, 10.

In response to respondent's expert Dr. Safran's view that petitioner in this case could not have had an adverse reaction to hepatitis B vaccine because his serum did not measure positive to antibodies to hepatitis B surface antigen, Dr. Tornatore said that the immune response is much more complicated than that. Tr. at 12. MS is a T-cell-mediated disease, which is not related to antibodies. *Id.* Dr. Roland Martin co-authored a paper that was an Omnibus exhibit (Ex. 22) and also an exhibit in this case (Ex. 32) discussing MS in which the authors do not discuss antibodies as relevant to the pathogenesis of MS. Tr. at 12, 13, 17, 18. A very small amount of antigen can trigger the CD4 cell response which crosses into the brain and interacts with microglia and myelin, causing demyelination. Tr. at 12, 14. Not having an antibody response to the vaccine just means that petitioner received a small antigen load which was inadequate to set off the humoral immune system which makes antibodies. It does not mean petitioner did not have an immune response to the vaccine that was T-cell-mediated. Tr. at 15. All the animal models concerning MS (EAE or experimental allergic encephalomyelitis) discuss the T-cell response and not the humoral immune response. *Id.* CD4 cells are the T-cells. *Id.* B-cells make antibodies. Tr. at 16. The antibody is a late response of the immune system, not an early response. The CD4 cells may or may not trigger the B-cells to make antibody. *Id.* The lack of any antibody response does not mean that the immune system is not primed to that antigen. Tr. at 19.

Petitioner probably had some antibodies after vaccination but not high enough to protect him against hepatitis B infection. Tr. at 20. Two hepatitis B vaccinations may be more than adequate to have a T-cell response against the antigen. *Id.*

Dr. Tornatore agrees with Dr. Safran that petitioner never had GBS. Tr. at 30. Petitioner had myelitis. Tr. at 32. Genes predispose people to MS. Tr. at 33-34. Here, petitioner had the predisposition to develop an antigen leading to T-cells causing inflammation in his spinal cord and ultimately in the optic nerve. Tr. at 34. Multiple genes are at play in MS. Tr. at 35.

Dr. Tornatore testified that petitioner's first hepatitis B vaccination primed his immune T-cells. *Id.* With the second hepatitis B vaccination, the T-cells had some memory of the antigen and the subsequent response happened very quickly, within 24 hours. It makes absolute sense. Immune responses can be very quick *Id.* This was an anamnestic response. Tr. at 36. The second hepatitis B vaccine was a rechallenge of petitioner's immune system. *Id.*

One day after his second hepatitis B vaccination, petitioner had tingling in his feet which progressed up to his knees over the course of seven days and then to his waist. *Id.* The progression of numbness to his waist is typical of myelitis or inflammation of the spinal cord. Tr. at 36-37. Because his reflexes were intact, he did not have GBS. Tr. at 37. After he had optic neuritis months later, petitioner was diagnosed with MS. Tr. at 39.

Dr. Tornatore testified that petitioner's reaction one day after his second hepatitis B vaccination is not too early for an immune-mediated reaction because it was his second vaccination. Tr. at 42. His first hepatitis B vaccination primed his immune system, and his second one resulted in an anamnestic response, which can happen very quickly. Tr. at 42-43. There was no other potential cause for petitioner's MS. Tr. at 43. Dr. Tornatore's opinion is that there is a temporal relationship, plausible biological mechanism, and reasonable sequence of cause and effect that petitioner's hepatitis B vaccinations caused his demyelination and MS. Tr. at 43-44.

The undersigned commented that one of petitioner's treating doctors (Dr. Cabin) diagnosed petitioner with postimmunization neuropathy. Tr. at 44. Dr. Tornatore said Dr. Cabin got the process right (due to vaccination) but the diagnosis of neuropathy wrong since petitioner did not have a peripheral neurological disease but a central neurological disease. *Id.*

Dr. Tornatore disagreed with Dr. Vera Byers' Omnibus testimony for petitioners when she said MS was a B-cell process. Tr. at 47. It is a T-call process instead. Tr. at 48. There is a big protein load in hepatitis B vaccine. *Id.* The blood vessels in the tissue of someone with MS are surrounded by T-cells. Tr. at 49. Just a little inflammation causes these symptoms. Tr. at 50. It might not even be demyelination initially but a little irritation or swelling that could cause the symptoms. *Id.* Hepatitis B surface antigen stimulates the T-cells. Tr. at 51. Antigens on the myelin basic protein in petitioner's body look like hepatitis B surface antigen to petitioner's T-cells and they start to attack the myelin and break it down. *Id.* The idea of molecular mimicry is that the hepatitis B is mimicking petitioner's own myelin proteins. *Id.*

Petitioner was exposed to the antigen. Tr. at 64. Not everyone will have a response immediately to the antigen, but there is a response to it. *Id.* For 40 years, the medical community has known that MS is primarily a T-cell disease. Tr. at 65. Once you are immunized, the T-cells are the first to process the antigen and then turn on the B-cells to make antibodies. Tr. at 67. We know petitioner's immune system was primed because he had the first hepatitis B vaccination. *Id.* Testing a vaccine for antibodies to surface antigen and core antigen determines if the vaccinee has antibodies high enough to keep him from being infected, but does not tell you whether his immune response has been stimulated. Tr. at 68. Just because

petitioner's blood did not yield any antibodies does not mean he did not have activated T-cells. Tr. at 70.

Petitioner did not mount a humoral or B-cell response to hepatitis B virus, but we cannot say he did not mount a cellular immune response via the T-cells. Tr. at 72. Dr. Tornatore stated petitioner probably had an initial T-cell response based on how hepatitis B vaccine works. *Id.* Those vaccinees who receive three hepatitis B vaccinations are bound to have higher antibodies than petitioner who received only two hepatitis B vaccinations. Tr. at 74.

Inflammation ultimately leads to demyelination. Tr. at 90. Very mild irritation of the nerves without demyelination can cause symptoms. *Id.* Petitioner's tingling in his feet extending to the thoracic level started with inflammation. Tr. at 92. The fact that it persisted tells us petitioner must have had some demyelination that followed very quickly. *Id.* Inflammation can lead to demyelination in hours. *Id.* Rather than accept that petitioner's onset of MS one day after his second hepatitis B vaccination was coincidental, Dr. Tornatore stated that in making a differential diagnosis between coincidence and causation, causation from the vaccination is biologically plausible. Tr. at 95-96.

MS is an autoimmune disease. Tr. at 96. In defining "plausible," Dr. Tornatore stated it means there is a reasonable mechanism that has been looked at that has some basis in biology. Tr. at 97-98. In other words, it makes sense within the body of knowledge of medicine. Tr. at 98. It fits into our general understanding of how diseases progress even though we might not know the mechanism. *Id.* We do not know the exact cause and mechanism of MS, but we do know the pathogenesis is inflammatory. *Id.* The goal of vaccination is to stimulate the immune response. If someone has an immune problem after receiving vaccine, causation makes sense

and is plausible. *Id.* Molecular mimicry is one explanation of the process of how vaccination leads to autoimmune disease. Tr. at 99. Dr. Tornatore phrased his explanation of process as a probable hypothesis with some support in the medical literature, both preclinical and clinical. Tr. at 102, 104.

Dr. Arthur P. Safran testified for respondent. Tr. at 105. He is director of a clinic in MS as well as a clinic in neurology. Tr. at 106. He sees 100 MS patients per month. Tr. at 111. He partially retired 18 months ago. *Id.* He does not know the cause of MS in any patient. *Id.* There is no single cause. *Id.* No one knows the cause of MS. *Id.* MS is a variable disease. There is no epidemiologic support for the proposition that hepatitis B vaccine causes MS. *Id.* One large population study of hepatitis B vaccination and MS concludes there is no relationship but it has a large number of flaws. Tr. at 112. Dr. Safran believes there is no other way to determine causation beyond an epidemiological analysis. *Id.* He believes the cause of everything is a combination of heredity and environment. Tr. at 113. He thinks MS is almost certainly an autoimmune disease. *Id.* Some studies show a protective effect of hepatitis B vaccine but he does not believe it. You can do a lot with statistics that is not medically true. Tr. at 122. When a medical doctor determines causation, he or she looks at the scientific literature. Tr. at 124.

Dr. Safran's opinion is that petitioner's MS is not due to hepatitis B vaccine. *Id.* His basis is lack of positive epidemiologic studies, the absence of petitioner having antibodies to hepatitis B surface antigen in his serum, and the timing of petitioner's onset of symptoms. Tr. at 125. Dr. Safran does not know what the proper interval of time would be between vaccination and onset to show causality. Tr. at 126. In terms of antibody response, it could be really very quick, but in terms of delayed hypersensitivity, it gets confusing. *Id.* He stated no one can

determine it. *Id.* He did not know if antibodies show up after the first or second hepatitis B vaccination and could not cite literature that would answer that question Tr. at 138, 139. Dr. Safran agreed that the immune response was more than antibodies. Tr. at 140. He stated that the medical community has not accepted that molecular mimicry is the mechanism by which hepatitis B vaccine causes MS. Tr. at 140. In order to prove this is not coincidence, he would need animal testing and epidemiologic studies. Tr. at 146. Dr. Tornatore, in response to the undersigned's question, stated there are no animal studies linking hepatitis B vaccine to MS, but his analysis does not require there to be animal testing. Tr. at 148. Dr. Safran stated that if petitioner had reacted to hepatitis B vaccine one day later, he would assume it was due to a humoral immune response rather than a cellular immune response because humoral immune responses are quicker. But since petitioner did not have any measurable antibodies to hepatitis B vaccine, that could not have happened. Tr. at 149.

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 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).

The Federal Circuit emphasized in Capizzanno the opinions of treating physicians in the special master's determination of whether petitioner has proven causation in fact. 440 F.3d at 1326. In Capizzano, four of petitioner's treating physicians thought her rheumatoid arthritis was due to hepatitis B vaccine.

In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. One of respondent's two expert neurologists, Dr. Thomas P. Leist, opined that petitioner's MS could not have been a reaction to her hepatitis B vaccinations because her serum titers were negative for hepatitis B surface antigen on two occasions, indicating to him that she

did not have a fulminant immune response to hepatitis B vaccine, at least as measured by serum titers. 2006 WL 1672884, at *21. The undersigned rejected Dr. Leist's reasoning:

> Dr. Leist's statement presumes that whatever biologic mechanism is involved in petitioner's body's attacking itself is linked to antibody production. But since we do not know the specific biologic mechanism involved, the undersigned cannot conclude that petitioner's failure to produce antibodies to hepatitis B vaccine's surface antigen means she did not have another type of mechanism unrelated to antibody production in response to hepatitis B vaccine that caused or exacerbated her MS. Dr. Martin, respondent's expert, testified that some patients' MS is antibody-mediated, but other patients' MS is T-cell-mediated. In addition, Dr. Martin said there are four subgroups of MS, and antibodies are relevant for only one of those four subgroups. Dr. Leist's conclusion that hepatitis B vaccine, since it failed to produce antibodies in Mrs. Werderitsh, could not have caused or exacerbated her MS ignores the other three types of MS that Dr. Martin described for which antibodies are irrelevant.

2006 WL 1672883, at *25.

Dr. Safran, in the instant case, also stated that petitioner's MS could not be due to hepatitis B vaccine because petitioner's serum titers tested negatively for hepatitis B surface antigen. But, as Dr. Tornatore stated at the hearing (and as Dr. Martin testified in the Omnibus proceeding), antibody production may have nothing to do with the cause of MS, particularly if T-cells are involved. The undersigned notes that Dr. Tornatore's emphasis on T-cell-mediation (cellular immunity) differs from Dr. Byers' emphasis on B-cell-mediation (humoral immunity) at the Omnibus proceeding, but the Federal Circuit stated in Knudsen that petitioner does not bear the burden of proving the specific biologic mechanism underlying his reaction in order to prevail.

Dr. Safran also stated that petitioner's MS could not be due to hepatitis B vaccine because epidemiologic studies have not shown any increase in the occurrence of MS after hepatitis B

vaccination. This was the same defense Dr. Leist used at the Omnibus proceeding. But the Federal Circuit in Knudsen stated that epidemiologic studies might not only be unhelpful but lead someone to conclude another cause was more likely and still petitioner could prevail because the vaccinee's reaction was rare. The Federal Circuit reiterated its lack of concern over objective medical literature confirming petitioner's allegations in Althen. As in Werderitsh, the undersigned holds that lack of epidemiologic support for petitioner's allegations is not an impediment to petitioner's fulfilling the three Althen criteria. 2006 WL 1672884, *25.

In the Omnibus proceeding, Dr. Martin testified that if he were to accept that a vaccination could cause a demyelinating disease such as MS, he would expect onset between three to 30 days. *Id.* at *18. The exception would be in the case of a superantigen (which he stated was not in a vaccine). *Id.* at *18-19. Dr. Byers testified in the Omnibus proceeding that if someone had preformed antibodies from a prior vaccination, the vaccinee could have onset in one day.

Dr. Tornatore testified in the instant case in agreement with Dr. Byers that petitioner's prior exposure to hepatitis B vaccine shortened the onset of his MS after his second vaccination, calling this an anamnestic response, i.e., a worsened response to the same antigen. Petitioner received hepatitis B vaccine 35 days before his second hepatitis B vaccination and was thus primed for a quick reaction after his second vaccination.

Moreover, Dr. Tornatore's testimony was consistent with the Markovic-Plese article of which Dr. Martin, respondent's neuroimmunological expert at the Omnibus proceeding, was a co-author, which describes MS as a T-cell-mediated disease in which inflammation plays a major role. Dr. Tornatore testified that, after his second hepatitis B vaccination, inflammation led to

petitioner's numbness and tingling, and continued, extending up his body, leading to demyelination through the effect of CD4 or T-cells. As a matter of interest, the Piaggio article showed the production of cross-reactive anti-self immune responses in recipients of hepatitis B vaccine even though they clinically remained well and these anti-self responses diminished over time.

Dr. Tornatore is not alone in attributed petitioner's neurologic condition to hepatitis B vaccine. One of petitioner's treating doctors, Dr. Ralph Cabin, diagnosed him with post-immunization neuropathy. The Federal Circuit in Capizzano stressed the importance of acknowledging the opinions of treating physicians in deciding whether petitioners prevail.

The issue in this case came down to whether or not petitioner's expert could convince the undersigned that onset of MS can occur sooner than the three-day minimum established from the testimony of Dr. Byers and Dr. Martin in the Omnibus proceeding. The undersigned finds that Dr. Tornatore's testimony shows a plausible biologic medical theory, a logical sequence of cause and effect, and a medically appropriate timeframe because it echoes that of Dr. Byers in the Omnibus proceeding: in rare cases, someone exposed to the same antigen in a prior vaccine may develop demyelinating disease more quickly (one day here) after exposure to the same antigen in a subsequent vaccination.

Respondent requested at the hearing that the undersigned rule whether petitioner received one hepatitis B vaccination or both of the hepatitis B vaccinations because Dr. Safran doubted at the hearing that petitioner actually received both vaccinations or even one due to petitioner's lack of measured antibodies to hepatitis B serum and core antigens. The undersigned ruled at the hearing that petitioner had proved he received both vaccinations. The records show that

petitioner received his first hepatitis B vaccination on June 24, 1996 (Ex. 6, p. 3). There is no vaccination record for the second hepatitis B vaccination, but there is a health care report of a work-related incident in which petitioner relates that he received hepatitis B vaccine on July 29, 1996 followed, a day later, by tingling and numbness in his feet and stomach pains. All of petitioner's contemporaneous medical records reflect a history of this second vaccination and his onset of symptoms one day after it. The undersigned now reiterates her ruling from the bench that petitioner received both hepatitis B vaccinations and had onset of neurologic symptoms the day after his second hepatitis B vaccination.

Petitioner has proved a prima facie case of causation in fact. He has shown a biologically plausible medical theory (preformed exposure to the same antigen primed his immune system to respond to the second exposure), a logical sequence of cause and effect (the second hepatitis B vaccination caused MS due to the prior exposure), and a medically appropriate timeframe (prior sensitization led to quicker reaction).

CONCLUSION

Petitioner has prevailed on the issue of entitlement. The undersigned encourages the parties to settle damages in this case. A telephonic status conference shall be set soon to discuss how to proceed with damages.

IT IS SO ORDERED.

September 28, 2007
DATE

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