OFFICE OF SPECIAL MASTERS

No. 04-205V

(Filed: November 30, 2004)

DANA F. EVERETTE,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Douglas E. Acklin, Arlington, VA, for petitioner.
James A. Reistrup, III, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

Petitioner filed a petition on her own behalf on February 11, 2004 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that hepatitis B vaccination on February 14, 2001 caused her Bell's palsy after she experienced malaise and myalgias the day after her vaccination. Petitioner had a history of type II diabetes before vaccination.

A hearing was held on September 21, 2004. Testifying for petitioner was Dr. David Rosenstreich, board-certified in internal medicine, allergy and immunology, who is the Director of the Division of Allergy and Immunology at the Albert Einstein College of Medicine. He also has

a certificate in Diagnostic and Laboratory Immunology. Testifying for respondent was Dr. Melvin Berger, board-certified in pediatrics, allergy and immunology, who is Professor of Pathology at Case Western University.

FACTS

Ms. Everette was born on October 7, 1945. She received her first hepatitis B vaccination on February 14, 2001. On February 26, 2001, she saw Dr. Leo E. Waivers, an internist, and told him that, after receiving hepatitis B vaccine, she had malaise and some myalgias. She was concerned that her blood sugar (which was normally 120) might be up (and it was 245). He diagnosed her with Bell's palsy. Med. recs. at Ex. 4, p. 1.

Also on February 26, 2001, Ms. Everette saw Dr. Cynthia L. Lopez, a neurologist, and told her that her blood sugar had risen to 245. Dr. Lopez wrote, "We discussed that certainly the Bell's palsy could have been precipitated by the hepatitis B vaccine or be coincidental and unrelated." Med. recs. at Ex. 4, pp. 2, 3.

On March 2, 2001, an MRI was done, showing two white matter lesions in the left parietal region which were nonspecific. Med. recs. at Ex. 4, p. 5.

On March 27, 2001, Dr. Lopez diagnosed a severe 7th nerve lesion with axial loss. Med. recs. at Ex. 4, p. 7.

On April 17, 2001, Dr. Yash Kataria noted that Ms. Everette needed 10 to 14 hours of sleep a night since the onset of Bell's palsy and she was markedly overweight at 182 pounds, being 63 inches tall. Med. recs. at Ex 4, p. 13. Her antinuclear antibodies (ANA) were negative. Med. recs. at Ex. 4, p. 15.

Dr. Kataria thought Ms. Everette might have sarcoidosis[1] clinically on June 1, 2001, but he could not establish that diagnosis with confidence, as he noted on July 9, 2003. Med. recs. at Ex. 4, pp. 56, 67, 68.

In April 2003, Dr. William A. Wooden, a plastic surgeon, performed a brow lift on Ms. Everette for brow ptosis (drooping of the upper eyelid) and inserted a gold weight for her right lid. Med. recs. at Ex. 4, p. 64.

On July 9, 2003, Dr. Kataria noted that Ms. Everette was markedly improved from her Bell's palsy and had some reconstructive surgery because she was complaining of ptosis with closing of her right eye when she looked down and during eating. Med. recs. at Ex. 4, p. 68.

Additional Material

Petitioner submitted on June 27, 2004, an article entitled "Postmarketing Surveillance for Neurologic Adverse Events Reported After Hepatitis B Vaccination. Experience of the First Three Years" by F.E. Shaw, et al., 127 *Amer J Epidem* 2:337, et seq. (1988). It discusses ten cases of Bell's palsy after vaccination with the plasma-derived hepatitis B vaccine.

Respondent filed "Use of the Inactivated Intranasal Influenza Vaccine and the Risk of Bell's Palsy in Switzerland," by M. Mutsch, et al., 350 *New Eng J Med* 9:896-903 (2004) (Ex. D) and "Perspective. Nasal Vaccination, *Escherichia coli* Enterotoxin, and Bell's Palsy," by R.B. Couch, 350 *New Eng J Med* 9:860-61 (2004) (Ex. E). The authors in Ex. D state, "the causes and pathogenesis of Bell's palsy remain unclear. Herpes simplex has been suspected, but autoimmune process have also been considered." Ex. D, p. 902. The vaccine was no longer in clinical use

---

[1] "Sarcoidosis is a multi system disorder characterized in affected organs by a type of inflammation called granulomas. The cause is unknown." http://www.sarcoidcenter.com/sardef.htm

because of the risk of Bell's palsy even though it had previously been licensed albeit only in Switzerland.

Dr. Couch in his editorial (Ex. E) states that the article (Ex. D) provides "very strong evidence that the occurrence of Bell's palsy resulted from the use of the vaccine." Ex. E, p. 860. He continues, "The prevailing notion is that most cases of Bell's palsy represent an autoimmune disorder or a reactivation of a latent herpesvirus infection. Both herpes simplex virus and varicella-zoster virus have been shown to be latent in a high proportion of seventh-nerve ganglia. ... Herpes simplex virus is less well established as a cause of Bell's palsy, but the evidence of a causal relation is strong, and it is possible that a herpesvirus infection was reactivated in the patients in whom the palsy developed." Ex. E, p. 861.

TESTIMONY

Dr. David Rosenstreich testified that the day after petitioner received her hepatitis B vaccination, she began to feel sick and very fatigued. Ten to twelve days later, the right side of her face was paralyzed and she was diagnosed with Bell's palsy. Tr. at 28. He testified that there is direct relationship between hepatitis B and her Bell's palsy because she immediately became sick. Petitioner's mild adult onset diabetes predisposed her to developing Bell's palsy. Tr. at 29.

Bell's palsy is not preceded by malaise and fatigue, but they show that the hepatitis B vaccine exaggerated petitioner's immune response. Tr. at 30. As Dr. Rosenstreich explained the basis for his opinion of causation, hepatitis B vaccine caused an inflammatory reaction leading to both systemic symptoms (the malaise and fatigue) and reactivation of a latent virus (most likely herpes simplex or zoster) that petitioner had, causing Bell's palsy. The inflammatory reaction released proteins causing the symptoms, resulting in starting the latent virus to grow in her nerves. Tr. at 31-

32. The virus infection growing in the nerve kills the nerve which then no longer functions and one gets paralysis. Tr. at 35.

Dealing with respondent's expert Dr. Berger's objection that there was no proof here of an unusual immune response to the vaccine, Dr. Rosenstreich testified that there is no medical definition of an excess antibody response and it was not measured. Tr. at 36. There can be excessive lymphocyte reactivity which produces proteins called cytokines, but this was not measured. Tr. at 37. There can furthermore be stimulation of self-reactive lymphocytes by hepatitis B vaccine (and one would measure the lymphocytes killing petitioner's nerve cells), but no one documents this process in Bell's palsy and it was not done in petitioner's case. Tr. at 38-39.

Dr. Rosenstreich admitted he could not state whether this was a cell-mediated response in petitioner's case or an antibody-mediated reaction. Tr. at 41. The viral vaccine stimulates a reaction immunologically. The recombinant hepatitis B vaccine contains proteins without the virus. Tr. at 46. In the Shaw article, there were 10 cases of Bell's palsy following plasma-derived hepatitis B vaccination (not the recombinant vaccine) out of 41 neurologic events or 25%. In other words, Bell's palsy was the predominant diagnosis among vaccinees. Most had onset within the first week of vaccination. Tr. at 43.

In the Vaccine Adverse Event Report system or VAERS, Bell's palsy keeps getting reported. When nasal influenza vaccine was used, it led to an increase in Bell's palsy. However, hepatitis B vaccine is not as potent. Tr. at 46.

Petitioner's type 2 diabetes predisposed her to develop a neuropathy. Five to ten percent of Bell's palsy patients have diabetes. Tr. at 56.

On cross-examination, Dr. Rosenstreich said that the hepatitis B vaccine's reactivation of the herpes virus in petitioner was the cause of her Bell's palsy, not the autoimmune processes. Tr. at 60. Herpes virus is latent in all of us, but no test can see if it is in the facial nerve. Tr. at 663. The tingling and numbness in petitioner's legs for the prior year could be due to her diabetes, but he is not sure. Tr. at 68. Bell's palsy is a peripheral neuropathy. Tr. at 65.

Petitioner's neurologist said that her diabetes is mild, and her numbness and tingling disappeared. Petitioner's diabetes was not well-controlled after her vaccination. Over the prior four years, petitioner's blood sugar ran at 120, but on February 26, 2001, 12 days after vaccination, it was 245. Tr. at 70. She was then put on medication and her blood sugar decreased. Dr. Rosenstreich testified that the hepatitis B vaccine aggravated petitioner's diabetes. Systemic inflammation from the hepatitis B vaccine sent her blood sugar out of control. Tr. at 71.

Dr. Rosenstreich testified that cold sores are a clinical response to herpes virus. Tr. at 62. On questioning, Ms. Everette testified that she had cold sores and fever blisters two years ago. Tr. at 76. In response, Dr. Rosenstreich stated that Ms. Everette has herpes virus. Tr. at 78.

On cross-examination, Dr. Rosenstreich admitted that the 7 cases of Bell's palsy seen among the vaccinees with plasma-derived hepatitis B vaccine were actually smaller than the 42.5 expected during the three-week risk interval based on a background rate of 31.4 cases per 100,000. Tr. at 79, 80. He has seen a lower background rate of Bell's palsy in the medical literature. Tr. at 81..

Dr. Melvin Berger testified for the respondent that he had insufficient evidence to conclude what caused petitioner's Bell's palsy. Tr. at 89. He thought there was only a temporal association with the vaccine. Tr. at 90. He thinks a systemic inflammatory response to the vaccine is possible. Id. A systemic inflammatory response such as malaise and fatigue is common in vaccinations, and

he believes hepatitis B vaccine caused malaise and fatigue in petitioner here.. Id. And the temporal association is enough for Dr. Berger to conclude that hepatitis B vaccine probably caused Ms. Everette's malaise and fatigue. Tr. at 91. But he will not say that the vaccine caused an inflammatory reaction leading to a reactivation of her latent herpes virus which caused her Bell's palsy. Id. He did not see an exceptional immune response in this case. Tr. at 92. Ms. Everette was not tested for excessive lymphocyte reaction or stimulation of self-reactive lymphocytes by hepatitis B vaccine, which does not mean she does not have them. Tr. at 96. Doctors do not look for a herpes virus to treat in Bell's palsy cases because they expect the Bell's palsy to be self-limited, meaning it will just go away. Tr. at 97. Petitioner's neurologist, Dr. Cynthia Lopez, considered using Prednisone but did not because petitioner has diabetes. Id.

A systemic inflammatory reaction with symptoms of malaise and fatigue can, in certain circumstances, provoke a specific attack. Tr. at 101-02. Only in the Mutsch article was there a statistical analysis saying that the temporal association was strong enough to blame the intranasal flu vaccine for Bell's palsy. Tr. at 102. The Mutsch article and editorial show that autoimmunity may be involved in Bell's palsy. Tr. at 104. He cannot make any conclusions. Tr. at 108.

Dr. Berger admitted on cross-examination that the time interval between petitioner's hepatitis B vaccination and her Bell's palsy was compatible with an immune reaction. Tr. at 108-09. Moreover, Bell's palsy following her vaccination is biologically plausible. Tr. at 109. There may have been a reactivation of virus in petitioner or autoimmunity in this case. Id. However, he does not have any data to see if either occurred in this case. Tr. at 110.

Dr. Berger stated he would tell Ms. Everette not to take a second hepatitis B vaccination. Tr. at 113. There would not be much benefit and there could be some risk of malaise and fatigue and may be a risk of another episode of Bell's palsy. A principle of medicine is first to do no harm. Id.

DISCUSSION

Petitioner is proceeding on a theory of causation in fact. To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccine she would not have had Bell's palsy and an exacerbation of her diabetes, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 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.

Although the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), listed various criteria for the federal district court judges to follow in their role as gatekeeper for the admission of scientific and medical evidence, such criteria are merely aides in evaluation, rather than prescriptions, for the Office of Special Masters. Even in federal district courts, "Daubert's list of specific factors neither necessarily nor exclusively applies . . . in every case . . . [and its] list of factors was meant to be helpful, not definitive." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141, 151 (1999).

In the Office of Special Masters, even the Federal Rules of Evidence are not required.[2] Invariably, consistent with the legislative intent in creating the Vaccine Program, the special masters admit most evidence. But see, Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

[2] CFC Rules, Vaccine Rule 8(b) Evidence. "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties."

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." Thus, the task before the undersigned is not to delineate how petitioner's evidence of inflammatory response does or does not satisfy the Daubert litany of support in peer-reviewed medical literature, concurrence among a majority of physicians in the field of immunology and/or neurology, and confirmative testing of methodology. Rather, the task is to determine medical probability based on the evidence before the undersigned in this particular case.

Both experts agree that petitioner has Bell's palsy. Respondent's expert, Dr. Berger, agrees with Dr. Rosenstreich, petitioner's expert, that the time interval between petitioner's hepatitis B vaccination and the onset of her Bell's palsy is compatible with an immune reaction, that Bell's palsy following hepatitis B vaccination is biologically plausible, and that there may have been a reactivation of virus in petitioner or autoimmunity in this case. But Dr. Berger will not opine that hepatitis B caused petitioner's Bell's palsy because he does not have statistical evidence as in the Mutsch article dealing with intranasal flu vaccine or sufficient understanding of the pathological mechanism. The Federal Circuit in Knudsen, supra at 548-49, specifically holds that petitioner need not prove a biological mechanism in order to prevail.

As for epidemiological support for causation, the Federal Circuit in Knudsen ruled for petitioners even when epidemiological evidence directly opposed causation from a vaccine.
In Knudsen, even though epidemiological evidence supported the opposite conclusion, i.e., that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, the Federal Circuit stated:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP

> encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

So too, in this case, although the medical literature establishes only that intranasal flu vaccine causes Bell's palsy, the theory underlying that causation is the same as Dr. Rosenstreich expressed in this case: an inflammatory response that provokes autoimmunity or that reactivates a latent herpes infection that grows in and kills the seventh nerve, resulting in paralysis that is the hallmark of Bell's palsy.

The timing here is appropriate for an immune response. The pathological process described in the medical literature and in Dr. Rosenstreich's testimony is consistent with what happened to petitioner clinically, and shows a logical sequence of cause and effect. Dr. Berger admits both hypotheses (autoimmunity and reactivation of herpes virus) are biologically plausible. The only ingredients missing are pathologic certainty and epidemiologic support. Dr. Berger testified he would like one or the other to convince him that hepatitis B caused petitioner's Bell's palsy, but the Federal Circuit held that they are not essential to petitioner's case. Even when epidemiology leads to a conclusion opposite to vaccine causation, petitioners may still prevail if they show a logical sequence of cause and effect, and biologic plausibility. .

Dr. Rosenstreich's testimony is more credible than Dr. Berger's. Dr. Rosenstreich, consistent with the medical literature, testified that hepatitis B vaccine caused petitioner's Bell's palsy by either autoimmunity or reactivation of a latent herpes virus which grew in and destroyed her seventh nerve. The immediate reaction of malaise and fatigue is also a consequence of hepatitis B vaccine, and one which Dr. Berger agrees hepatitis B vaccine caused. Dr. Rosenstreich also stated, and Dr. Berger

agreed, that the interval between vaccination is compatible with an immune reaction. Petitioner has shown biologic plausibility, compatible timing interval, and a logical sequence of cause and effect. Petitioner has prevailed in this case, proving that hepatitis B vaccine caused her Bell's palsy.[3]

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon to discuss damages. Should the parties not be able to settle this case, the undersigned will hold a damages hearing.

IT IS SO ORDERED.

______________________________ ____

DATE Laura D. Millman
Special Master

[3] Dr. Rosenstreich also testified that hepatitis B vaccine exacerbated or significantly aggravated petitioner's diabetes because, before her vaccination, her diabetes was mild and under control, but after the vaccination, her blood sugar shot up and she needed medication. Respondent's expert never dealt with this issue, and the undersigned must therefore assume it is conceded. Petitioner has the burden of proving that this exacerbation lasted more than six months in order to recover under the Vaccine Act. See subsection 300aa-11(c)(1)(D)(i).