OFFICE OF SPECIAL MASTERS No. 05-286V September 29, 2005

MILLMAN, Special Master

DECISION¹

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States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.

Petitioner filed a petition dated March 10, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that hepatitis B vaccinations she received on March 28, 2003 and May 15, 2003 caused her rashes and other problems.

Petitioner's counsel, in a status conference dated September 27, 2005, stated that petitioner was dismissing because she could not find an expert to support her allegations after consulting with two different doctors, Dr. Mary M. Hagerty, a treating rheumatologist, and Dr. Allen Morrison, an infectious diseases expert. The undersigned never ordered respondent to file a Rule 4(b) report since petitioner had not made out a prima facie case.

FACTS

Petitioner was born on July 23, 1960.

On October 9, 1996, she was diagnosed with hypothyroidism. Her weight was 215 pounds. Med. recs. at Ex. 8, p. 13.

On April 9, 1997, she was diagnosed with hypothyroidism and obesity. She weighed 213 pounds. Med. recs. at Ex. 8, p. 18.

On September 8, 1997, she saw the doctor, complaining of ringing in her ears. Her weight was 215 pounds. Med. recs. at Ex. 8, p. 22.

In 2001 (the date is obscured in the records), petitioner saw a doctor. She had been diagnosed with hypothyroidism when she was 28. She had been overweight since adolescence. She generally felt tired most of the time and occasionally felt somewhat dizzy and had what she called "fading spells." She had some mild vertigo and felt she was off-balance or leaning over. She had chronic difficulty with pain in her feet since having broken her left foot and badly

spraining her right ankle. Occasionally, she got sciatica in her right hip area. Med. recs. at Ex. 7, p. 1.

On December 14, 2001, petitioner went to the doctor. She weighed 206 pounds. Two weeks earlier, she had pain in the left side of her neck extending to her shoulder which had worsened a great deal and now extended down to her elbow with sharp electrical type pains that also shot down her back. She had a history of trauma to her neck with some kind of injury that had a spinal fluid leak a number of years ago. She had some vague numbness in her hand but the pain did not really go below her elbow. Med. recs. at Ex. 7, p. 2.

On December 20, 2001, petitioner returned to the doctor. Her neck and back were still causing trouble. Her cervical spine x-rays were entirely normal. She complained of feeling dizzy and, on one occasion, almost fainted while in a hot shower. The doctor thought that much of the dizziness and light headedness was probably related as much to the discomfort with some vasomotor difficulty. Med. recs at Ex. 7, p. 3.

On March 28, 2002, petitioner told the doctor that she had problems with swelling in her right knee for the last three weeks. It turned black and blue. The doctor thought it was probably tendonitis. *Id*.

On March 15, 2003, petitioner went to the emergency department of Shenandoah Memorial Hospital where she saw Dr. B. Cummings with a sore throat and productive cough that she had had since Thursday, March 6, 2003. She had body aches, chills, frontal headache, nasal congestion, sinus pressure, increased shortness of breath, a red rash on her left cheek which she had had for 10 days, and itching. [This was 13 days before petitioner's first hepatitis B

vaccination.] She was prescribed Keflex. Her strep test was negative. Med. recs. at Ex. 13, pp. 89, 92, 94.

On March 28, 2003, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 2, p. 1.

On April 11, 2003, petitioner went to the doctor with an eruption primarily on her face and arms which was quite pruritic. Two weeks previously, she had a painful eruption on her left cheek and was seen in the emergency room which informed her that she had shingles.

Petitioner's boyfriend had a similar recurrent eruption and the doctor suspected that this was herpes simplex. It was healing pretty well. She was given Keflex for some sinus infection she had at the same time. Over the last week or so, she developed a rash on her face and arms below the elbows that was quite pruritic. It seemed directly related to her work making jello where she was exposed to a good deal of dust. She said she came home from work with her arms swollen and very pruritic and, if she started itching, she developed the eruption. On physical examination, she had excoriations on both forearms and hands, and an erythematous papular eruption on her face. The lesion on her left cheek was a more dense erythematous area that appeared to be healing. The doctor's impression was probably contact dermatitis, probably from some of the colorings or dyes in the jello, and resolving herpes simplex. Med. recs. at Ex. 7, p. 4.

On May 15, 2003, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 2, p. 1.

On May 16, 2003, petitioner saw Dr. Richard C. Moore of Occupational Health Services, stating that she noticed a rash on her body about a week after she started working in the Kool-Aid department of Kraft and a week after getting her first hepatitis B vaccination. She had "shingles"

on her face in February on the lower left side of her jaw. This resolved in late March 2003. She had her first hepatitis B vaccination shortly thereafter. She began working in a different line and developed a rash on both forearms. Yesterday, she had her second hepatitis B vaccination. Several hours later, her face and neck were burning. The rash itched everywhere. She did not have fever, chills, fatigue, weight loss, or tingling of her hands and fingers. On physical examination, she had two distinct rashes: one was erythematous and flat on the anterior mandible bilaterally, a bit more on the left than on the right, with small central papules rather than vesicles, and the second was an excoriated pustular rash covering the hair-bearing portions of both forearms with a single lesion above the elbow on the right arm in various stages of healing. Dr. Moore concluded that neither rash appeared to be a reaction to the vaccine or to any environmental substance. The forearm rashes were impetiginous-looking and certainly follicular in distribution. The rash might also be. Med. recs. at Ex. 2, p. 2.

On May 20, 2003, petitioner returned to Shenandoah Memorial Hospital emergency department with a right ankle injury. She had a weak ankle from previous injury. She had stepped on a block and twisted her ankle. She then fell, was nauseated and vomited once. She had crutches at home. Med. recs. at Ex. 13, p. 98.

On May 27, 2003, petitioner saw Dr. Suzanne Stevens. Petitioner had injured her right ankle while making fences on her boyfriend's farm. She was seen in the emergency room for severe pain and swelling. She had a history of previous severe ankle sprains with an associated avulsion fracture. The date of the injury was May 20, 2003. The assessment was third degree right ankle sprain with prior history of ankle sprains and old avulsion fractures. She had contusion and sprain of her right foot. Med. recs. at Ex. 10, p. 1.

On May 29, 2003, petitioner went to Dermatology Associates, complaining of a rash on her face and arms that had lasted for two and one-half months. She was diagnosed with shingles three months ago. She had erythematous plaques on her cheeks with erythematous papules on her forearms. The assessment was cutaneous lupus vs. drug eruption. Med. recs. at Ex. 4, p. 1.

On June 5, 2003, petitioner returned to Dr. Stevens with sores on her arms. Med. recs. at Ex. 10, p. 2.

On October 13, 2003, petitioner saw Dr. Mary M. Hagerty for problems with a rash. Six months earlier, she had shingles on the left side of her face and a strep throat. She was given hepatitis B vaccine and developed a diffuse, facial rash which gradually spread to her arms. A booster shot made her worse. She had ongoing problems with the rash since April. She was told this could be contact dermatitis. Grape Kool-Aid made her worse. She also developed episodes where her legs gave out on her. She had injured her right ankle and had surgery. She had a history of hypothyroidism and mild depression. Her mother had possible lupus vs. psoriasis. She has several aunts with lupus. Med. recs. at Ex. 5, p. 5.

She had two headaches per week, some blurred vision, and some dysphagia due to her thyroid problem. She had a pruritic skin rash and was sensitive to the sun. Her lower extremities were weak. On physical examination, her skin was remarkable for a fairly bland, slightly raised, slightly erythematous rash on her arms. It was more papular in some places and more confluent in others. Petitioner had 14 out of 18 trigger points for fibromyalgia. Med. recs. at Ex. 5, p. 6.

On October 21, 2003, petitioner had an antinuclear antibody (ANA) test done which showed a titer of 1:320. Med. recs. at Ex. 5, p. 1. On November 5, 2003, Dr. Hagerty prescribed Plaquenil because petitioner's ANA was positive. Med. recs. at Ex. 5, p. 11.

On November 17, 2003, petitioner saw Winchester Neurological Consultants, Inc. She spoke with nurse Cheryl A. Cole and complained of pain, falling, tremors, weakness, fatigue, rash, and headaches. She stated she had a possible reaction to hepatitis B vaccine. Her past medical history included depression, being knocked unconscious, memory loss, thyroid problems, and pain in her neck, back, arm, and hand. She smoked 10 cigarettes daily and weighed 194 pounds. Med. recs. at Ex. 12, p. 1.

On November 18, 2003, she saw Dr. Patrick M. Capone, a neurologist, and complained of dizziness, headaches, and frequent falls. She felt her symptoms started in March shortly after receiving hepatitis B vaccine. She noticed her symptoms exacerbate after the second injection. She felt a daily occipital pressure and dizziness, was not sleeping well, felt fatigue, and was recently diagnosed with lupus and possible fibromyalgia. Med. recs. at Ex. 12, p. 2. Dr. Capone's impression was muscle contraction pattern cephalgia and facial neck pain, and weakness of uncertain etiology. Med. recs. at Ex. 12, p. 3.

On December 4, 2003, petitioner had an electromyography and nerve conduction study. She had no generalized neuropathy. She had mild sensory-only left carpal tunnel syndrome. Med. rec. at Ex. 12, pp. 5, 6.

On December 8, 2003, she had an MRI which was normal. Med. recs. at Ex. 12, p. 11. On the same date, she had visual evoked potentials, which were normal, and sensory evoked potentials, which were normal. *Id*.

On December 23, 2003, petitioner returned to Dr. Capone. She was feeling better and had less headaches and less peripheral pain. She was not sleeping well and snored. Med. recs. at Ex. 12, p. 15.

On December 30, 2003, petitioner had a normal EEG Tilt table test. Med. recs. at Ex. 12, p. 16.

On January 20, 2004, petitioner returned to Dr. Stevens complaining of recurrent bouts of falls. She was not sure what caused them. She was diagnosed with lupus in 2003 after hepatitis B vaccination, as well as fibromyalgia. She had right shoulder pain. Dr. Stevens' assessment was rotator cuff tendonitis of the right shoulder, right ankle osteoarthritis medially, a history of recurrent and frequent falls (reason unknown), lupus, and fibromyalgia. Med. recs. at Ex. 10, pp. 6, 7.

On February 9, 2004, Dr. Stevens noted that petitioner had a long history of falls. Med. recs. at Ex. 10, p. 8.

On February 20, 2004, Dr. Stevens noted that ultrasound demonstrated impingement of petitioner's supraspinatus tendon with range of movement, but no obvious tear. She diagnosed right shoulder impingement rotator cuff tendonitis. Med. recs. at Ex. 10, p. 9.

In February 2004, petitioner wanted to discuss lupus and if there were a possible relationship to her hepatitis B vaccinations. Med. recs. at Ex. 7, p. 6.

On March 29, 2004, petitioner returned to Dr. Stevens with left carpal tunnel syndrome. Med. recs. at Ex. 10, p. 10.

On April 5, 2004, petitioner had a thyroid TSH of 7.28 which meant she was underactive. Med. recs. at Ex. 7, p. 10.

On April 16, 2004, petitioner returned to Dr. Stevens two days after decompressive acromioplasty of her right shoulder. She was given Keflex post-operatively. She spiked a 101° fever and had significant sinusitis. She was prescribed Zyrtec and Benadryl. Petitioner came in

because she had retained fluid and was itching all over. On physical examination, petitioner had a lot of redness around her wound consistent with contact dermatitis to the adhesive the nurses placed on the wound. She had broken out in a rash that was itchy in multiple areas on her chest and arms. Dr. Stevens stopped the Keflex. She prescribed a Z-pack. Med. recs. at Ex. 10, p. 11.

On April 20, 2004, petitioner returned to Dr. Stevens with fluid retention affecting her lower extremities below the knees but not so much in the hand. She was no longer itching or having an allergic reaction. Her sinusitis was better and she was afebrile. Med. recs. at Ex. 10, p. 12.

On May 25, 2004, Dr. Stevens noted that petitioner's rheumatologist and neurologist diagnosed her with bilateral carpal tunnel syndrome. Med. recs. at Ex. 10, p. 13.

On May 25, 2004, petitioner saw Dr. Patricia A. Daly because of her hypothyroidism. She was diagnosed with this many years ago. She was diagnosed with lupus in October 2003 which petitioner felt hepatitis B vaccination in March 2003 caused because her rash began just after that. She had periodic falls which she attributed to weakness rather than to balance. Med. recs. at Ex. 3, p. 1. She was 5'1½ " tall and weighed 212 pounds. She had apparent diabetes, type 2. Med. recs. at Ex. 3, p. 2.

On July 13, 2004, petitioner returned to Dr. Stevens. A hornet stung her recently and she developed cellulitis which had resolved. X-rays demonstrated progressing osteoarthritis. She had chronic pain and swelling of her right ankle. Med. recs. at Ex. 10, p. 14.

On July 30, 2004, petitioner returned to Dr. Stevens. She had an angulated fracture of her coccyx secondary to a fall on July 29, 2004. Med. recs. at Ex. 10, p. 15.

On August 11, 2004, petitioner returned to Dr. Daly, complaining of arthritis in her ankles and shoulders and diabetes mellitus, type 2. She did not have hypoglycemic episodes since her last visit, showing that she tolerated Glucophage well. Her weight had increased 5 pounds since her last visit. She was prescribed an increase in Glucophage. Med. recs. at Ex. 3, pp. 11, 12.

On September 13, 2004, petitioner returned to Dr. Stevens. She had chronic right carpal tunnel syndrome and decided to have carpal tunnel release. She fell on September 5th while going fishing. Bees chased her and she slipped on the bank and fell on her right outstretched arm, jamming her right shoulder which had some swelling. She was to have carpal tunnel release for both hands, one at a time. Med. recs. at Ex. 10, p. 16.

On October 1, 2004, she had a post-operative check. Petitioner did not have any complaints. The numbness and tingling in her right hand were gone. She had right carpal tunnel release one week previously. Med. recs. at Ex. 10, p. 17.

DISCUSSION

Petitioner does not allege a Table injury. Therefore, she must prove her allegations by 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." <u>Grant, supra, 956 F.2d at 1149</u>. Mere temporal association is not sufficient to prove causation in fact. <u>Hasler v. US, 718 F.2d 202, 205</u> (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the vaccine, she would not have had her rashes and other complaints, 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).

Petitioner has not filed any expert medical report supporting her allegations that hepatitis B vaccine caused her rashes and other complaints which, notably, occurred three weeks before her first hepatitis B vaccination. Moreover, the medical records do not support her allegations that hepatitis B vaccine caused her problems. The Vaccine Act, 42 U.S.C. §300aa-13(a)(1) does not permit the undersigned to rule in favor of petitioner based solely on her allegations without supporting medical records or medical opinion.

Petitioner has not satisfied her burden of proof. A failure to prosecute her case will lead to dismissal. Hayman v. US, No. 02-725, ___Fed. Cl. ____ (May 9, 2005) (failure to provide a complete expert report results in dismissal, citing Sapharas v. Sec'y of DHHS, 35 Fed. Cl. 503 (1996); Tsekouras v. Sec'y of DHHS, 26 Cl. Ct. 4439 (1992); and, outside the Vaccine Program context, Claude E. Atkins Enters., Inc. v. US, 899 F.2d 1180 (Fed. Cir. 1990); Adkins v. US, 816 F.2d 1580, 1583 (Fed. Cir. 1987); and Kadin Corp. v. US, 782 F.2d 175, 177 (Fed. Cir. 1986)).

Petitioner has not made a prima facie case that hepatitis B vaccine caused in fact her rashes, weakness, dizziness, falls, or any other physical condition. This petition must be dismissed.

CONCLUSION

Petitioner's petition is dismissed with preju	dice. In the absence of a motion for review
filed pursuant to RCFC Appendix B, the clerk of the	ne court is directed to enter judgment in
accordance herewith. ²	
IT IS SO ORDERED.	
DATE	Laura D. Millman Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.