

OFFICE OF SPECIAL MASTERS
No. 05-277V
initially filed March 13, 2006; refiled redacted March 24, 2006
Not to be Published

* * * * *
JANE DOE, *
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Petitioner, *
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v. *
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SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *
*
Respondent. *

* * * * *
Jane Doe, Everywhere, USA, for petitioner pro se.
Heather L. Pearlman, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

¹ On March 24, 2006, 11 days after issuing this unpublished decision, the undersigned received by UPS Next Day Air a series of pages from petitioner in which she asserts that the undersigned has made numerous mistakes in her decision and that there is a stigma against her psychological problems which she does not want publicized. The undersigned will interpret her pages as a Motion for Redaction of her decision so that petitioner’s identity will not be known by anyone perusing the website of the US Office of Federal Claims. The undersigned will file petitioner’s pages by her leave in an Order. The undersigned had her law clerk telephone petitioner March 24, 2006 to ascertain if petitioner wanted to file a Request for Reconsideration or Notice of Appeal. Petitioner’s answer to both was in the negative. Petitioner is reminded that she has the option, within 90 days of the entry of Judgment, to file a Notice to File a Civil Action if she wants to file a civil suit against the vaccine manufacturer or administrator. If petitioner files nothing after judgment is entered, she will not be able to file a civil action. One of petitioner’s assertions is that her former counsel told her that the undersigned “does not like adults with adverse reactions.” If petitioner’s former counsel stated this, it is untrue. The undersigned’s decisions are based solely on the evidence. Petitioner’s treating doctors, except for Dr. Waisbren who stands markedly alone in his opinions, have uniformly found nothing wrong medically with petitioner except for a transient reaction to her vaccination.

Jane Doe filed a petition on March 4, 2005 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., for herself, alleging that a hepatitis A vaccine she received on December 11, 2003 caused her headache, dizziness, joint pain, nausea, followed by chronic illness including fatigue, body aches, paresthesia, elevated blood pressure, optic neuritis, and carcinoma at the site of injection. Petition, ¶1(b)

Petitioner's counsel moved to withdraw during a telephonic status conference on January 10, 2006, followed by a written motion which the undersigned granted. Petitioner proceeded pro se and the undersigned had a status conference with her and respondent on January 27, 2006. On March 9, 2006, Ms. Doe telephoned the undersigned's law clerk and asked the undersigned to issue a ruling based on the records submitted in this case.

FACTS

Ms. Doe was born on October 9, 1945. She received a hepatitis A vaccination on December 11, 2003. Med. recs. at Ex. 2, p. 1. On December 16, 2003, two weeks later, she phoned her doctor to say she had a received a hepatitis vaccination at work and had a reaction. She was dizzy and nauseated. Med. recs. at Ex. 9, p. 8. Ms. Doe came in to see the doctor that same day. She had lightheadedness, nausea, and a pulsating head since she received the vaccine. She was lethargic and, for the prior five days, had facial flushing, headaches, and elevated blood pressure. The diagnosis was hypersensitivity. Med. recs. at Ex. 9, p. 9.

On December 22, 2003, she complained of not feeling well. Her nausea came and went. The symptoms began four hours after hepatitis A vaccination. She had numbness and tingling in her fingers, fever and chills, and high blood pressure. Med. recs. at Ex. 9, p. 10.

On December 29, 2003, she was still not well. She had the worst headache of her life. She was lightheaded with bone pains, and an increase in perspiration. Her laboratory tests were normal. She complained of tingling in both arms, and had high blood pressure. Med. recs. at Ex. 9, p. 11.

On January 5, 2004, Ms. Doe saw Dr. Arlene Sagan for a reaction to hepatitis A vaccine, hypertension, and numbness. She had been seen by three other doctors since then. She complained that the night of the vaccination, she was lightheaded, insomniac, tingling, headachy, and nauseated. Med. recs. at Ex. 21, p. 1. Dr. Sagan writes in her notes: Unlikely to be secondary to hepatitis A shot due to longevity of symptoms (not resolved within three days). *Id.*

On February 23, 2004, Ms. Doe saw Dr. Jesse Taber, a neurologist. Her neurological examination was normal. Dr. Taber felt that carpal tunnel syndrome or ulnar nerve compression at the elbows might be contributing to her complaints. Anxiety was probably playing a role in her symptoms. Med. recs. at Ex. 5, p. 1.

On March 19, 2004, Dr. Terrence C. Moisan wrote that he evaluated Ms. Doe and reviewed her records. He examined her and found neurologically that she had normal strength of all four extremities, intact light touch and pinprick, normal proprioception, and normal gait and balance. He reviewed Dr. Taber's records which showed in a thorough examination that she is normal. Med. recs. at Ex. 19, p. 3. Dr. Moisan describes Ms. Doe's reaction to the vaccine as unusual and puts quotation marks around the word "reaction." He states, "[T]he persistence of such symptoms with an entirely negative examination seems unlikely. ... There certainly are no neurologic findings at this time to suggest residual myelitis or other symptoms to suggest a cerebritis. Her cognitive function appeared clinically normal. I suspect that the residual

symptoms may be somatoform in disorder and these may be heightened by anxiety or fear of an underlying illness. ... The exact nature of the ‘reaction’ may remain obscure, but would have to be considered at this time to be either idiosyncratic or a somatoform response. Currently, I believe her symptoms are residual somatoform disorder with anxiety as described above. The hypertension is in my opinion independent of any prior immunization...” Med. recs. at Ex. 19, p. 4.

(“Somatoform” means “denoting psychogenic symptoms resembling those of physical disease.” Dorland’s Medical Illustrated Dictionary, 27th ed. (1988) at 1547. “Psychogenic” means “produced or caused by psychic or mental factors rather than organic factors.” Dorland’s at 1384.)

On March 22, 2004, Ms. Doe had a basal cell carcinoma on her arm. Med. recs. at Ex. 13, p. 2.

On March 23, 2004, Dr. Taber wrote that an MRI of Ms. Doe’s cervical spine showed disc herniation at the C5-C6 levels on the left. An MRI of her brain was normal. An MRI of her thoracic spine was basically normal. Med. recs. at Ex. 5, p. 6. Dr. Taber’s impression was: “There is no evidence for either post-vaccinal partial transverse myelitis or possibly encephalomyelitis based upon the MRI scans. Fortunately, Mrs. Doe’s neurologic examination is normal.” Med. recs. at Ex. 5, p. 8.

On March 30, 2004, Dr. Burton A. Waisbren diagnosed Ms. Doe with serum sickness. Med. recs. at Ex. 6, p. 1.

On May 10, 2004, she saw Dr. Kevin L. Sullivan, an ophthalmologist, who stated Ms. Doe's symptoms were only subjective. Dr. Sullivan noted, "I was unable to find any objective signs." Med. recs. at Ex. 11, p. 1.

On June 15, 2004, Ms. Doe saw Dr. Martin D. Herman, a neurosurgeon. He stated Ms. Doe had a long history of anxiety and thyroid disease. Dr. Burton Waisbren felt she might have multiple sclerosis due to the vaccine. On physical examination, Ms. Doe was grossly intact neurologically with good overall strength, sensation, and gait. Her brain MRI was normal. Med. recs. at Ex. 12, p. 1. Her MRI scans were essentially normal. Med. recs. at Ex. 12, p. 2.

On June 18, 2004, Dr. Taber's impression was that Ms. Doe's headache and back pain were apparently due to muscle spasm. He stated: "There is no evidence for any other significant underlying process causing these symptoms." Med. recs. at Ex. 5, p. 13. Her persistent numbness and tingling had an uncertain etiology, most compatible with nerve compression either involving the ulnar nerve at the elbow or the median nerve at the wrist. There was no convincing evidence for her having either post-vaccinal partial transverse myelitis or possible encephalomyelitis. There was a question of optic neuritis raised. Dr. Taber stated that anxiety was "strongly contributing to her symptoms." Med. recs. at Ex. 5, p. 13. She had hypertension.

On July 13, 2004, Ms. Doe had an electromyograph and nerve conduction study. She had give away weakness in all four extremities. She had a mildly abnormal study consistent with mild median mononeuropathy at her right wrist (carpal tunnel). Med. recs. at Ex. 5, p. 28.

On July 26, 2004, Dr. Taber noted that the results of somatosensory evoked potentials, both of the upper and lower extremities, visual evoked potentials, and brainstem auditory evoked potentials were all normal. An electromyography-nerve conduction study revealed mild carpal

tunnel syndrome on the right. Med. recs. at Ex. 5, p. 15. Dr. Tabor wrote: “There is no evidence that Mrs. Doe suffered any clear cut permanent injury to either her central or peripheral nervous system as a result of the hepatitis vaccination, although she clearly had a bad reaction to the vaccine.” Med. recs. at Ex. 5, p. 18. The reason for her headache, back and neck pain, muscle spasm, and anxiety was that she stopped exercising after the vaccination. *Id.*

On October 1, 2004, Ms. Doe saw Dr. Barbara Drevlow, a rheumatologist. Laboratory tests showed no chronic evidence of inflammation. She had mild osteoarthritic changes of her hands and muscle spasms of her lower paraspinal muscles. She had diffuse myalgias after her reaction to the vaccine. This was more consistent with fibromyalgia. It was necessary to rule out myofascial pain, osteoarthritis of the hands, and degenerative disc disease of the lower spine. Med. recs. at Ex. 14, p. 3.

On October 12, 2004, Dr. Herman stated that arthritis and/or muscular pain was the etiology for Ms. Doe’s symptoms. Med. recs. at Ex. 12, p. 3.

On November 1, 2004, Dr. Taber wrote that Ms. Doe was exercising and in so much pain that she could not stand up without difficulty. Since then, she had an exacerbation of her symptoms with constant headaches, constant neck and back pain, intermittent shooting pain radiating into her right arm and, to a lesser degree, left arm, constant soreness in her leg bones, intermittent dizziness, constant numbness and tingling in both hands, but not in the legs, and all over weakness. Med. recs. at Ex. 5, p. 19.

On December 20, 2004, Dr. Taber noted that Ms. Doe still had numbness and tingling in her arms and hands, pain in her hips and knees, and general weakness but stable strength. Dr. Drevlow was treating her for arthritis. Med. recs. at Ex. 5, p. 19. Ms. Doe had a normal

neurological examination. The cause of her persistent headache, back and neck pain, muscle spasm, anxiety, and increased blood pressure was her inability to exercise since the vaccination. Her lower back pain was due to paravertebral muscle spasm. She had mild carpal tunnel syndrome with symptoms of persistent numbness and tingling, but no objective motor or sensory deficits on examination. Med. recs. at Ex. 5, p. 27.

On January 27, 2005, Ms. Doe went back to see Dr. Moisan. He notes that on his last evaluation, which was almost a year previously, he “suggested that she had no hard physical findings to correlate with her symptoms, but did consider the diagnosis of a transient serum sickness like reaction after the hepatitis A vaccine.” Med. recs. at Ex. 19, p. 1. Dr. Moisan saw no evidence of a chronic inflammatory pattern in her lab studies. Ms. Doe complained to Dr. Moisan that she has severe pain in all four limbs and in her head which is almost continuous but worse with exercise. She complains she can barely do activities of daily living and cannot go out with friends because of pain in her limbs and trunk. She also complained of tingling and numbness of her legs. *Id.* Dr. Moisan examined Ms. Doe again. His conclusion was: “I find no objective evidence of any significant cardiovascular, respiratory, serologic or neurologic abnormalities. The normal somatosensory evoked potentials, EMG studies and MRI studies all mitigate against a neurologic reaction. The serologic studies that I was provided are essential[ly] unremarkable with a borderline IgG level but normal sed rate and C-reactive protein.... Therefore, the abnormal peripheral sensations and pain do not appear to have a physiologic or structural basis. In my initial report, I commented on this being a somatoform response. ... In summary, I find that she developed no long term structural, physiologic or immunologic events from hepatitis A vaccine. She may have had a serum sickness reaction transiently but there does

not appear ... to be any obvious residual immunologic or neurologic definable dysfunction. ... She has no mechanical/structural or definable illness which would preclude the ultimate resumption of work duties. ... I find no residual/permanent structural, immunologic or serologic abnormalities subsequent to the hepatitis A exposure, which presumably caused the possible transient serum sickness like reaction.” Med. recs. at Ex. 19, p. 2.

On January 29, 2005, Ms. Doe was rear-ended in a motor vehicle accident and had new neck pain for which she received physical therapy. Med. recs. at Ex. 21, p. 20. On January 25, 2005, Dr. Drevlow noted that Ms. Doe had been hospitalized three weeks earlier for diverticular disease. Med. recs. at Ex. 14, p. 6.

On February 16, 2005, Dr. Leo S. Weinstein noted that he has been treating Ms. Doe for moderate anxiety and depression since August 1994. Med. recs. at Ex. 15, p. 1. He also states that somatization has not been a significant feature of her psychopathology. (It is unclear if Dr. Weinstein has read all or any of the medical records produced in this case in which the treating doctors opine that Ms. Doe’s complaints are due to somatization.) Dr. Weinstein’s records are at Exhibit 17. On August 26, 1994, Ms. Doe came to him with weeks of anxiety symptoms, claustrophobia, along with some depressive symptoms, including anhedonia, irritability and guilt. Precipitants include relationship stresses and family illnesses. Med. recs. at Ex. 17, p. 1. The notes indicate visits or phone calls occurring nearly every day in 1994. Med. recs. at Ex. 17, pp. 32, 33. On October 9, 1994, Ms. Doe phoned Dr. Weinstein and complained of some numbness in her hands and arms. Med. recs. at Ex. 18, p. 24. On January 22, 1997, Ms. Doe left a job after two days. Med. recs. at Ex. 18, p. 18. On December 21, 1996, she had a panic attack, her first in over a year. *Id.* On December 14, 2002, Ms. Doe told Dr. Weinstein that she had had a

malignant poly removed and had precancerous lesions in her uterus. Med. recs. at Ex. 18, p. 7. On September 29, 2003, Dr. Weinstein recorded there was a strong family history of anxiety symptoms in the daughter, mother and sister. Med. recs. at Ex. 18, p. 6. Between August 26, 1994 (her first visit) and December 11, 2003 (the day of the vaccination), Ms. Doe saw or called Dr. Weinstein 513 times. Med. recs. at Ex. 18, pp. 6-38.

On March 8, 2005, Dr. Richard J. Miller disagreed with Dr. Waisbren's ordering Zocor for Ms. Doe's elevated LDL. Dr. Waisbren had done the bloodwork after Ms. Doe had eaten two meals that day. She should have had the fasting cholesterol done first. Secondly, if her LDL were elevated, Dr. Miller would try lifestyle changes first for a few months before putting her on medication. Med. recs. at Ex. 21, p. 21. In addition, Dr. Waisbren prescribed Atenolol 50 mg for Ms. Doe's hypertension. Dr. Miller disagreed with his prescription because of the possibility of a rebound of hypertension if the medication were stopped. Only if Ms. Doe had hypertension more than 50% of the time should she use the medication. *Id.*

On April 13, 2005, Ms. Doe went to the Mayo Clinic and saw Dr. Stephanie S. Faubion, an internist. Dr. Faubion notes that Ms. Doe had no evidence of an obvious radiculopathy or focal neurological deficit on examination by Dr. Edward Laskowski. She also notes that Dr. Young found no worrisome ocular condition. Med. recs. at Ex. 18, p. 2.

On April 22, 2005, Dr. Richard J. Miller noted that Dr. Waisbren interpreted Ms. Doe's slight increase in anti-smooth muscle antibody as diagnostic of autoimmune hepatitis. Dr. Miller disagreed. Med. recs. at Ex. 21, p. 20.

Other Submissions

Petitioner filed as Exhibit 16, Dr. Burton A. Waisbren's hand-written record, which is undated, that Ms. Doe has lab studies suggesting she has an autoimmune problem with her smooth muscles. There is no statement about causation in fact or basis therefor.

Petitioner filed a letter, dated June 15, 2005, from Dr. Arlene Sagan in which she states that Ms. Doe had an acute reaction to hepatitis A vaccine and has had prolonged symptoms (chronic pain, headaches, and fatigue) ever since. She does not give a basis for her opinion that the prolonged symptoms are a reaction to the vaccine, and in fact, if Dr. Sagan believes this, her letter contradicts her medical records in which she states that she does not believe Ms. Doe's complaints beyond the immediate few days after her vaccination are related to the vaccine because they have lasted so long. P. Ex. 20. The undersigned gave petitioner an opportunity to file a supplemental report from Dr. Sagan explaining the discrepancy between her records and her letter, and also giving a basis for her opinion (if it is her opinion) that petitioner's lingering symptoms are caused by the vaccination. Dr. Sagan declined to give a supplemental report.

The undersigned gave Ms. Doe the opportunity to submit a medical expert report from someone else, but there was no further submission.

Respondent filed an expert report from Dr. Alan I. Brenner, a rheumatologist, as Exhibit A. Dr. Brenner reviews Ms. Doe's medical records and states that she had systemic complaints after vaccination, including lethargy and dizziness followed by headache. Her "subsequent complaints of numbness and tingling, color desaturation and diffuse musculoskeletal pain were on a non anatomic, non immunologic basis in that all laboratory, imaging and electrophysiologic studies were normal, except for the finding of mild right carpal tunnel on EMG/NCV. Specifically, the medical record clearly rules out the diagnosis of optic neuritis (or any other

demyelinating illness) despite the allegation in Ms. Doe's petition. Similarly, the notion that vaccination led to the development of a basal cell carcinoma is also at variance with the medical record in [that] she had a long history of basal cell cancers requiring dermatologic management and removal. (Ex. 13)." R. Ex. A, p. 5.

Dr. Brenner concludes that "it is unlikely that the hepatitis A vaccination that she received on 12/11/2003 was in any way responsible for the chronic functional complaints that she now manifests. It is more likely, as stated by several observers and documented in the above review of medical records, that her underlying psychiatric condition and overlying ongoing anxiety have been responsible for her current condition...." *Id.*

DISCUSSION

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). Althen v. Secretary, HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005); 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. 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, she would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The undersigned believes that Ms. Doe had a transient serum sickness reaction to her hepatitis A vaccination, but that is not sufficient to enable her to receive compensation under the Vaccine Act, which requires that the vaccine injury last more than six months. 42 U.S.C. §11(c)(1)(D)(i)—the petitioner must have “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine....”

By February 23, 2004, Dr. Taber, a neurologist, found her objectively normal. That is just two and one-half months post-vaccination. By March 19, 2004, Dr. Moisan found her normal in all respects. That is three months post-vaccination. Both doctors, and others who have examined her, noted that her complaints were subjective, not objective, that they were psychological (somatic) not physiological, and that Ms. Doe’s longstanding anxiety played a major role in her complaints. She does have osteoporosis, high blood pressure, carpal tunnel syndrome, and basal cell carcinoma, all unrelated to her hepatitis A vaccination.

Other than Dr. Sagan’s half-heart letter, in which she does not give a basis for her opinion, the only support for petitioner’s allegations comes from Dr. Burton A. Waisbren, Sr., about whose opinion the undersigned has doubts. First of all, except for the opinion that immediately after her vaccination, Ms. Doe had serum sickness, no other doctor who has seen Ms. Doe agrees with Dr. Waisbren’s diagnoses, which include an autoimmune disease of the smooth muscles, multiple sclerosis or a vaccine-induced demyelinating disease. Dr. Brenner,

respondent's expert, also disagrees with the idea that Ms. Doe's complaint of chronic symptoms after her transient reaction to hepatitis A vaccine is caused by the vaccine or is even somatically-based.

There is nothing in Dr. Waisbren's opinion or notes to reflect that he actually read Ms. Doe's other medical records, particularly those criticizing his conclusions about her condition or his recommendations for her treatment. There is also no report from Dr. Waisbren in which he gives the basis for his opinions. The undersigned found interesting the disagreements in the records over the medical advice and treatment that Dr. Waisbren was giving Ms. Doe. The undersigned understands that Dr. Waisbren's advice was not good medical advice and that his conclusions were unwarranted.

Petitioner has failed to make a prima facie case that her vaccine injury lasted more than six months. There is no option here but to dismiss the petition.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the 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.