

In the United States Court of Federal Claims

Office of Special Masters

No. [Redacted]

June 17, 2010¹

Not to be Published

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JANE DOE/69,

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Petitioner,

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v.

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Dismissal on motion of petitioner;

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failure to provide evidence in

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

*

support of allegation of syncope

*

and rheumatoid arthritis after

*

receiving human papillomavirus

Respondent.

*

vaccine

* * * * *

Lawrence R. Cohan, Philadelphia, PA, for petitioner.

Darryl R. Wishard, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION²

¹ This decision was initially issued on June 10, 2010 in paper form due to an error of not realizing that, on April 7, 2010, it had been converted to an electronic case.

² Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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 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. Because of the personal nature of the medical records, the undersigned hereby redacts petitioner's name sua sponte on the same date as the issuance.

Petitioner filed a petition on March 4, 2010 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she had syncope³ and a variant of rheumatoid arthritis after receiving her second human papillomavirus (HPV) vaccination on May 24, 2007.

On June 7, 2010, during a telephonic status conference, petitioner's counsel stated that he had conferred with petitioner about the difficulty of proving her case and that she had consented to his orally moving for a ruling on the record. The undersigned grants petitioner's motion.

FACTS

Petitioner was born on October 13, 1989.

On February 24, 2004, petitioner went to East Rockaway Pediatrics complaining of intermittent palpitations since the prior summer (August 2003). On that day, she felt that she had an increase in heart rate which then went to normal and then elevated. The doctor noted to rule out arrhythmia. Med. recs. at Ex. 1, p. 21.

On March 5, 2004, petitioner saw Dr. Sean G. Levchuck, a pediatric cardiologist, who noted that petitioner had a history of palpitations for several years which had now worsened on a daily basis for several minutes. She had premature ventricular contractions with palpitations. Med. recs. at Ex. 1, pp. 36, 37, 40.

On March 13, 2004, petitioner had an echocardiogram which was normal and an electrocardiogram which showed normal sinus rhythm. Med. recs. at Ex. 1, p. 21.

³ Syncope is "a temporary suspension of consciousness due to generalized cerebral ischemia; called also *faint*." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1807.

On December 27, 2004, petitioner went to East Rockaway Pediatrics for a rhinoplasty.⁴
Med. recs. at Ex. 1, p. 17.

On November 27, 2006, petitioner went to East Rockaway Pediatrics for a rhinoplasty.
Med. recs. at Ex. 1, p. 15.

On November 28, 2006, petitioner saw Dr. Ambrose M. Vallone, a pediatric cardiologist, because of a syncopal episode. Her friend slammed her finger in the door and petitioner became dizzy, lightheaded, nauseated, and sick to her stomach. She had a brief syncopal episode and a subsequent syncopal episode as well. She was out very briefly. There were no preceding palpitations. Dr. Vallone diagnosed petitioner with vasovagal⁵ near syncope and syncope, and advised her to add salt and fluid to her diet. An echocardiogram administered on that date was normal. Med. recs. at Ex. 1, pp. 40, 41, 42.

On January 31, 2007, petitioner went to East Rockaway Pediatrics for a rhinoplasty.
Med. recs. at Ex. 1, p. 14.

On March 6, 2007, petitioner went to East Rockaway Pediatrics complaining of anxiety, stress, and depression. She received her first HPV vaccination. Med. recs. at Ex. 1, pp. 1, 12.

On May 24, 2007, petitioner went to East Rockaway Pediatrics complaining of a headache the prior night. She received her second HPV vaccination. Med. recs. at Ex. 1, pp. 1, 10.

⁴ Rhinoplasty is “a plastic surgical operation on the nose, either reconstructive, restorative, or cosmetic.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 1629.

⁵ Vasovagal is “vascular” and pertains to the vagal nerve which involves the 10th cranial nerve. Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 2003, 2011.

On July 20, 2007, petitioner went to East Rockaway Pediatrics where she was diagnosed with either sinusitis or upper respiratory infection. Med. recs. at Ex. 1, p. 11.

On November 20, 2007, petitioner saw Dr. Eric J. Hanauer, a neurologist, giving a history of having seen Dr. Colucci, a psychiatrist, for the last several years. She stopped taking her medications (Adderall, Lamictal, Zoloft, and Seroquel) in the summer of 2007 and now complained of anxiety/panic attacks, dysphoria, and poor concentration. These were the same symptoms she had before she took the medications. She had moodiness, anxiety, and depression. She was unemployed and not a student. She smoked one pack of cigarettes every three days, used marijuana four times a week, and occasionally took ethanol. Med. recs. at Ex. 7, pp. 18, 23.

On December 10, 2007, petitioner saw Dr. Charnjit Singh, a gastroenterologist, and gave a history of depression. She complained of dyspepsia (stomach pain and burning in her chest) for the last couple of months. Zantac helped. She smoked five cigarettes a day. Dr. Singh diagnosed dyspepsia and loose stools. Med. recs. at Ex. 4, p. 7.

On November 24, 2008, petitioners saw Dr. Singh who diagnosed her with mild gastritis.⁶ Med. recs. at Ex. 4, p. 10.

On January 31, 2009, petitioner went to Southern Nassau Community Hospital complaining of diffuse joint pain. Med. recs. at Ex. 8, p. 1.

On February 2, 2009, petitioner saw Dr. Lenore J. Brancata, a rheumatologist, giving a history of five months of joint pains, which were worse in the mornings. She was diagnosed

⁶ Gastritis is “inflammation of the stomach.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 757.

with carpal tunnel syndrome, the right greater than the left, and she was right hand dominant. Petitioner had difficulty holding things and felt her hands were weak. She smoked three to four cigarettes a day. Dr. Brancata noted that petitioner did not meet the criteria for a diagnosis of fibromyalgia. She also noted that petitioner was unlikely to have an autoimmune or collagen-vascular disease. She was rheumatoid factor negative. Her C-reactive protein was normal. Petitioner had no evidence of a rheumatological disorder. Med. recs. at Ex. 3, pp. 4, 5.

On February 9, 2009, petitioner went to Southern Nassau Community Hospital with diffuse pain. She said she passed a pebble while urinating. Med. recs. at Ex. 7, p. 25.

From February 9-12, 2009, petitioner was at Southern Nassau Community Hospital. Dr. Richard Rubin diagnosed her with enthesopathy⁷ of the hip, systemic lupus erythematosus, dehydration, tobacco use disorder, dizziness and giddiness, pain at multiple sites, myalgia, and myositis.⁸

On February 26, 2009, petitioner saw Dr. Stephen J. Roth, a neurologist, complaining chiefly of diffuse joint pains which started in the right wrist. Over the past four to five months, the pain affected every joint from wrists, shoulders, fingers, toes, neck, and lower back. The pain was present all day with and without movement. The pain could travel into the arms and legs with resulting numbness and paresthesias that went into the hands and feet. She also had severe hip pain. About three months ago, she had a fall with neck trauma. Over the past year, she had had two car accidents. She had some photophobia with the pain. Her past medical

⁷ Enthesopathy is “disorder of the muscular or tendinous attachment to bone.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 622.

⁸ Myositis is “inflammation of a voluntary muscle.” Dorland’s Illustrated Medical Dictionary, 30th ed. (2003) at 1216.

history included depression, anxiety, carpal tunnel syndrome, two rhinoplasties, daily marijuana, occasional alcohol, and tobacco once a week. Her family history was positive for rheumatoid arthritis in multiple generations as well as carpal tunnel syndrome and coronary artery disease. Petitioner's parvovirus IgG was elevated. Her ANA (antinuclear antibodies) were negative. Dr. Roth diagnosed petitioner with diffuse polyarthropathy of unclear etiology. Her current rheumatologic workup including labs and x-rays was negative. He also diagnosed her with anxiety and depression. Med. recs. at Ex. 3, pp. 6, 7.

On March 25, 2009, petitioner had a brain MRI which was negative. Med. recs. at Ex. 7, p. 1.

On May 27, 2009, petitioner saw Dr. Jonathan Klahr, a rheumatologist, complaining of significant pain since May 2008. She recently also experienced lightheadedness and vomiting. She had completely negative serology with a negative rheumatoid arthritis latex, negative ANA, normal sedimentation rate, and normal C reactive protein. Dr. Klahr diagnosed petitioner with a variant of seronegative rheumatoid arthritis. She had symmetrical synovitis of the small joints of both hands. There was a strong family history of rheumatoid arthritis as well as morning stiffness and pain. Med. recs. at Ex. 6, pp. 1, 2.

On June 3, 2009, petitioner returned to Dr. Klahr with definite improvement in all her pain (60-70%). Her dramatic improvement on low-dose Prednisone supported the diagnosis of rheumatoid arthritis. Med. recs. at Ex. 6, p. 3.

On June 5, 2009, petitioner went to East Rockaway Pediatrics. She was diagnosed with fibromyalgia. Her toenails turned blue. She had possible rheumatoid arthritis. Med. recs. at Ex. 1, p. 6.

On July 10, 2009, petitioner saw Dr. Jerome B. Zisfein, a cardiologist, giving a history that, about six months previously, she began to have pain and swelling in various joints. Over the prior month or so, she started to complain of numbness, tingling, and blue discoloration in the toes of both feet. A vascular surgeon, Dr. Xenatos, felt she did not have Raynaud's syndrome. She was in the emergency room on July 9, 2009 after complaining of shortness of breath after walking upstairs as well as tingling and numbness in both legs, and tingling and pallor in the fingers of her right hand. The ER diagnosed her with asthma. She said she lost about 15 pounds over the last six months but put back five pounds. She had a bull's eye rash on her forearm last November or December while at Lake George. Her grandmother had Lyme disease, rheumatoid arthritis, and fibromyalgia. Dr. Zisfein diagnosed petitioner with Lyme disease and some variant of Raynaud's⁹ syndrome. Med. recs. at Ex. 8, pp. 256, 257.

On July 14, 2009, petitioner went to South Nassau Community Hospital giving a history of syncope and collapse. Med. recs. at Ex. Ex. 8, p. 147. On that same date, she saw Dr. Mark Kessler, a cardiologist, giving a long history of recurrent joint pains. Med. recs. at Ex. 8, p. 187.

On July 20, 2009, petitioner saw Dr. Louis Saffran, a pulmonary and sleep medicine specialist, giving a history that, in 2007, she had an episode of syncope once a month. She also had joint pains. She was treated for Lyme disease with doxycycline in the past. She complained of shortness of breath and palpitations. Her toes were occasionally cyanotic. She was currently on doxycycline 100 mg twice a day. She quit smoking two months previously. She smoked a

⁹ Raynaud's is "a primary or idiopathic vascular disorder." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 541.

pack a week for two years. Her mother had asthma and obstructive sleep apnea. Med. recs. at Ex. 2, p. 9.

On August 19, 2009, petitioner had an EEG which was normal. Med. recs. at Ex. 7, p. 5.

On September 2, 2009, petitioner saw Dr Saffran on follow-up. She reported no further episodes of shortness of breath. She did have another episode of syncope. She said she felt it coming on. She got weak and her eyes rolled back and she started shaking. Dr. Saffran diagnosed petitioner with resolved dyspnea. She probably had mild asthma. Med. recs. at Ex. 2, p. 10.

On September 3, 2009, petitioner complained of an episode of syncope two weeks previously and felt weak. Med. recs. at Ex. 7, p. 39.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(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 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence

of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen....”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148.

Petitioner must show not only that but for the HPV vaccination, she would not have had syncope and joint pains, but also that the vaccination was a substantial factor in bringing about her syncope and joint pains. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner has failed to find any medical expert to opine that her symptoms and complaints are causally related to her HPV vaccination, much less to give a basis for such an opinion. Petitioner complained of syncope in 2006 before she ever received HPV vaccine. Her joint complaints occurred long after she received HPV (she told Dr. Klahr on May 27, 2009 that she had significant pain since May 2008 which is one year after her second HPV vaccination). She had two car accidents and Lyme disease, both of which can lead to joint pain, as well as a strong family history of rheumatoid arthritis.

The Vaccine Act states that the undersigned may not rule in favor of petitioner based solely on her claims alone “unsubstantiated by medical records or by medical opinion.” 442 U.S.C. § 300aa-13(a)(1). Here there are no medical records or medical opinion ascribing petitioner’s syncope and joint pains more likely than not to HPV vaccine.

Petitioner has failed to make a prima facie case of causation in fact and has not fulfilled any of the three prongs listed in the Federal Circuit's decision in Althen. This petition must be dismissed.

CONCLUSION

This petition is dismissed. 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.¹⁰

IT IS SO ORDERED.

June 17, 2010
DATE

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

¹⁰ 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.