In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-1012V
August 30, 2016

GARRY REHN,	*	
	*	
Petitioner,	*	
	*	
v.	*	influenza ("flu") vaccine;
	*	pancreatitis; coronary artery
SECRETARY OF HEALTH	*	disease; no expert support;
AND HUMAN SERVICES,	*	dismissal.
	*	
Respondent.	*	

Garry Rehn, North Branch, MN, for petitioner (pro se).
Adriana R. Teitel, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On October 20, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that the influenza ("flu") vaccine he received on October 26, 2011, caused reactive airway disease, acute respiratory distress, tachypnea, pneumonia, pleurisy, and pancreatitis. Pet. at ¶ 12.

On August 9, 2015, petitioner filed an amended petition, adding that the flu vaccine significantly aggravated his pre-existing autoimmune disorder. Am. Pet. at ¶ 6. He also alleges that flu vaccine caused his mycoplasma infection due to his compromised immune system from

[1] Vaccine Rule 18(b) states that special masters shall make all decisions available to the public unless the decision contains trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When a special master files a decision, a petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access. See also 42 U.S.C. § 300aa-12(d)(4)(B)(i) and (ii).

his pre-existing autoimmune disorder. Id. at ¶ 13. Petitioner further alleges that Crohn's disease, hypertriglyceridemia, chronic pain including joint pain, hypertension, and fibromyalgia were all pre-vaccination symptoms of his autoimmune disorder. Id. at ¶¶ 17-20, 23. Petitioner finally alleges that flu vaccine and the significant aggravation of his autoimmune disorder, caused his cardiac arrest in April 2014. Id. at ¶ 37.

An attorney initially represented petitioner but withdrew on June 1, 2015, whereupon a second attorney represented him. This second attorney withdrew on May 23, 2016, whereupon petitioner became pro se and could not find anyone else to represent him.

During a recorded telephonic status conference on August 30, 2016, petitioner said he could not find a medical doctor to support his allegations and preferred to sue civilly in Minnesota courts. The undersigned explained to petitioner the process that the election to sue civilly entailed (dismissal decision, judgment entered by the clerk of court, petitioner's filing of a Notice to Sue Civilly).

This case is **DISMISSED** for failure to prove a prima facie case.

FACTS

Petitioner was born on March 7, 1963, and is now 53 years old.

He received a flu vaccination on October 26, 2011. Med. recs. Ex. 3, at 3. Petitioner has previously received four trivalent influenza vaccines and one H_1N_1 vaccine, according to the medical records he filed. (There may be other flu vaccinations administered prior to the dates reflected in the records.) Petitioner received trivalent influenza vaccine on December 4, 2006, December 11, 2007, October 8, 2008, and October 29, 2009. Med. recs. Ex. 8, at 4. He received H_1N_1 vaccine on December 21, 2009. Id.

Pre-vaccination records

On February 5, 2008, petitioner saw PA Jenny E. Enstrom for pneumonia, anxiety, and chronic obstructive pulmonary disease ("COPD"). Id. at 8. He told her that he had ongoing cold symptoms for over the past two weeks, and his symptoms were not improving. Id. at 10. A chest x-ray showed questionable increased density along the right mid-lobe. Id. at 11.

On February 12, 2009, RN Melissa J. Fowler noted that petitioner's triglycerides were elevated. Id. at 61.

On February 2, 2010, RN Jacqueline A. Miller noted that petitioner's triglycerides were still elevated, and he may want to consider taking medication since his triglycerides were high in 2009. Id. at 133.

On March 11, 2010, PA Enstrom noted that petitioner had sleep apnea. Id. at 141.

On September 1, 2010, PA Enstrom noted that petitioner's triglycerides were still elevated. Id. at 178.

On February 2, 2011, RN Melissa Fowler noted petitioner's triglycerides were still elevated and were higher. Id. at 191. Petitioner was on medication for this condition. Id. RN Fowler told petitioner to increase his dosage. Id.

On May 25, 2011, petitioner saw PAC Lena Truong at a pain clinic. Med. recs. Ex. 10, at 111. Petitioner was managing his pain only with medications, including opioids, and had cancelled five behavioral health visits. Id. PAC Truong diagnosed petitioner with chronic pain syndrome with complex physical and psychosocial emotional components. Id.

On May 31, 2011, Dr. Blair M. Anderson noted that petitioner had sleep apnea. Med. recs. Ex. 8, at 199.

On June 6, 2011, PA Enstrom noted that petitioner had hypertriglyceridemia. Id. at 201.

On October 26, 2011, petitioner saw PA Enstrom, who noted he had a history of anxiety, hypertension, lipid disorder, muscle cramps, hypertriglyceridemia, chronic pain, and herniated disc, and he needed a flu vaccination. Med. recs. Ex. 3, at 1. Petitioner had seen a psychologist two times a week for the past eight months. Id. at 3. He was also doing group counseling. Id. Petitioner was also having stress from his family, chronic back pain, herniated discs, muscle cramps in his calves, a history of hypertriglyceridemia, and a strong family history of high cholesterol. Id. His active problem list included CPAP dependence, obstructive sleep apnea, hypertension, and anxiety disorder. Id. Petitioner's blood pressure was 132/82, and he weighed 215 pounds. Id. at 4. Petitioner received a flu vaccination. Id. at 3.

Post-Vaccination Records

On October 26, 2011. petitioner received flu vaccine. Med. recs. Ex. 3, at 3.

On November 1, 2011, at 10:17 a.m., petitioner telephoned his personal care physician and spoke to PA Enstrom. Id. at 6. At 10:18 a.m., petitioner spoke to Jennifer L. Victor and said that, since his last appointment, he had had an upper respiratory infection, nasal congestion, and a runny nose. Id. at 7. He had been using Tamiflu for his symptoms. Id. At 10:33 a.m., he left a message for RN Fowler. Id. At 10:41 a.m., Beverly J. Graham attempted to return his call. Id. At 10:50 a.m., he spoke to RN Alicia R. Johnson. Id. at 9. Petitioner had the flu shot on October 26, 2011, and had been symptomatic since then (six days). Id. His symptoms included nasal drainage, sinus headache, body aches, productive cough with greenish brown sputum, and a fever of 100 degrees. Id. He took Theraflu with negative results. Id. Petitioner said his symptoms were becoming progressively worse. Id.

On November 2, 2011, petitioner went to Allina-Cambridge Medical Center Emergency Department. Med. recs. Ex. 4, at 1. Dr. Karl Elser noted that petitioner complained of shortness of breath, non-productive cough for the last nine days (which would put onset on October 24, 2011, two days before vaccination), tightness of his right anterior chest, and pain going down his chest, back, and both sides. Id. at 2. Contrary to his history to RN Johnson on November 1, 2011, that he had fever of 100 degrees, petitioner denied any fevers or chills. Id. Petitioner stated he did not have much energy. Id. Petitioner had a 20-year history of smoking, as well as anxiety and tachycardia. Id. He did not have ear pain, sore throat, eye redness, abdominal pain, muscle or joint pain, swelling, or headache. Id. His past medical history included hypertension, irritable bowel syndrome, chronic low back pain, anxiety disorder, unspecified sleep apnea, spinal fusion, nasal surgery, and attempted implantation of a spinal cord stimulator in his lumbar spine. Id. at 3. Petitioner smoked 0.8 packs of cigarettes per day for 26 years. Id. He had been unemployed since 2004 or 2005 because of chronic low back pain and was on disability. Id.

On November 2, 2011, petitioner had a consultation with Dr. Jennifer A. Lessard. Id. at 11. Petitioner said he first noticed symptoms nine days earlier (which would put onset on October 24, 2011, two days before vaccination) with rhinorrhea, sore throat, headache, and overall fatigue. Id. at 12. About three days before his visit, petitioner felt as if an elephant were sitting on his chest. Id. He had symptoms of feeling hot and cold but did not take his temperature. Id. He had associated sweats, diffuse myalgias, bloating, dizziness, weakness, fever, chills, sweating, fatigue, nasal congestion, and sore throat, which had started nine days earlier. Id. He was transferred to Abbott Northwestern Hospital. Id. at 19.

On November 2, 2011, at Abbott Northwestern Hospital, petitioner saw Dr. Paul J. Odenbach, who took a history of the present illness. Med. recs. Ex. 5, at 1. About nine days earlier (putting onset two days before his vaccination), petitioner developed rhinorrhea, coughing, and some shortness of breath, mostly non-productive. Id. Petitioner's sister stated this started after petitioner hooked up his CPAP machine for the first time, with distilled water as humidification. Id. Petitioner's chest was tight and wheezy. Id. He was mildly hypoxic and anxious. Id.

On November 14, 2011, PA Enstrom wrote that petitioner had been hospitalized from November 2 – 7, 2011, and diagnosed with reactive airway disease and pneumonia. Med. recs. Ex. 3 at 13. He still had tightness in his chest, shortness of breath with occasional wheezing, and some swelling in his lower legs and ankles. Id.

On December 1, 2011, PA Enstrom noted that petitioner had a clear runny nose and had been diagnosed with pleurisy. Id. at 18.

From December 2 – 11, 2011, petitioner was hospitalized at Abbott Northwestern Hospital for acute pancreatitis. Med. recs. Ex. 5, at 31.

On May 30, 2012, petitioner saw Dr. Irshad H. Jafri. Med. recs. Ex. 3, at 99. Dr. Jafri noted that petitioner's CT scan did not reveal any evidence of pancreatitis and that petitioner's pancreatic enzymes were entirely normal. Id. In addition, petitioner's gallbladder ultrasound was not significant, except for some sludge. Id. Dr. Jafri concluded that petitioner had a history of chronic abdominal pain. Id. at 100.

On September 10, 2102, PA Enstrom noted that petitioner had tiny cysts in his pancreas, but an endoscopic ultrasound did not show any current evidence of chronic pancreatitis. Id. at 145. Petitioner had an indeterminate cystic structure on his left hepatic lobe. Id.

On June 3, 2013, PA Enstrom noted that petitioner began taking Norvasc instead of Lisinopril in October 2012 due to a concern that Lisinopril was causing his pancreatitis.[2] Id. at 207.

On April 4, 2014, RN Susan A. Stogenson referred to a VAERS report. Id. at 273.

On April 8, 2014, PA Enstrom noted that petitioner had chest pain on March 25 and was sent to the Emergency Department because of his chest pain, history of coronary artery disease, and tobacco use. Id. at 276. Petitioner had a cardiac MRI and the emplacement of a pacemaker and defibrillator after an episode of cardiac arrest. Id. He was hospitalized from March 25 – 28, 2014. Id.

On June 5, 2015, petitioner saw Dr. James Nelson, a gastroenterologist. Med. recs. Ex. 12, at 1. Petitioner was screened for autoimmune pancreatitis with an IgG 4 subclass level in March 2014, which was unremarkable along with a negative ANA. Id.

On August 3, 2015, petitioner filed a "To Whom It May Concern" letter dated January 29, 2015 from PA Enstrom. Med. recs. Ex. 11, at 1. She states that the River Way Clinic had been seeing petitioner since 2006. She further states, "I cannot directly relate Mr. Rehn's recent medical conditions with receiving the flu shot as he has received the flu shot in previous years." Id. After going through petitioner's history, she states, "I have consulted with Dr. Erickson, and we are not aware of pancreatic and cardiac side effects from the flu shot." Id.

From January 8-10, 2016, petitioner was in Massachusetts General Hospital for chronic abdominal pain. Med. recs. Ex. 20, at 7. Basic laboratory tests did not show any active pancreatitis or inflammation. Id.

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[2] On October 11, 2012, Dr. Charles B. Erickson actually noted he was concerned Lisinopril was causing petitioner's hepatitis. Id. at 160. This is the only reference to hepatitis in petitioner's medical records. Dr. Erickson may have meant to write petitioner's pancreatitis, not hepatitis, was possibly due to Lisinopril.

On July 7, 2016, petitioner pro se filed a letter from PA Enstrom dated June 21, 2016, stating that two different specialists felt his medical issues were directly related to the flu shot, although she did not specialize in these areas. Petitioner did not affix an exhibit number to this letter.

DISCUSSION

To satisfy his 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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 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[.]"

Althen, 418 F.3d at 1278.

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 flu vaccination, he would not have pancreatitis and cardiac disease, as well as purported autoimmune disease, but also that the vaccine was a substantial factor in causing or significantly aggravating these conditions. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act does not permit the undersigned to rule for petitioner based on his claims alone, "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

Petitioner's medical records do not support his allegations. Although he had two separate attorneys endeavoring to prove his allegations, neither of them found a medical doctor to support his allegations. PA Enstrom's earlier letter of January 29, 2015 states that Dr. Ericson does not support petitioner's allegations. PA Enstrom's later letter of June 21, 2016 states mysteriously that two unnamed medical specialists do support petitioner's allegations although she has no opinion herself on the matter. This does not provide evidentiary support. The undersigned asked petitioner to obtain letters from these two unnamed medical specialists and petitioner stated he could not obtain them during a subsequent status conference.

This case is **DISMISSED** for failure to prove a prima facie case.

IT IS SO ORDERED.

August 30, 2016
DATE

Laura D. Millman
Special Master