In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-1025V
July 25, 2017
Not to be Published

CHRISTOPHER PURVIS,	*	
	*	
Petitioner,	*	Not to be Published
	*	
v.	*	Influenza ("flu") vaccine;
	*	diskitis; testicular pain;
SECRETARY OF HEALTH	*	not immune-mediated;
AND HUMAN SERVICES,	*	not autoimmune; dismissal
	*	
Respondent.	*	

Howard S. Gold, Wellesley Hills, MA, for petitioner.
Ryan D. Pyles, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On October 22, 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 August 15, 2013, caused burning pain in his back, abdomen, and testicles. Pet. ¶ 4.

On July 7, 2017, the undersigned held a hearing. Testifying for petitioner was Dr. David Axelrod, an immunologist and allergist. Testifying for respondent was Dr. Kathleen L. Collins, an infectious disease specialist.

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). 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 constitute a clearly unwarranted invasion of privacy. When such a decision is filed, 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 banned categories listed above, the special master shall redact such material from public access.

Dr. Axelrod's explanation for flu vaccine causing petitioner's diskitis was based on his assumption that diskitis was an autoimmune disease because petitioner was ill, and that cytokines from flu vaccine caused increased vascularization and nerve sensitivity. Dr. Collins' response was that spinal discs do not contain blood vessels or nerves and, therefore, whether or not cytokines could breach the blood-brain barrier would be irrelevant to inflammation of his spinal discs. Because the undersigned found Dr. Collins' testimony more credible than Dr. Axelrod's, the undersigned **DISMISSES** this case.

FACTS

Petitioner was born on October 12, 1959. Med. recs. Ex. 1, at 1.

Pre-vaccination records

Petitioner gave a history in numerous medical records that a car hit him when he was a pedestrian in 2009, and he has had back problems since then. Med. recs. Ex. 5, at 313. He has been disabled since 2000. Id.

On August 9, 2010, petitioner was at Lawrence & Memorial Hospital, complaining that he flew over his motorcycle handlebars and landed on his right hip. Id. at 18. He complained of pain in his right arm and shoulder, although the shoulder pain was chronic. Id.

On August 12, 2010, petitioner saw Dr. Robert J. Keitner, Jr., in follow-up. Med. recs. Ex. 4, at 2. Petitioner had a history of asthma, hypertension, hyperlipidemia, seizure disorder, migraine headaches, depression, chronic pain, and probable post-traumatic injury. Id. Earlier that year, he had acute renal insufficiency, probably related to excessive use of diuretics and NSAIDs and inadequate fluid intake. Id. At the time of his visit, petitioner was taking

Lamictal,[2] Klonopin,[3] Geodon,[4] Lexapro,[5] Ambien,[6] Zetia,[7] Clonidine,[8] Trilipix,[9] and Percocet.[10] Id. He also used Levitra for erectile dysfunction as needed. Id. He weighed 250 pounds. Id.

On November 16, 2010, petitioner saw Dr. Keitner. Id. at 8. Petitioner had a history of previous drug abuse and was on methadone[11] maintenance. Id. He had a history of hepatitis C and cirrhosis. Id.

On February 24, 2011, petitioner saw Dr. Keitner again. Id. at 11. For the last two or

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[2] Lamictal is "trademark for a preparation of lamotrigine." Dorland's Illustrated Medical Dictionary 1000 (32d ed. 2012) (hereinafter, "Dorland's). Lamotrigine is "an anticonvulsant used in the treatment of partial seizures in adult patients . . . ." Id. at 1003.

[3] Klonopin is "trademark for a preparation of clonazepam." Dorland's at 989. Clonazepam is "a benzodiazepine used as an anticonvulsant in the treatment of Lennox-Gastaut syndrome and of atonic and myoclonic seizures and as an antipanic agent in the treatment of panic disorders . . . ." Id. at 373. Benzodiazepine is "any of a group of compounds having a common molecular structure and acting similarly as depressants of the central nervous system, their actions including antianxiety, sedative, hypnotic, amnestic, anticonvulsant, and muscle relaxing effects." Id. at 209.

[4] Geodon is "trademark for a preparation of ziprasidone hydrochloride." Dorland's at 772. Ziprasidone hydrochloride is "an antipsychotic used in the treatment of schizophrenia." Id. at 2092.

[5] Lexapro is "trademark for a preparation of escitalopram oxalate." Dorland's at 1032. Escitalopram oxalate is "a selective serotonin reuptake inhibitor (SSRI) . . .; used as an antidepressant." Id. at 647.

[6] Ambien is "trademark for a preparation of zolpidem tartrate." Dorland's at 57. Zolpidem tartrate is "a non-benzodiazepine sedative-hypnotic . . . in the short-term treatment of insomnia." Id. at 2092.

[7] Zetia is "trademark for a preparation of ezetimibe." Dorland's at 2091. Ezetimibe is "an inhibitor of intestinal cholesterol absorption . . . in the treatment of primary hypercholesterolemia." Id. at 667.

[8] Clonidine hydrochloride is "an α_2-adrenergic agonist-antagonist . . .administered . . .as an antihypertensive. . . ." Dorland's at 373.

[9] Trilipix is "trademark for a preparation of fenofibric acid." Dorland's at 1967. Fenofibric acid is "the active form of fenofibrate, used in combination with statins to reduce elevated serum lipids." Id. at 688.

[10] Percocet is "trademark for a combination preparation of oxycodone hydrochloride and acetaminophen." Dorland's at 1409. Oxycodone is "an opioid agonist analgesic derived from morphine." Id. at 1356.

[11] Methadone hydrochloride is "a synthetic opioid analgesic, possessing pharmacologic actions similar to those of morphine and heroin and similar potential for addiction; used as an analgesic and as a narcotic abstinence syndrome suppressant in the treatment of heroin addiction . . . ." Dorland's at 1146.

three weeks, petitioner had noted significantly increasing chest tightness or wheezing and cough. Id. He said he was smoking three or four cigarettes a day, but did not usually finish them. Id.

On May 9, 2011, petitioner went to Lawrence & Memorial Hospital Emergency Department after he fell in the shower, complaining of back pain that had lasted one month. Med. recs. Ex. 5, at 64.

On May 16, 2011, petitioner saw his orthopedist, Dr. Frank W. Maletz, because he had a very nasty fall in the shower. Med. recs. Ex. 7, at 1. He slipped and fell backwards as his right knee gave out. Id. He struck his lower back, twisted, hit his head on the side of the bathtub, and injured his upper back as well. Id. Dr. Maletz wrote that petitioner was struggling significantly with his lower back and had greater difficulty with his right knee. Id. Petitioner had Lidoderm[12] patches all over his lower lumbar spine and over the mid-shaft of his tibia. Id. Dr. Maletz was very concerned about the limited range of motion petitioner displayed in his lower back as well as the marked crepitation in his patellofemoral joint. Id. Petitioner had very poor extension of his back and pain on deep palpation, primarily over the iliolumbar[13] ligaments on the left. Id.

On May 21, 2011, petitioner had an MRI of his lumbar spine performed. Id. at 2. This MRI was compared with a prior one done in August 2008. Id. Petitioner previously had a hemangioma[14] in the L1 vertebral body. Id. At the L2-L3 vertebral level, there was degenerative disc signal with degenerative endplate change and disc space narrowing. Id. At the L3-L4 vertebral level, there was a diffuse disc bulge, which had slightly increased since the August 2008 MRI with some increased degenerative disc signal. Id. At L4-L5, there was degenerative disc signal and disc space narrowing with mild to moderate diffuse bulging. Id. From L5-S1 of the lumbar and sacral spinal vertebrae, there were moderately severe degenerative changes with degenerative endplate changes. Id. A superiorly migrating left-sided disc herniation on the August 2008 study could be partially calcified in the current study. Id. at 3.

On August 12, 2011, petitioner went to Lawrence & Memorial Hospital, complaining of an abdominal lump. Med. recs. Ex. 5, at 105. He complained of pain in his left lower quadrant, which was intermittent. Id. A CT scan of his abdomen and pelvis on September 16, 2011, showed no significant abnormality. Id. at 111. Petitioner also gave a history that he had right leg surgery in 2008 when a rod was placed in his right leg. Id. at 105.

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[12] Lidoderm is "trademark for a preparation of lidocaine." Dorland's at 1034. Lidocaine is "a drug having anesthetic, sedative, analgesic, anticonvulsant, and cardiac depressant activities, used as a local anesthetic." Id.

[13] Iliolumbar pertains "to the iliac and lumbar regions, or to the flank and loin." Dorland's at 914.

[14] Hemangioma is "a common type of vascular malformation, usually seen in infancy and childhood, consisting of newly formed blood vessels that result from malformation of angioblastic tissue of fetal life." Dorland's at 831.

On September 19, 2011, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 20. Petitioner complained of discomfort with slight swelling in the left lower quadrant of his abdomen and left groin area near his hip. Id. Dr. Keitner examined him and found minimal tenderness, but no mass. Id. Petitioner had chronic pain involving his lower back, left arm, and left shoulder with some pain in his right hand and wrist. Id. A recent CT scan showed no abnormality of his abdomen and pelvis except for a small right inguinal hernia, which was not the area where petitioner noted pain. Id.

On November 15, 2011, petitioner saw Dr. Keitner. Id. at 21. Petitioner complained of a marked increase in cough, chest congestion, and sore throat over the past several days. Id. Petitioner had a history of prostatitis.[15] Id. Dr. Keitner diagnosed petitioner with acute bronchitis. Id. Petitioner asked for a check of his PSA[16] level. Id.

On April 30, 2012, petitioner saw Dr. Keitner. Id. at 27. Petitioner complained of symptoms of prostatitis. Id. Dr. Keitner prescribed Zithromax.[17] Id.

On September 27, 2012, petitioner saw Dr. Keitner. Id. at 32. Petitioner said he started smoking again because he was bored. Id. He had an increase in coughing and wheezing. Id. He smoked about 12 cigarettes a day. Id. Dr. Keitner noted that petitioner's hypertension was not as well controlled as usual. Id. Petitioner blamed this on anxiety and stress for a number of different reasons. Id.

On March 26, 2013, petitioner saw Dr. Keitner. Id. at 35. Petitioner had asthma associated with cigarette smoking, hypertension, gastroesophageal reflux disease, hyperlipidemia, and erectile dysfunction. Id. Petitioner had been seeing a psychiatrist for a history of bipolar disease and depression. Id. Other problems included chronic pain, degenerative arthritis, migraine headaches, previous cocaine abuse for which he was on methadone maintenance, hepatitis C, and acute bronchitis. Id. Recently, petitioner complained of vague discomfort in his chest with deep breathing. Id. Petitioner was still smoking one-half pack of cigarettes daily. Id. Lately, his psychiatrist reduced his dose of Klonopin and petitioner had felt more jumpy and, sometimes, took additional Clonidine. Id.

On June 17, 2013, petitioner was at Lawrence & Memorial Hospital Emergency Department, complaining of chest pain. Med. recs. Ex. 7, at 153. He gave a history of prior myocardial infarction in the setting of cocaine abuse. Id. Petitioner became more agitated during the course of his evaluation and left the Emergency Department against medical advice.

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[15] Prostatitis is "inflammation of the prostate." Dorland's at 1530.
[16] PSA is "prostate-specific antigen." Dorland's at 1540.
[17] Zithromax is "trademark for a preparation of azithromycin." Dorland's at 2092. Azithromycin is "an azalide antibiotic, derived from erythromycin, that inhibits bacterial protein synthesis, effective against a wide range of gram-positive, gram-negative, and anaerobic bacteria; used in the treatment of mild to moderate infections caused by susceptible organisms." Id. at 187.

Id. at 154. He said he had to go home because he left his fan and coffee pot on. Id. A chest x-ray done before petitioner left showed minimal bibasilar opacities, which could represent atelectasis.[18] Id. at 172.

On July 23, 2013, petitioner saw Dr. Keitner. Id. at 42. Dr. Keitner diagnosed petitioner with pre-diabetes, hyperlipidemia, and hypertension, suggesting metabolic syndrome. Id.

Post-Vaccination Records

On August 15, 2013, petitioner received flu vaccine. Med. recs. Ex. 3, at 1.

On August 18, 2013, petitioner went to Lawrence & Memorial Hospital Emergency Department, complaining of back pain. Med. recs. Ex. 5, at 216. He had been taking muscle relaxants, methadone, and oxycodone, without any significant relief of the pain, which he said went from the top of his hips to his back. Id. He did not have any weakness, paresthesias, or radicular symptoms in his lower extremities. Id. He denied any fever, chills, or urinary complaints. Id. He had no headache, nausea, vomiting, or trauma. Id. On physical examination, petitioner was in mild discomfort without significant distress. Id. He had bilateral paraspinal muscle tenderness and bilateral sacroiliac joint tenderness in his low back. Id. His reflexes were normal. Id. Petitioner had a history of chronic low back pain. Id. He was on extremely high doses of pain medication and complained of acute worsening of his lower back pain. Id. Petitioner left the Emergency Department prior to completing his treatment. Id.

On August 19, 2013, a CT scan of petitioner's lumbar spine showed mild to moderate lumbar spondylosis.[19] Id. at 242. The CT scan was compared to a May 22, 2006 exam. Id. Mild disc space narrowing and endplate degenerative changes throughout the lumbar levels had progressed slightly since the May 22, 2006 exam. Id.

On August 26, 2013, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 43. Petitioner complained of severe lower back pain. Id. He said that two weeks earlier, he received flu vaccine in his left upper arm and, the next day, awoke with severe pain in his lower back on both sides, which radiated to his testicles. Id. He said the pain did not radiate into his legs. Id. He went to the emergency room twice and personnel told him to use Lidocaine patches. Id. He was also using muscle relaxants, such as Soma,[20] his usual pain medicine Percocet, his daily methadone, and Motrin.[21] Id. Petitioner had no problem urinating. Id. He did have an episode of prostatitis the prior week, but Zithromax cleared it up. Id. Petitioner did not have any muscle weakness. Id. On physical examination, petitioner did not have localized tenderness in the

[18] Atelectasis is "incomplete expansion of a lung or a portion of a lung . . . ." Dorland's at 171.
[19] Spondylosis is "degenerative spinal changes due to osteoarthritis." Dorland's at 1754.
[20] Soma is "trademark for combination preparations of carisoprodol and aspirin." Dorland's at 1734. Carisoprodol is "a centrally acting skeletal muscle relaxant, for the symptomatic management of acute, painful musculoskeletal disorders." Id. at 296.
[21] Motrin is "trademark for preparations of ibuprofen." Dorland's at 1182.

lumbosacral area, but he did have mild muscle spasticity. Id. Dr. Keitner's impression was lower back muscle strain, possibly with acute inflammation. Id. Dr. Keitner wrote: "[I] doubt relationship to recent influenza vaccination although this has been reported very rarely. Normal reflexes and lack of muscle weakness make diagnosis of Guillain-Barre syndrome extremely unlikely." Id. Dr. Keitner prescribed a trial of Prednisone and said petitioner could also use Flexeril.[22] Id.

On September 17, 2013, petitioner went to Lawrence & Memorial Hospital Emergency Department. Med. recs. Ex. 5, at 256. He complained of right leg pain. Id. Petitioner had a history of chronic back pain and presented with right-sided thigh pain radiating down to his knee. Id. There was no obvious injury or swelling. Id. On physical examination, petitioner's leg was soft and non-tender to palpation. Id. Dr. Melissa L. Monte could not reproduce his pain. Id.

On September 20, 2013, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 44. Petitioner still complained of severe lower back pain radiating into his buttocks. Id. He had no problems urinating or defecating. Id. Dr. Keitner diagnosed petitioner with persistent, severe lower back pain with significant muscle spasm. Id.

On September 26, 2013, petitioner saw his orthopedist Dr. Maletz. Med. recs. Ex. 7, at 9. Petitioner had a significant second-degree burn of his back. Id. His lumbar spine was the problem. Id. Petitioner was developing significantly increased pain and muscle spasms. Id. For his lumbar spine symptoms, he used all of the medicines prescribed for his left knee following arthroscopic surgery, but much in excess of what was prescribed then. Id. On physical examination, petitioner had multiple pain patches all over his back. Id.

On September 27, 2013, petitioner went to Lawrence & Memorial Hospital Emergency Department, complaining of right thigh pain and back pain. Med. recs. Ex. 5, at 287. Petitioner had a history of chronic lower back pain, hepatitis C, hypertension, hyperlipidemia, and acute myocardial infarction. Id. Petitioner stated he did not have urinary incontinence, urinary retention, or bleeding. Id. He said he had been immobilized for the past couple of months because of his back pain. Id. On physical examination, petitioner had no guarding of his abdomen. Id. He had paraspinal lower back pain, but no midline lumbar, cervical, or thoracic spinal tenderness. Id. He had good range of motion of his black with flexion and extension, turning to the left as well as to the right. Id. He had mild tenderness of the right thigh. Id. at 288. Dr. Monte noted that the pain in petitioner's right leg began one day earlier. Id. at 289. Petitioner was concerned he had a blood clot. Id. Dr. Monte explained that, in light of his physical examination, the risk of his having deep vein thrombosis was low. Id. Petitioner had a deep vein sonographic evaluation, which showed no deep venous thrombosis in his right lower extremity. Id. at 294.

[22] Flexeril is "trademark for a preparation of gallamine triethiodide." Dorland's at 717. Gallamine triethiodide is "a quaternary ammonium compound used to induce skeletal muscle relaxation . . . ." Id. at 755.

On October 8, 2013, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 46. Petitioner complained of poorly healing sores and an infection in his perianal area, which had been ongoing for at least a month or more. Id. Petitioner had been on several different antibiotics: Cipro for urinary tract infection in late September and then Keflex starting October 4, 2013. Id. He said the infection started when he was having diarrhea about a month or so prior. Id. Dr. Keitner saw two superficial skin ulcers on either side of the anal orifice, with minimal cellulitis, which appeared to be slowly healing. Id.

On October 9, 2013, petitioner had an MRI of his lumbar spine performed. Med. recs. Ex. 7, at 10. This MRI was compared to the scan done in May 2011. Id. Petitioner had lumbar lesions involving the L1, L4, and T11 vertebral bodies, which were present on the May 2011 exam. Id. They were nonspecific but could represent a benign etiology, such as hemangiomas. Id. There was abnormal irregularity of the endplates of L2-L3 with high T2 signal seen in the disc space at this level, as well as paravertebral soft tissue and heterogeneous signal seen in the region of the right psoas muscle. Id. There was subluxuation/retrolisthesis[23] at this level measuring about 0.6 cm. Id. Spondylosis was detailed at the following vertebral levels from L1 to S1:

- L1-L2 (mild diffuse disc osteophyte[24] complex and facet hypertrophy);
- L2-L3 (as in L1-L2 and at least moderate central canal stenosis[25] with neural foramen[26] encroachment particularly on the right side);
- L3-L4 (diffuse disc ossific complex with facet hypertrophy thickening ligamentum flavum and mild mass effect on the nerve roots as they exited laterally bilaterally);
- L4-L5 (diffuse disc ossific complex with facet hypertrophy thickening ligamentum flavum with a focal extrusion in the central and left paracentral location measuring about 1.2 x 0.8 cm, and at least moderate central canal stenosis, mass effect on the thecal sac and the nerve roots particularly on the left side and nerve root exiting medially inferior, plus moderate left neural foramen encroachment); and
- L5-S1 (diffuse disc osteophyte complex with facet hypertrophy with a diffuse extrusion extending slightly caudal, plus mild bilateral neural foramen encroachment, focal area signal alteration in the right aspect of the sacrum which was nonspecific but could represent a hemangioma).

Id. at 10-11.

The radiologist's conclusion for the October 9, 2013 MRI examination of petitioner's lumbar spine was that petitioner's disc disease had progressed compared to his May 2011 MRI examination. Id. at 11.

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[23] Subluxation is "an incomplete or partial dislocation." Dorland's at 1791. Retrolisthesis is also known as retrospondylolisthesis, which is "posterior displacement of one vertebral body on the subjacent body." Id. at 1636.

[24] Osteophyte is "a bony excrescence or osseous outgrowth." Dorland's at 1348.

[25] Stenosis is "an abnormal narrowing." Dorland's at 1769.

[26] Foramen is "a natural opening or passage, especially one into or through a bone." Dorland's at 729.

Also on October 9, 2013, a CT scan was performed on petitioner's pelvis and lumbar spine. Id. at 13. This was compared with CT scans of petitioner's abdomen and pelvis on September 16, 2011 and his lumbar spine on August 19, 2013. Id. The lumbar spine showed destruction of the endplates and irregularity of the disc space of the L2-L3 level. Id. There were marginal disc osteophyte complexes with osteopenia.[27] Id. There was also retrolisthesis at the L2-L3 level. Id. The pelvis showed nonspecific calcification, which could represent phleboliths. Id. There was also osteopenia and mild osteoarthritic changes of the bilateral hip joints. Id. The impression was that the findings were most consistent with diskitis/osteomyelitis involving the L2-L3 level, spondylosis, and osteopenia. Id.

On October 11, 2013, petitioner went to Lawrence & Memorial Hospital where he signed out against medical advice. Id. at 15. Dr. Jeffrey A. Salkin wrote the discharge summary, saying that the plan for dealing with petitioner's diskitis was intravenous antibiotics, an infectious disease consult, and a special procedure biopsy. Petitioner said this was inconvenient for him. Id.

On October 23, 2013, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 50. Petitioner still complained of discomfort and a rash in the perirectal area. Id. He completed his course of antibiotics (Cephalexin) and there was improvement. Id. He noted more redness now and some redness around the urethral meatus and glans penis. Id. Dr. Keitner noted on physical examination that the rectal rash looked like Candida.[28] Id. Petitioner also had mild erythema around the glans penis without discharge. Id. Dr. Keitner prescribed Diflucan and Nystatin cream. Id.

On November 22, 2013, petitioner saw Dr. Keitner. Id. at 51. Petitioner's perirectal and perineal Candida infection finally cleared up, as did his Candida balanitis. Id. Since his prior visit, petitioner's lower back pain was a little better, but he still had significant muscle spasticity. Id. Petitioner's psychiatrist discontinued Klonopin and Ambien, which upset petitioner considerably. Id.

On December 5, 2013, petitioner returned to his orthopedist Dr. Maletz. Med. recs. Ex. 7, at 16. Dr. Maletz writes that petitioner had lumbar discopathy from L2-L3 to L5-S1. He also had bilateral knee pain. Dr. Maletz attributed much of petitioner's problem at L3-L4 and L4-L5 to degeneration. Id.

On March 11, 2014, petitioner saw Dr. Keitner. Med. recs. Ex. 4, at 55. About four or five days previously, petitioner developed severe low back pain. Id. Dr. Keitner wrote, "He has had low back pain before, and this has been attributed to disk disease . . . ." Id. Dr. Maletz, petitioner's orthopedist, said petitioner would need an eight-hour surgery, and it might not work. Id. Petitioner was taking methadone and Percocet. Id. He got a Fentanyl patch from his brother,

[27] Osteopenia is "any decrease in bone mass below the normal." Dorland's at 1347.
[28] Candida is a yeast-like fungal infection. Dorland's at 280.

which relieved the pain for several days. Id. On physical examination, petitioner had minimal tenderness over the L4-L5 region of his back, without radiation. Id. Dr. Keitner's impression was acute low back pain with a history of longstanding lumbar disc disease. Id.

Treating Physicians' Opinions

The Federal Circuit in Capizzano emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 440 F.3d at 1326. See also Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009).

On August 21, 2013, Dr. Keitner, petitioner's personal care physician, opined that he doubted flu vaccine had anything to do with petitioner's complaints of back and testicular pain.

None of petitioner's doctors prescribed the type of drugs someone with an autoimmune or immune-mediated disease would receive, e.g., plasmapheresis, intravenous immunoglobulin, or prednisone. They did prescribe pain-relievers and muscle relaxants which he had already been taking for years. In fact, he was on so many drugs including methadone that he may have had diskitis before flu vaccination but the anti-pain drugs masked the diskitis until the pain became too much.

The treating doctors, believing petitioner's diskitis was due to an infection, planned to have petitioner receive intravenous antibiotics, an infectious disease consultation, and a biopsy to find the source of his infection. Petitioner however chose to leave the hospital against medical advice. Thus, these procedures were never performed nor was a culture done to find the source of his infection.

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 had burning pain in his back, abdomen, and testicles, but also that flu vaccine was a substantial factor in causing burning pain in his back, abdomen, and testicles. 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).

Moreover, petitioner is required to prove that his alleged vaccine injury lasted for more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Nothing in the medical records supports a conclusion that petitioner's stomach and testicular pain and his genital infection lasted more than six months. What remains is petitioner's attempt to prove that flu vaccine caused his back pain.

Dr. Axelrod based his opinion on autoimmune illness by rejecting that petitioner's diskitis could be due to an infection. However, the failure to find the source of the infection is not sufficient legally to satisfy petitioner's burden to prove a prima facie case. As the Federal Circuit stated in Grant, 956 F.2d at 1149, not knowing any other factor than the vaccine predated the alleged injury is insufficient to satisfy petitioner's burden of proof. Petitioner has to provide affirmative evidence of causation.

Dr. Axelrod's thesis relies on there being blood vessels and nerves within the spinal disc. However, Dr. Collins testified there are no blood vessels or nerves within a spinal disc. Blood vessels go around a spinal disc, not through it. Nerve fibers exit the spinal cord but do not sit within spinal discs. See Exhibit C, a schematic drawing of an intervertebral disc. Dr. Axelrod did not refute Dr. Collins' testimony. Dr. Collins testified that vertebral osteomyelitis is not autoimmune.

Dr. Axelrod's thesis that flu vaccine causes a rise in cytokines, thus breaching the blood-brain barrier, has nothing to do with vertebral discs. The blood-brain barrier, as Dr. Collins explained, deals with the central nervous system (the brain and spinal cord). The vertebral discs are outside the spinal cord and do not contain nerve tissue. Dr. Axelrod's thesis that flu vaccine produces cytokines, which increase vascular tissue and affect nerve tissue, is thus irrelevant to the cause of petitioner's diskitis at the L2-L3 level. Dr. Collins persuasively proved that spinal discs do not contain blood vessels or nerve tissue. Therefore, Dr. Axelrod's thesis is not credible.

Dr. Axelrod admitted on cross-examination that no one in the medical community believes that flu vaccine causes diskitis.

Althen Analysis

Prong One

Petitioner has failed to prove that flu vaccine can cause diskitis because the theory that cytokines increase vascular tissue and affect nerve tissue has nothing to do with spinal discs and spinal disc inflammation.

Prong Two

Petitioner has failed to prove that there is a logical sequence of cause and effect in the flu vaccination he received and his diskitis. There is nothing logical about flu vaccine causing inflammation of petitioner's lumbar discs, particularly in light of petitioner's long history of degenerative disc disease. If petitioner had had an adverse reaction to flu vaccination due to cytokine inflammation increasing vasculature and affecting nerve tissues from cytokine permeation of the blood-brain barrier, his symptoms would not have been restricted to his back, abdomen, and testicles. He would have had systemic symptoms, such as fever.

Prong Three

Petitioner has failed to prove that any time period, much less one day, is appropriate for influenza vaccine to cause diskitis.

CONCLUSION

The petition is **DISMISSED** for failure to make a prima facie case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.[29]

IT IS SO ORDERED.

July 25, 2017
DATE

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

[29] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.