

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-945V

September 15, 2016

Not for Publication

ONA DEANE GORDLY, Representative of *
the Estate of TYRONE GORDLY, deceased, *

Petitioner, *

v. * influenza (“flu”) vaccine;

SECRETARY OF HEALTH * significant aggravation of

AND HUMAN SERVICES, * pneumonia; death from

Respondent. *

John D. Groseclose, Port Orchard, WA, for petitioner.

Alexis B. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On October 6, 2014, petitioner Tyrone Gordly 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 24, 2011, caused “latent effects” and a cardiac event. Pet. at ¶ 6.

¹ Because this unpublished decision contains a reasoned explanation for the special master’s action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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.

On October 23, 2015, petitioner filed an amended petition, alleging significant aggravation. Am. Pet. at ¶ 6.

Unfortunately, on January 1, 2016, petitioner died. His widow subsequently became petitioner.

On September 15, 2016, during a telephonic status conference, petitioner's counsel said that he spoke to petitioner and received permission from her not proceed further with the case. Petitioner's counsel moved to dismiss.

The undersigned **GRANTS** petitioner's motion and **DISMISSES** this case.

FACTS

Petitioner was born on November 20, 1937.

He received a flu vaccination on October 24, 2011. Med. recs. Ex. 2, at 5. (Petitioner did not consecutively paginate Exhibit 2. The undersigned numbered the pages so that the undersigned and the parties could refer to specific pages.)

Pre-vaccination records

On September 1, 2011, petitioner saw his personal care physician, Dr. Kathryn Tonder, at Community Health Care. Med. recs. Ex. 2, at 1. Petitioner had a history of coronary artery bypass graft, mixed hyperlipidemia, lumbosacral degeneration, uncontrolled Type 2 diabetes, obesity (he weighed 268 pounds at this visit), atopic dermatitis, proteinuria, hypertension, prostate cancer, retinopathy due to diabetes, hypokalemia, osteoarthritis/degenerative joint disease, diabetic neuropathy, and chronic kidney disease (stage 2). Id. Petitioner underwent an EKG for a pre-operative assessment. Id. He had brachytherapy seeds implanted for his prostate cancer two weeks earlier (or mid-August 2011). Id. His blood pressure was 130/90. Id. at 2. Petitioner was taking the following drugs: Carvedilol,² Simvastatin,³ Metformin Hcl,⁴

² Carvedilol is "a beta adrenergic-blocking agent used in the treatment of essential hypertension and as an adjunct in the treatment of mild or moderate congestive heart failure." Dorland's Illustrated Medical Dictionary 301 (32d ed. 2012) (hereinafter "Dorland's").

³ Simvastatin is "used to lower blood lipid levels in the treatment of hypercholesterolemia and other forms of dyslipidemia and to reduce the risk of morbidity and mortality associated with atherosclerosis and coronary heart disease." Dorland's, supra note 1, at 1718.

⁴ Metformin hydrochloride is "used in the treatment of type 2 diabetes mellitus." Dorland's, supra note 1, at 1146.

Furosemide,⁵ Amlactin, Melatonin, Aspirin, and Benadryl. Id. Dr. Tonder added the following drugs to petitioner's therapy: Lisinopril,⁶ Cartia XT⁷ (180 mg once daily and 300 mg once daily) for blood pressure, Prazosin Hcl,⁸ Klor-con M20.⁹ Id. at 3.

On October 24, 2011, petitioner returned to Dr. Tonder's office for a flu vaccination. Id. at 4. LPN David Thebo noted that petitioner was 73 years old, and was slow to walk, with a history of prostate cancer. Id. LPN Thebo also noted it was okay to administer the vaccination because petitioner's last radiation treatment was at the beginning of the month. Id.

⁵ Furosemide is "a loop diuretic used in the treatment of edema associated with congestive heart failure or hepatic or renal disease, as an adjunct in the treatment of acute pulmonary edema, and in the treatment of hypertension, usually in combination with other drugs." Dorland's, supra note 1, at 751.

⁶ Lisinopril is an ACE (angiotensin-converting enzyme) inhibitor "used in the treatment of hypertension (alone or in combination with a thiazide diuretic), congestive heart failure, and acute myocardial infarction." Dorland's, supra note 1, at 1065. Possible side effects of Lisinopril are a light-headed feeling as if you might pass out, swelling, rapid weight gain, fatigue, muscle weakness, dizziness, and depression. Lisinopril, Drugs.com, www.drugs.com/lisinopril.html (last visited Dec. 2, 2014).

⁷ Cardia XT (diltiazem hydrochloride) is a calcium antagonist to reduce blood pressure. Its possible side effects are swelling in the hands or feet, trouble breathing, dizziness, fainting, and fast or pounding heartbeat. Cartia XT, RxList: The Internet Drug Index (Jan. 19, 2010), www.rxlist.com/cartia-drug.htm.

⁸ Prazosin hydrochloride is "a quinazoline derivative with vasodilator properties, used as an oral antihypertensive." Dorland's, supra note 1, at 1507. Possible side effects are dizziness, drowsiness, frequent urination, headache, lack of energy, weakness, swelling of hands or feet, fainting, fast or irregular heartbeat, and depression. Beta-blockers taken with Prazosin hydrochloride may increase the risk of side effects of Prazosin. Prazosin, Drugs.com, www.drugs.com/cdi/prazosin.html (last visited Dec. 2, 2014). Carvedilol, which petitioner was also taking, is a beta-blocker. Carvedilol, Drugs.com, www.drugs.com/carvedilol.html (last visited Dec. 2, 2014).

⁹ Klor-Con (potassium chloride) is used to prevent or to treat low blood levels of potassium (hypokalemia). Klor-Con, Drugs.com, www.drugs.com/klor-con.html (last visited Dec. 2, 2014). Patients are not supposed to take Klor-Con if they have kidney failure or take certain diuretics. Id. Possible side effects are confusion, anxiety, feeling like you might pass out, uneven heartbeat, increased urination, leg discomfort, and muscle weakness or limp feeling. Id. Drugs that can interact with Klor-Con include an ACE inhibitor such as Lisinopril, and any type of diuretic such as Furosemide. Id. Petitioner was on both Lisinopril and Furosemide when he was taking Klor-Con. Med. recs. Ex. 2, at 2.

Post-Vaccination Records

On October 26, 2011, at 1:15 p.m., petitioner saw Dr. Tonder, complaining of hypoxia. Id. at 6. Petitioner had an initial oxygen saturation of 85 percent on room air. Id. After he was given albuterol nebulizer once, he had some symptomatic improvement, but his oxygen saturation continued to be low (up to 88 percent). Id. He improved to 94–95 percent on 2L oxygen by nasal cannula. Id. Dr. Tonder wrote that petitioner clearly had bronchitis, but also had leg swelling consistent with congestive heart failure. Id. Considering petitioner also had prostate cancer, petitioner was at risk for a pulmonary embolism and pneumonia. Id. Dr. Tonder recommended he take an ambulance to the emergency room. Id. He had poor blood pressure control that day (likely due to respiratory distress), congestive heart failure exacerbation (he had underlying cardiac disease), and bronchitis. Id. Petitioner stated that, for the past five days (meaning onset was October 21, 2011 or three days before vaccination), he had noted wheezing and difficulty breathing. Id. He also noted leg swelling and a 12-pound weight gain over the past few months. Id. Petitioner had a cough with a little bit of phlegm and also had a fever for the first two days of his symptoms. Id. Petitioner weighed 270 pounds at this visit. Id. at 7. His blood pressure was 158/100. Id.

On October 26, 2011, petitioner went to Good Samaritan Hospital Emergency Department and spoke to Dr. Jacques W. Kobersy. Med. recs. Ex. 3, at 26. Petitioner complained of shortness of breath and hypoxia. Id. He said that he had some wheezing, shortness of breath, and a non-productive cough for the last four to five days (putting onset on October 21, 2011 or October 22, 2011, two or three days before vaccination). Unlike his history to Dr. Tonder earlier the same day, petitioner denied having had any fevers. Id. He had underlying cardiac disease and gained about 12 pounds in the last month or so. Id. Petitioner thought his leg swelling was secondary to chemotherapy. Id. Petitioner's blood pressure was 187/101. Id. His white blood cell count was normal but with a left shift.¹⁰ Id. at 27. Petitioner's brain natriuretic peptide was elevated at 518.¹¹ Id. Dr. Kobersy diagnosed petitioner with pneumonia. Id. An October 26, 2011 chest x-ray showed a right lower lobe infiltrate, likely pneumonia. Id. at 30.

¹⁰ A left shift means a high number of young, immature white blood cells, indicating an infection or inflammation, with the bone marrow producing more white blood cells and releasing them into the blood before they are fully mature. WBC Differential, Lab Tests Online (Aug. 16, 2013), www.labtestsonline.org/understanding/analytes/differential/tab/faq.

¹¹ An elevated BNP means the heart is working harder. Brain Natriuretic Peptide (BNP) Test, WebMD (Mar. 12, 2014), www.webmd.com/heart-disease/brain-natriuretic-peptide-bnp-test. The normal range is 0–99. Id.

Dr. Aftab A. Memon wrote a history of the present illness (“HPI”) when petitioner was admitted to Good Samaritan Hospital on October 26, 2011. Id. at 8. Petitioner said he had not been feeling well for about one week (putting onset on October 19, 2011, five days before vaccination). Id. Petitioner had shortness of breath, mostly on exertion, but he had orthopnea and paroxysmal nocturnal dyspnea¹² as well. Id. He complained of fever up to 99.8 degrees for the past four days. Id. He also complained of a cough with clear phlegm. Id. He said he had chronic leg swelling that had not changed recently. Id. He also had chronic urinary frequency. Id. After receiving the nebulizer treatment earlier that day, he felt a lot better. Id. His past medical history included prostate cancer (diagnosed in May 2011). Id. His last brachytherapy was in the first week of September 2011. Id. He had a coronary artery bypass grafting of four vessels in 1999. Id. Doctors diagnosed petitioner with diabetes mellitus 12 years earlier, and peripheral neuropathy was a complication of his diabetes. Id. Petitioner also had hypertension, hyperlipidemia, and chronic back pain. Id. In 1999, when diagnosed with coronary artery disease, he had symptoms of shortness of breath. Id. Dr. Memon also took petitioner’s family history. Id. Petitioner’s mother died at age 65 of a heart problem. Id. at 9. She also had end-stage renal disease and was on hemodialysis. Id. Petitioner’s father died at age 83 of congestive heart failure complications. Id. Petitioner’s father also had an acute myocardial infarction while in his 70s. Id. Petitioner’s blood pressure was 187/101. Id. His temperature was 98.6 degrees. Id. His oxygen saturation was 100 percent. Id. He had coarse crackles in the right and left lower lobes of his lungs. Id. He also had scattered wheezes. Id. His extremities showed 2+ edema, which petitioner said was chronic. Id. A chest x-ray showed right lower lobe infiltrate. Id. at 10. Dr. Memon diagnosed petitioner with hypoxemia/pneumonia. Id. He said that petitioner’s hypoxemia¹³ was likely related to his right-sided pneumonia. Id.

On October 29, 2011, Dr. Martin Lee, a critical care consultant at Good Samaritan Hospital, visited petitioner. Id. at 11. Petitioner complained he had shortness of breath, wheezing, and cough. Id. The doctors diagnosed him with pneumonia and prescribed empiric antibiotics. Id. He continued to be symptomatic with shortness of breath and wheezing. Id. at 12. Petitioner had never smoked but was exposed to a lot of secondhand smoke from his wife, who smoked for 20 years. Id. Petitioner’s mother had heart problems and end-stage renal disease. Id. His father had acute myocardial infarction and congestive heart failure. Id. Petitioner’s height was 5’11”, and his weight was 271 pounds. Id. at 16. Dr. Lee diagnosed petitioner with acute respiratory failure, secondary to pneumonia, and diastolic cardiac heart failure. Id. at 19. Dr. Lee attributed petitioner’s coughing and wheezing to cardiac asthma due to cardiac heart failure, noting petitioner had significant secondhand smoke exposure. Id.

Dr. Girish M. Bhambhani wrote petitioner’s discharge summary from Good Samaritan Hospital on November 3, 2011. Id. at 6. Petitioner had acute hypoxic respiratory failure,

¹² Dyspnea is “breathlessness or shortness of breath; difficult or labored respiration.” Dorland’s, supra note 1, at 582. Orthopnea is “dyspnea that is relieved by assuming an upright position.” Id. at 1338.

¹³ Hypoxemia is “deficient oxygenation of the blood.” Dorland’s, supra note 1, at 908.

pneumonia, congestive heart failure, diabetes mellitus type 2, and accelerated hypertension. Id. His acute hypoxic respiratory failure was multifactorial, due to pneumonia/bronchitis and diastolic heart failure. Id. His hypoxemia was related to his right-sided pneumonia. Id. On discharge, petitioner did not have any significant respiratory distress and was ambulating well. Id. He had undergone a full antibiotic course. Id.

On November 10, 2011, petitioner returned to Dr. Tonder. Med. recs. Ex. 2, at 9. He was still quite fatigued, but his oxygen saturation, lung sounds, and blood pressure were normal. Id.

On December 1, 2011, petitioner returned to Dr. Tonder. Id. at 13. She noted petitioner had excellent blood pressure control, but was very fatigued and winded. Id. He was not sleeping well, which he attributed to the increased dose of Furosemide, a diuretic that necessitated rising four to five times a night to urinate. Id.

On December 12, 2011, petitioner returned to his personal care physician's practice and saw Danielle Nicholson, who noted petitioner's progressive fatigue and worsening dyspnea since his hospitalization. Id. at 17. His blood pressure was poorly controlled that day, measuring 150/78. Id. at 17–18. A prior basic metabolic profile showed worsening of his renal function. Id.

On December 19, 2011, petitioner saw Dr. Tonder. Id. at 20. He told her he was feeling much better since he got a good night's sleep the previous night, after taking hydralazine with a quart of water and some popcorn. Id. at 20. His blood pressure remained elevated at 160/80. Id. at 21.

On November 4, 2015, petitioner visited the Pulmonary Clinic at Tacoma General Hospital with a significant underlying history of systolic and diastolic heart failure and it was felt his shortness of breath was related to this issue. Med. recs. Ex. 14, at 1.

On January 1, 2016, petitioner died from acute congestive heart failure exacerbation and acute gastrointestinal bleed. Med. rec. Ex. 1 [sic], at 1.

The decedent told three different doctors at different times that his symptoms began before he received flu vaccine on October 24, 2011. He told Dr. Tonder, his personal care physician, on October 26, 2011, two days after vaccination, that his symptoms of wheezing and difficulty breathing began five days earlier, which would be October 21, 2011. He also complained of chronic leg swelling. LPN David Thebo noted two days before vaccination, in the medical records dated October 24, 2011, that petitioner was slow to walk.

The decedent told Dr. Kobersy at the Good Samaritan Hospital Emergency Department on October 26, 2011, two days after vaccination, that his symptoms of wheezing, shortness of

breath, and non-productive cough began four to five days earlier, which would be October 21 or 22, 2011.

The decedent, once admitted to Good Samaritan Hospital on October 26, 2011, two days after vaccination, told Dr. Aftab A. Memon that he had not been feeling well for about one week, which would be October 19, 2011. He complained of fever for the past four days, which would put onset of fever on October 22, 2011, two days before vaccination.

Medical Expert Reports

On February 25, 2015, Tyrone Gordly filed a letter from his personal care physician, Dr. Kathryn Tonder, as Ex. 1. She states:

After detailed review of the record, I do not believe that Mr. Gordly's claim has any merit. I do not think that the subsequent pneumonia and diastolic heart failure, for which he was treated in the hospital, is related to administration of the flu vaccine. First, he had a known history of heart failure. Second, he had been undergoing treatment for prostate cancer. . . . Mr. Gordly was having respiratory symptoms for several days prior to the administration of the flu vaccination. . . . Further, inactivated influenza vaccine, like the one given to Mr. Gordly, cannot cause reactions like pneumonia and heart failure.

Id.

Mr. Gordly also filed, as Exhibit 1, a statement from his subsequent personal care physician in 2014, Dr. Jean M. Riquelme. Dr. Riquelme states:

On 5/14/14 [Mr. Gordly] and his wife came to the clinic and asked me "for help" in establishing their claim that illness was due to flu vaccine. . . . My opinion is that the medical records do not support the vaccine as cause of illness for the following reasons. [Mr. Gordly had] progressive respiratory distress and fever for 3-7 days before admission, that is, before vaccine administration. . . . The cause of acute respiratory failure was right sided pneumonia which was treated with antibiotics for bacterial (not viral) pneumonia. . . . [Mr. Gordly] did improve with antibiotic therapy, making allergic lung disease less likely. . . . Contributing to respiratory failure was acute diastolic heart failure, supported by elevated level of BNP (a heart failure marker) and the opinion of the consulting critical care doctor. . . . The differential blood count [on] 10/26/2011 does not support allergic reaction, having normal

eosinophils. His neutrophils were increased consistent with bacterial infection. None of the attending physicians at the hospital attributed illness to flu vaccine. The peculiarity in Mr. Gordly's case is the presence of wheezing, which was new for him. This can be an allergic symptom, but also [is] present with bronchitis, pneumonia and even heart failure ("cardiac asthma"). I cannot attribute this specifically to the flu vaccine.

Id.

Since the decedent's onset of wheezing, difficulty breathing, fever, pneumonia, and bronchitis began before the flu vaccination, the flu vaccination could not have caused these conditions or the cardiac problems that followed his pneumonia and bronchitis. Shalala v. Whitecotton, 514 U.S. 268, 275 (1995) ("[A] claimant who has actually suffered symptoms . . . before vaccination cannot make out a prima facie case of the injury's onset after vaccination").

This was thus a significant aggravation case, i.e., that flu vaccination significantly aggravated his pre-existing pneumonia, bronchitis, and cardiac problems. The Vaccine Act defines significant aggravation as follows:

The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

42 U.S.C. §300aa-33(4).

As Exhibit 3, Mr. Gordly filed a letter dated January 29, 2015 from Dr. Riquelme to Mr. Gordly's attorney, who had asked her opinion on significant aggravation. She states that, if the 2011 Vaccine Information Sheet for flu vaccine contained the warning not to vaccinate at the time someone is ill, she would support a claim of aggravation, although the 2014 sheet, which was the only sheet she had, did not specifically state the vaccine could aggravate illness. Id.

Subsequently, on April 17, 2015, Mr. Gordly filed a declaration from Dr. Riquelme as another Exhibit 1, in which she states that flu vaccine did not cause Mr. Gordly's medical issues in October 2011. Id. at 2. She concludes that flu vaccine significantly aggravated Mr. Gordly's pre-existing pneumonia because it made his health significantly worse and prolonged his hospital stay. Id. at 3-4. The Exhibit 2 attached to this declaration is Dr. Riquelme's CV, which shows that is board-certified in family practice. Id. at 2.

On June 24, 2016, respondent filed the expert report of Dr. Kenneth Fife, board-certified in internal medicine and board eligible in infectious diseases. Ex. A, at 1. At the time of Mr. Gordly's vaccination, he was 73 years old with a history of hypertension that was under

moderate control, stage 2 chronic kidney disease, type 2 diabetes, and prostate cancer. Id. He also had a history of coronary artery disease, lumbosacral spine disease, degenerative joint disease, hyperlipidemia, obesity, diabetic retinopathy, and diabetic neuropathy. Id. Mr. Gordly had symptoms starting on October 21 or 22, 2011, at least two days prior to receiving flu vaccine. Id. at 3. His pneumonia progressed, leading to his hospitalization. Mr. Gordly had several risk factors for a poorer outcome from pneumonia, including his age, concomitant medical conditions, and cancer. Id. Dr. Fife did not find it surprising that Mr. Gordly's recovery was relatively slow. Id. Dr. Fife states he is unaware of any medical literature report of an exacerbation of pneumonia from flu vaccine. Id. His conclusion is, "The influenza vaccine played no causative role in his illness." Id.

In Exhibit 15, which petitioner filed September 6, 2016, Dr. Riquelme states she read recent medical records that petitioner's counsel sent to her and also read Dr. Fife's report but "did not see any new information." She said she stood by her previous opinion. Id.

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. 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, her husband would not have had significant aggravation of his pneumonia and other illnesses, but also that the vaccine was a substantial factor in causing significant aggravation of his pneumonia and other illnesses. 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 her claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1) (2006).

The undersigned finds most significant Dr. Tonder’s opinion and Dr. Riquelme’s initial opinion in which they list the reasons for their separate conclusions that flu vaccine did not significantly aggravate Mr. Gordly’s pre-existing pneumonia. He did not have an allergic reaction to flu vaccine. He had bacterial pneumonia. Moreover, Dr. Fife and Dr. Tonder capably describe Mr. Gordly’s numerous chronic conditions, including the heart disease from which he died. By contrast, Dr. Riquelme’s subsequent opinion that flu vaccine significantly aggravated Mr. Gordly’s pneumonia is threadbare. She based her opinion on the general advice from the flu vaccine information sheet not to vaccinate an ill individual and extrapolated that advice to Mr. Gordly’s case, ignoring his numerous chronic disease factors and advanced age, to conclude there was significant aggravation. The undersigned does not find her subsequent opinion credible.

The undersigned **GRANTS** petitioner’s motion to dismiss and **DISMISSES** this case.

IT IS SO ORDERED.

September 15, 2016
DATE

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