

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 10-55V

Filed: July 19, 2018

Not to be Published.

SHINGSHAN LIU and SUE WANG LIU, *
as Personal Representatives of the Estate of *
DAN LIU, Deceased, *

Petitioners, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

F. John Caldwell, Sarasota, FL, for petitioners.
Althea W. Davis, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

Petitioners filed a petition on January 27, 2010, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that Menactra (meningococcal) vaccine administered to their son Dan on May 30, 2008, caused an adverse reaction leading to his death on June 22, 2008. Pet. at ¶ 11.

This is a tragic case and the undersigned extends sympathy to petitioners for their loss.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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

FACTS

Prevaccination records

On February 22, 2008, fourteen weeks before Dan received Menactra, he had a neurologic consultation with Dr. James Zu, a neurologist, because of symptoms of depression, for which Dan was seeing a psychiatrist. Med. recs. Ex. 2, at 2. Dan and his mother noticed he had been feeling inactive, had an increase of sleep, and a loss of interest for at least one to two years. Id. He was recently diagnosed with sleep apnea. Id. Dr. Zu concluded Dan had no neurologic disease that would cause him depression but sent him for a brain MRI and blood tests. Id. at 3.

On February 29, 2008, Dan had a brain MRI without contrast. Id. at 9. There was no hemorrhage or edema. Id. There was a solitary punctate² focus of signal abnormality in Dan's left frontal subcortical white matter, consistent with a focus of gliosis,³ demyelination,⁴ or ischemia.⁵ Id.

On March 4, 2008, Dan was seen at the Respiratory Center for Children, where he was diagnosed with circadian rhythm disorder and mild OSA (obstructive sleep apnea),⁶ and it was noted that Dan was sleeping better on 3 milligrams of Melatonin (taken at 10:30 p.m.). Med. recs. Ex. 1, at 27. Dan usually fell asleep in 10 to 15 minutes and woke at 6:00 to 7:00 a.m. Id. He had an intermittent snore and complained of fatigue in the morning. Id. The doctor noted that depression could affect Dan's sleep pattern. Id. at 28. Dan also had chronic/allergic rhinitis. Id. To deal with his rhinitis and cough, the doctor prescribed 2 sprays/nose drops of Nasonex, 10 milligrams of Singulair, and Maxair for cough. Id.

Dan's difficulty with being able to fall asleep began in 2004. Id. at 36. During a visit to Dr. Dagnachew Assefa of the Respiratory Center for Children on November 13, 2006, Dan's father noted that Dan was tired during school days and had difficulty with attention. Id. Mr. Liu thought that Dan might be having some anxiety problems. Id.

In 2002, Dan was diagnosed with asthma and prescribed Albuterol. Id. at 73.

² The definition of "punctate" is "resembling or marked with points or dots." Dorland's Illustrated Medical Dictionary 1555 (32d ed. 2012) (hereinafter, "Dorland's").

³ Gliosis is "an excess of astroglia in damaged areas of the central nervous system; see also *astrocytosis*." Dorland's at 784. Astroglia or astrocytes are neuroglial cells of ectodermal origin. Dorland's at 169.

⁴ Demyelination is the "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's at 486.

⁵ Ischemia is a "deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel." Dorland's at 961.

⁶ Apnea is the "cessation of breathing." Dorland's at 116.

Postvaccination Records

Between his Menactra vaccination on May 30, 2008 and his death on June 22, 2008, Dan did not see a physician.

The autopsy report concludes that Dan died from cardiac arrhythmia of undetermined etiology. Med. recs. Ex. 4, at 5. The medical examiner notes that Dan was found unresponsive in bed, face up, after having been heard in the bathroom at 6:00 a.m. Id. at 9. The EMT report, states that Dan was found lying supine on his bed when his alarm clock sounded, but he did not come out of his room. Med. recs. Ex. 6, at 2. CPR was initiated at 8:30 a.m. and discontinued at 8:31 a.m. because of obvious signs of death. Id. at 3. The field diagnosis was cardiac arrest. Id.

The police arrived that morning as well. Ex. 9, at 2.⁷ CPR, defibrillation, oxygen, and chest compressions were attempted until the EMTs arrived. Id. at 4. Dan had the following medications on his night table: Nasonex,⁸ Zyrtec,⁹ Rhinocort,¹⁰ Astelin¹¹ (which the report spelled “Atelin”), and Tylenol.¹² Id. at 5. Officer Bradford Beirne spoke to both of Dan’s parents. Id. They said that Dan suffered from a sleeping disorder for which he took only over-the-counter medication. Id. Dan’s mother said that Dan did have asthma and was taking treatment for it. Id. She stated Dan was feeling and acting normally before he went to bed on Saturday night, June 21, 2008. Id. At about 6:20 a.m., she heard Dan get out of bed and use the bathroom. Id. She then heard him return to his bedroom and go back to bed. Id. She said he was supposed to wake at about 8:15 a.m. because he was going with a friend to see a show that day. Id. When his alarm rang, but he did not get up, she went into his bedroom and observed him lying on his bed not breathing. Id. Her husband called 911. Id.

⁷ Although petitioners filed the police report as Exhibit 9, it is stamped Exhibit 1 throughout. The undersigned will continue to refer to it as Exhibit 9 since there is a set of medical records already filed as Exhibit 1.

⁸ Nasonex is a “trademark for a preparation of mometasone furoate.” Dorland’s at 1232. Mometasone furoate is “a synthetic corticosteroid used topically for the relief of inflammation and pruritis in corticosteroid-responsive dermatoses and intranasally in the treatment of allergic rhinitis and other inflammatory nasal conditions.” Dorland’s at 1174.

⁹ Zyrtec is a “trademark for preparations of cetirizine hydrochloride.” Dorland’s at 2097. Cetirizine hydrochloride is “a nonsedating antihistamine (H₁-receptor antagonist) that is a metabolite of hydroxyzine, used in treatment of allergic rhinitis and chronic idiopathic urticaria, and as a treatment adjunct in asthma. . . .” Dorland’s at 334.

¹⁰ Rhinocort is a “trademark for preparations of budesonide.” Dorland’s at 1639. Budesonide is “an antiinflammatory glucocorticoid used by inhalation to treat asthma, intranasally to treat allergic rhinitis and other inflammatory nasal conditions. . . .” Dorland’s at 258.

¹¹ Astelin is a “trademark for a preparation of azelastine hydrochloride.” Dorland’s at 167. Azelastine hydrochloride is “an antihistamine (H₁ receptor antagonist) administered intranasally in the treatment of seasonal allergic rhinitis (hay fever). . . .” Dorland’s at 187.

¹² Tylenol is a “trademark for preparations of acetaminophen.” Dorland’s at 1992. Acetaminophen is “the amide of acetic acid and *p*-aminophenol, having analgesic and antipyretic effects similar to aspirin’s but only weak antiinflammatory effects.” Dorland’s at 12.

Officer James McCullough went to Dan's home, photographed the body, and spoke to Dan's parents. Id. at 6. Dan's father told him that Dan had been home the previous night acting normally. Id. Dan played the piano and listened to music while he was on the computer. Id. Dan's father said that Dan was not complaining of any illness and had not been sick. Id. Dan's father said that Dan ate supper and, around 10:00 p.m., told his father that he was hungry again, and his father cooked him some noodles. Id. Dan's mother then said that she and her husband went to bed, but Dan went into the bathroom around 11:00 p.m. and seemed to be there a long time. Id. She again heard Dan in the bathroom around 6:00 or 6:30 a.m. Id. At about 8:15 a.m., she heard Dan's alarm clock go off and, when she went to wake him, she found him in bed unresponsive. Id. Officer McCullough then asked for and received permission to investigate Dan's computer and found that, the night before, Dan had googled "inducing diarrhea." Id. Officer McCullough asked Dan's father about this, and he replied that Dan frequently had stomach problems with constipation since childhood. Id. Dan's father also stated that Dan had trouble sleeping at times for which he took Melatonin, but he had run out of it on Friday. Id. In its absence, Dan would take Tylenol P.M. (which was on the nightstand) to help him sleep. Id. Dan's father stated that the last time Dan was at the doctor's was several weeks earlier to get a shot necessary for him to attend camp. Id. He also stated that a couple of weeks ago, Dan had a low-grade fever for a day or two and took Tylenol until it went away. Id. at 7.

Petitioners' Medical Expert Reports

On June 5, 2012, petitioners filed the expert report of Dr. Douglas C. Miller, a pathologist, as Exhibit 14. Dr. Miller's CV is filed as Exhibit 15. He is board-certified in anatomic pathology and neuropathology. Ex. 15, at 1. He did residencies in anatomic pathology and neuropathology at Massachusetts General Hospital. Id. He won First Prize for his book "Modern Surgical Neuropathology" in the category of Neurology Books from the British Medical Association in 2010. Id. at 2. He is a founding member of the New York State Association of Neuropathologists. Id. at 4. Dr. Miller is on the editorial review board of the Journal of Child Neurology. Id. He is a reviewer for the following journals: Neurosurgery; Journal of Neuropathology and Experimental Neurology; Brain Pathology; Journal of Neuro-Oncology; Human Pathology; Archives of Pathology and Laboratory Medicine; Journal of Neurology, Neurosurgery & Psychiatry; Cancer; Neurobiology of Disease; Journal of Child Neurology; and American Journal of Clinical Pathology. Id. Dr. Miller is the author or co-author of three books and 145 articles. Id. at 5-14.

Dr. Miller states in his expert report that he reviewed the autopsy report and slides prepared by the Union County Medical Examiner, as well as additional fixed tissues in formalin, from which he chose additional samples for new slides. Ex. 14, at 1. Petitioners' counsel requested Dr. Miller render an opinion as to the cause of Dan's death. Id. Dr. Miller mentions that he has been involved in another alleged vaccine-caused death case and has been a consultant to pathologists in New York, New Jersey, and Missouri for decades. Id.

He notes that Dan's brain weight of 1,710 grams was extremely heavy. Id. at 2. Dan's

heart had pathologic indications of a lack of blood supply. Id. The lungs showed some intra-alveolar hemorrhage and considerable edema. Id. Dan's brain did not show any acute hypoxic/ischemic changes. Id. at 3. The brain's white matter did not have infiltration by lymphocytes or macrophages and did not have gliosis. Id. There was no indication of demyelinating disease in Dan's brain. Id. The cortex and hippocampus did not have changes suggestive of chronic seizure disorder. Id. Dr. Miller thought it unlikely that Dan, who did not have a history of epilepsy, had a first seizure and died. Id.

Dr. Miller said the brain specimens did show focal minimal to mild lymphocytic ("chronic") meningitis. Id. Both sections of the cerebellum Dr. Miller took showed small areas containing small aggregates of mature small lymphocytes in the subarachnoid space on top of the cerebellar foliar cortical tissue contained within the leptomeninges. Id. Dr. Miller wrote that this finding suggests Dan had viral meningitis ("aseptic meningitis"), although it might be a reaction to something else, perhaps even an autoimmune problem. Id. Symptoms of mild fever, headache, and lethargy are consistent with viral meningitis. Id. Dr. Miller states that he has difficulty believing that the severe brain swelling was caused by the meningitis because the degree and extent of meningeal inflammation was so slight. Id. Dr. Miller opines that it was coincidence that Dan had meningitis and something else which caused acute brain swelling and death. Id.

Dr. Miller concludes that the cause of Dan's death was brain swelling with brainstem compression. Id. at 4. Dan's pulmonary hemorrhage and edema were consistent with a severe cerebral event ("neurogenic pulmonary edema"). Id. The wavy fibers in Dan's heart sections were also consistent with a primary intracranial catastrophe ("encephalogenic visceral syndrome"). Id. Dr. Miller posits the following sequence occurred to Dan, leading to his death:

cerebral edema from some unknown catastrophic cause, leading to neurogenic pulmonary edema and histologic changes of subendocardial ischemia, with *death occurring rapidly from onset, certainly no more than about two hours and quite possibly in only minutes.*

Id. (emphasis added).

Dr. Miller states he has "no good answer" for what caused Dan's cerebral edema. Id. He writes that young people are sometimes prone to "flash edema," that is, the rapid onset and progression of severe brain swelling from otherwise trivial blunt head trauma without any focal brain injury. Id. He opines that Dan might have bumped his head when he went to the bathroom at six in the morning on the day of his death. Id. Dr. Miller repeats that he finds it implausible that the small amount of meningitis present at the time of Dan's death was responsible for his cerebral edema. Id.

Dr. Miller says it "makes no sense" to connect the meningitis vaccine to Dan's death even though he found meningitis in some of Dan's brain sections. Id. The vaccine is directed

against the bacterial form of meningitis caused by *Neisseria meningitides* and does not include live bacteria. Id. Meningococcal meningitis is a fulminant acute disease, which provokes an acute inflammatory response composed of polymorphonuclear leukocytes, unlike the course of viral meningitides which are characterized by inflammatory infiltrates composed of mononuclear cells, i.e., lymphocytes and some macrophage/histiocytic cells. Id. Dr. Miller states Menactra vaccine did not infect Dan with an organism or virus causing meningitis. Id.

Dr. Miller repeats his conclusion at the end of his expert opinion: the cause of Dan's death was cerebral edema from some unknown catastrophic event, leading "to neurogenic pulmonary edema and histologic changes of subendocardial ischemia, with *death occurring rapidly from onset, certainly no more than two hours and quite possibly in only minutes.*" Id. at 5 (emphasis added).

Petitioners should have moved to dismiss after filing Dr. Miller's expert report. That is when a reasonable basis to proceed ended. However, petitioners' counsel asked to find another medical expert.

Over numerous years, petitioners proceeded to file four other medical doctors' reports, all of which proved to be defective. Dr. Yehuda Shoenfeld, an immunologist, wrote a report which misstated Dr. Miller's conclusion. When the undersigned called this defect to petitioners' counsel's attention, he moved to strike Dr. Shoenfeld's report. The undersigned struck Dr. Shoenfeld's report from the record. Petitioners then retained Dr. Robert Waugh, a cardiologist, who wrote a report stating that Dan had eosinophilic myocarditis, although no eosinophils were detected in his heart. Dr. M. Eric Gershwin, an immunologist, then wrote a report stating that Menactra vaccine caused Dan's eosinophilic myocarditis. But then Dr. Waugh entered hospice and petitioners retained another cardiologist Dr. Frederick Yturralde who wrote Dan did not have eosinophilic myocarditis, but fulminant myocarditis. However, Dr. Yturralde could not say it was due to the vaccination. Dr. Gershwin wrote another report repeating his prior opinion that the vaccine caused eosinophilic myocarditis, apparently unaware that Dr. Yturralde wrote that Dan had fulminant myocarditis not eosinophilic myocarditis. Dr. Yturralde then wrote another expert report saying Dan died from fulminant myocarditis and stating the vaccination caused it but did not give any basis for his opinion other than Dr. Gershwin said it did, ignoring that Dr. Gershwin's prior report referred only to eosinophilic myocarditis and not to fulminant myocarditis. Following the undersigned's order, petitioners' counsel returned to Dr. Gershwin to see if he would support the new view that Menactra vaccine caused Dan to have fulminant myocarditis from which he died, but petitioners did not obtain a further report from Dr. Gershwin, meaning even if they could have proved Dan died from fulminant myocarditis, they could not prove the vaccine caused it.

On July 19, 2018, petitioners filed a Motion for a Decision Dismissing Their Petition. They state that "they will be unable to prove that they are entitled to compensation in the Vaccine Program" and that "to proceed further would be unreasonable and would waste the resources" of the court, respondent, and the Vaccine Program. Pet'rs' Mot. at 1.

The undersigned **GRANTS** petitioners' Motion for a Decision Dismissing Their Petition and **DISMISSES** this case.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners 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 of and effect showing that the vaccination was the reason for the injury [,]” the logical sequence being supported by a “reputable medical or scientific explanation[.]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioner’s 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.

Petitioners must show not only that but for Menactra vaccine, their son would not have died, but also that Menactra vaccine was a substantial factor in causing his death. Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioners based solely on their allegations unsubstantiated by medical records or medical opinion. The medical records do not support petitioners’ allegations. The expert reports petitioners filed do not support their allegations.

Petitioners move for a decision dismissing their petition.

The undersigned **GRANTS** petitioners’ motion and **DISMISSES** this petition.

CONCLUSION

The petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.¹³

¹³ 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.

IT IS SO ORDERED.

Dated: July 19, 2018

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