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OSM
US COURT OF FEDERAL CLAIMS

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-1225V
Filed: June 6, 2017
Not to be Published

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OSM
U.S. COURT OF FEDERAL CLAIMS

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DEBRA KELLY, *
*
Petitioner, *
*
v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
*
****

Influenza ("flu") vaccine; significant aggravation of chronic inflammatory demyelinating polyneuropathy ("CIDP"); no proof

Debra Kelly, Hampstead, NC, for petitioner *pro se*.
Darryl R. Wishard, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On October 21, 2015, petitioner filed a petition *pro se* under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that an influenza ("flu") vaccination she received on October 23, 2012 caused her significant aggravation of her preexisting chronic inflammatory demyelinating polyneuropathy ("CIDP"). Pet. Preamble and ¶ 2. Section 300aa-33(4) defines "significant aggravation:"

> 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

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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

of health.

Petitioner asserted that before her influenza vaccination of October 23, 2012, her CIDP was stable. Id.

On December 31, 2015, Peter Joseph Sarda entered a notice of appearance for petitioner. Subsequently, Mr. Sarda had medical treatment for a serious illness and moved to withdraw as counsel.

As for the merits of this case, evidence in the medical records shows that petitioner's CIDP was worsening before October 23, 2012, the date of her flu vaccination. Moreover, evidence in the medical records shows that her worsened CIDP after the October 23, 2012 flu vaccination was due to her receiving IVIG to treat her CIDP. After her second IVIG treatment, petitioner was hospitalized for 11 days. The reason she was administered IVIG in the first place was that her CIDP was worsening before the October 23, 2012 flu vaccination. Her IVIG treatment was switched to plasmapheresis, which resulted in an improvement of petitioner's CIDP. The issue is whether her flu vaccination of October 23, 2012 caused her worsened CIDP or, as her medical treaters noted in the medical records, her adverse reaction to two IVIG treatments caused her worsened CIDP. No medical doctor attributed petitioner's worsened CIDP to her vaccination.

The Federal Circuit in Capizzano v. Secretary of Health and Human Services 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 1317, 1326 (Fed. Cir. 2006); 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).

To satisfy her burden of proving causation in fact significant aggravation, 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 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.

Petitioner must show not only that but for her influenza vaccination, her CIDP would not have worsened, but also that her flu vaccination was a substantial factor in causing her CIDP to worsen. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Under 42 U.S.C. § 300aa-13(a), the undersigned may not rule in favor of petitioner "based on the claims of . . . petitioner alone, unsubstantiated by medical records or by medical opinion." Petitioner's medical records do not substantiate her allegations. In fact, they refute her allegations because they attribute the worsening of her CIDP after the flu vaccination to her receipt of IVIG treatments. When the CIDP treatment was changed to plasmapheresis, her CIDP improved. Petitioner has not filed an expert medical opinion in support of her allegations.

On June 27, 2016, the undersigned issued an Order to Show Cause by July 27, 2016 why this case should not be dismissed.

On July 18, 2016, petitioner filed a Motion for Extension of Time to Show Cause. Petitioner filed this motion *pro se* although counsel represented her at this time. On July 20, 2016, the undersigned issued an Order granting petitioner's motion, setting a new deadline of August 29, 2016 for her to respond to the Order to Show Cause.

On August 3, 2016, petitioner's counsel filed a Motion to Withdraw as Counsel, which the undersigned granted on the same date.

On August 8, 2016, the undersigned's law clerk contacted petitioner to schedule a status conference. Petitioner said she was seeking new counsel and was going to undergo hip replacement surgery on August 9, 2016. Petitioner asked for more time to respond to the undersigned's Order to Show Cause. In an Order dated August 8, 2016, the undersigned gave petitioner until September 30, 2016 to file a response to the undersigned's Order to Show Cause.

On August 29, 2016, petitioner contacted the undersigned's law clerk to request another extension of time to respond to the undersigned's Order to Show Cause. In an Order dated September 30, 2016, the undersigned granted petitioner's informal motion and set a new deadline of November 28, 2016 for petitioner to respond to the undersigned's Order to Show Cause.

Petitioner did not file a response to the undersigned's Order to Show cause by November 28, 2016. The undersigned's law clerk contacted petitioner who replied she thought the deadline was December 28, 2016 and requested more time to file her response. In an Order dated December 1, 2016, the undersigned granted petitioner's informal motion for an extension of time and set a new deadline of December 28, 2016 for petitioner to respond to the undersigned's Order to Show Cause.

On December 30, 2016, petitioner e-mailed the undersigned's law clerk to request another extension of time to file a response to the undersigned's Order to Show Cause. Petitioner said she had an appointment with two doctors in Chicago on March 2, 2017 and that two lawyers were interested in representing her depending on the outcome of these doctor visits. In an Order dated January 6, 2017, the undersigned granted petitioner's informal motion for an extension of time and set a new deadline of June 1, 2017 for petitioner to respond to the undersigned's Order to Show Cause.

Thus in the approximate year since the undersigned issued an Order to Show Cause why this case should not be dismissed, petitioner asked for five extensions of time to respond to the Order to Show Cause, but has still not responded, missing the last deadline of June 1, 2017 to respond. She has not obtained new counsel and has not filed any new medical records (including records from her two doctor visits on March 2, 2017).

Under Vaccine Rule 21(b)(1), this petition is **DISMISSED** for failure of petitioner to prosecute and failure to comply with six orders of the undersigned.

Medical Records

Prevaccination

On October 28, 2011, petitioner saw Dr. Nevin Shrimanker, stating she had a two-week to two and one-half week history of increasing pain symptoms involving her lower back, and numbness and tingling in her legs. Med. recs. Ex. 4, at 46.

From July 28 to August 7, 2012, petitioner was an inpatient at UNC Health Care, Chapel Hill, for a diffuse axonal sensorimotor neuropathy. Med. recs. Ex. 5, at 5. She had a history of being in her usual state of health until July 25, 2012 when she fell. Id. at 5. During the next 24 hours, her weakness and numbness worsened in her arms and legs, and she could not walk the next day. Id. Imaging of her cervical spine did not show anything to account for her symptoms. Id. at 8. Her lower extremity reflexes were absent and her upper extremity reflexes were 1+. Id. Petitioner noted occasional blurry vision and numbness and tingling about her mouth and in a band across her nose and cheeks. Id. at 12.

On July 31, 2012, petitioner had Dr. James F. Howard, Jr., perform a nerve conduction study and electromyography. Id. at 1. The result was a severe diffuse mixed sensorimotor polyneuropathy. Id. at 4. She had profound demyelination with widespread axonal abnormalities. Id.

On August 17, 2012, petitioner saw Dr. Shrimanker, complaining of inability to move her legs after a fall at home. She was diagnosed with possible axonal demyelinating disease. Ex. 4, at 23. She used a cane for balance. Id. at 15. She had a possible diagnosis of axonal demyelinating disease of the peripheral nerves. Id. at 24.

On October 17, 2012, petitioner saw Dr. Nizar Chahin, giving a history that her symptoms started one year earlier when she noticed electrical impulses in her back radiating down to her heels. Id. at 15. In October 2011, she noted loss of sensation in her feet and difficulty walking. She had to use a cane or a shopping cart when she was in a store. Her symptoms progressed slowly and, on July 22, 2012, she fell due to weakness. She noted two to three days after the fall that her weakness became more severe and she could not walk. She also noted numbness in her hands radiating up in her arms, and numbness in the center of her face, mostly her nose and around her mouth even inside her gums. Id. A few days before she had a Kenalog shot on October 12, 2012, she was severely weak and unable to get out of her wheelchair. Id. at 15-16. Petitioner's father complained of numbness in his feet in his 70s and he had a history of falls. Id. at 16. Petitioner's paternal uncle who was in his 70s also had numbness and falling. Id. On physical examination, petitioner's deep tendon reflexes were absent. Id. at 17. Dr. Chahin diagnosed petitioner with CIDP. He thought her mild axonal loss was secondary. He thought it interesting that petitioner had a family history of neuropathy in her father and paternal uncle. He considered her positive response to Kenalog shots an indication that she had an inflammatory process. Id. He thought petitioner would benefit from receiving intravenous immunoglobulin ("IVIG") and was going to arrange for that. Id. at 17, 25.

On October 19, 2012, Dr. Chahin did a nerve conduction study and EMG on petitioner and concluded she had findings consistent with a severe diffuse demyelinating neuropathy, i.e., CIDP. Id. at 26, 27.

Postvaccination

On October 23, 2012, petitioner received a flu vaccination in her left arm. Med. recs. Ex. 1, at 36. She complained of numbness, tingling, muscle spasms, and fatigue. Med. recs. Ex. 7, at 17.

From November 8-19, 2012, petitioner was hospitalized at UNC Health Care in Chapel Hill. Med. recs. Ex. 10, at 131. The history was that petitioner went to the emergency department because of worsening weakness in the setting of CIDP. She had a one-year history of paresthesias and weakness. She was diagnosed with CIDP about two weeks previously after a lumbar puncture revealed elevated protein in her cerebrospinal fluid. She was started two weeks previously on IVIG, with a second infusion of IVIG on November 6, 2012, and reported that, in the prior two weeks, she had gradually worsening left upper extremity weakness.[2] She began to have pins and needles and a numb sensation on her cheeks, nose, and inside her mouth on November 7, 2012 plus a more generalized worsened weakness requiring significant assistance to get up from a chair, but she could use a walker to get to the toilet. On November 8, 2012, she

[2] Petitioner reported on November 19, 2012, when she was admitted for inpatient rehabilitation at UNC Health Care, Chapel Hill that her weakness worsened after her second IVIG treatment for CIDP on November 6, 2012, prompting her admission to the hospital on November 8, 2012. She felt she was gradually regaining some of her strength, more in her upper extremities than her lower extremities. Med. recs. Ex. 10, at 135.

awoke and was unable to get out of bed. She could not pick up her arms or legs very well and could not stand. She also felt shortness of breath and saliva pooled in the back of her throat when she lay down. Three weeks ago, at her most recent baseline, she was ambulating well with a cane, and was able to rise from a seated position using her arms but without other assistance. She had not had any recent fever, chills, or illness. During her hospitalization, her strength improved markedly, though not quite back to her baseline. She was discharged to acute inpatient rehabilitation to continue physical therapy. Id. Her hepatitis C might be contributing to her CIDP. Id. at 132.

On December 17, 2012, petitioner saw Nurse Practitioner Jessica Hahn-Ketter at the Rex Healthcare Pain Clinic. Id. at 128. Petitioner had increasing pain symptoms the past couple of months and was recently diagnosed with CIDP. She also had lumbar degenerative disease and a herniated disk at L5-S1. Since petitioner's last visit on October 12, 2012 to the Pain Clinic, she had been receiving IVIG. However, the IVIG caused a reaction when she woke up one morning and could not move her legs. She went to the emergency department and was hospitalized where she began receiving plasmapheresis. Following hospitalization, she went to rehab and was now receiving outpatient plasmapheresis. Petitioner stated the plasmapheresis helped her numbness, particularly in her hands. Id.

On January 9, 2013, Dr. Chahin, the neurologist who did nerve conduction and electromyography testing on petitioner, wrote a history that, in October 2011, petitioner lost sensation in her feet and had difficulty walking. Med. recs. Ex. 11, at 1. She used a cane or shopping cart to walk when in a store. Her symptoms progressed slowly. On July 22, 2012, petitioner fell due to weakness. Two to three days after she fell, her weakness became more severe and she could not walk. She also had numbness in her hands radiating up her arms. She also had numbness in the center of her face, mostly nose and around the mouth and inside her gums. She was admitted to the University of North Carolina ("UNC") Hospital from July 28, 2012 and discharged on August 7, 2012 to rehab, from which she was discharged on August 11, 2012. On November 8, 2012, she was admitted again to UNC with worsening weakness, difficulty swallowing, and shortness of breath. Her limbs barely moved. Her protein level in her cerebral spinal fluid was elevated at 145 mg/dL. Id. Dr. Chanin noted petitioner had made remarkable improvement on therapeutic plasma exchanges. Id. at 2.

On May 24, 2013, Dr. Chahin did another EMG and nerve conduction study on petitioner. Id. at 7. His conclusion was the same as his earlier test results, which were that petitioner had severe diffuse demyelinating polyneuropathy consistent with her known history of CIDP. Id. at 8. However, clinically, petitioner was significantly improved. Id.

On June 5, 2013, petitioner worsened as a consequence of transitioning to a monthly plasmapheresis from a weekly plasmapheresis, and had gone two weeks from a recent plasmapheresis when she worsened. Id. at 11. As Dr. Chanin comments, in a note dated July 16, 2013, petitioner's recent exacerbation coincided with spacing her plasmapheresis from once every other week to once a month. Id. at 22. She had been doing well with every other week sessions. Dr. Chanin recommended she undergo weekly infusions for eight weeks and then

every other week infusions. Id.

On November 5, 2013, Dr. Chanin wrote that again petitioner had a relapse on August 28, 2013 when she was getting plasmapheresis every two weeks. Id. at 25. He encouraged her to make an appointment with a hepatologist to treat her hepatitis C infection because that would help with her CIDP. Id. at 26.

On February 10, 2014, Dr. Chanin saw petitioner again and noted that she could walk unaided, the numbness in her feet had improved and she could wiggle her toes better. Id. at 28. She was improving from CellCept. Id. Petitioner had been doing well until she developed a urinary tract infection and pyelonephritis and was treated with sulfa for two weeks. Id. at 33. After 10 days of treatment, she noticed numbness in her toes spreading to her feet. Her gait became unsteady and she had to use a wheelchair. She discontinued the sulfa medicine and her symptoms gradually improved. Id. Plasmapheresis also seemed to help. Id. at 34.

On October 17, 2014, Dr. Chanin saw petitioner again and noted her physical examination was almost entirely normal. Id. at 52. She had mild vibratory loss in her toes, but she was the best they had ever seen her. He opined that treating her hepatitis C may also have helped her CIDP. Id. She had normal muscle tone, bulk, strength, and deep tendon reflexes. Id. at 56. Patient's history included her father who had neuropathy. Id. at 67.

DISCUSSION

Before her October 23, 2012 flu vaccination, petitioner had episodes where she could not walk and was in a wheelchair. After her October 23, 2012 flu vaccination, petitioner had episodes where she could not walk and was in a wheelchair.

The medical treaters state that her CIDP exacerbation was a result of her adverse reaction to the IVIG treatment she received, not to her flu vaccination. When her treaters switched her from IVIG to plasmapheresis, she improved. When they made the intervals between her plasmapheresis treatments too long, she worsened. When they shortened the intervals, she improved. When they started to treat her hepatitis C infection, she also improved. She even got to a point where her only symptom was mild vibratory loss in her toes, but that level of improvement did not last. The nature of her CIDP seems episodic, depending on the type of treatment she receives.

There is no evidence in these medical records that petitioner reacted to her flu vaccination on October 23, 2012.

Petitioner has not made a prima facie case of causation in fact. Her medical records do not support her allegations. She has not filed a medical expert report in support of her allegations. This petition is **DISMISSED**.

CONCLUSION

The petition is **DISMISSED** for failure to prosecute, failure to respond to six orders of the undersigned, and 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.[3]

IT IS SO ORDERED.

Dated: June 6, 2017

Laura D. Millman
Special Master

[3] 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.