

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-281V

Filed: October 14, 2015

Not to be Published

SARAH MEYERS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Petitioner's motion for a decision
dismissing her petition granted;
Gardasil vaccine; hidradenitis
suppurative lymphadenopathy;
headaches; significant aggravation

Verne E. Paradie, Jr. Lewiston, ME, for petitioner.

Darryl R. Wishard, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On April 10, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that Gardasil vaccinations on August 22, 2007, November 29, 2010, and April 12, 2011 caused her hidradenitis suppurative lymphadenopathy and headaches. The three-year statute of limitations bars allegations of causation from the first two Gardasil vaccinations. 42 U.S.C. § 300aa-16(a)(2). On April 28, 2015, petitioner filed an amended petition to assert that the third Gardasil vaccination significantly aggravated her pre-existing medical conditions.

¹ Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). 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, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

The undersigned, having reviewed the medical records, finds they do not support petitioner's allegations. The undersigned cannot rule in petitioner's favor based solely on her allegations unsupported by medical records or credible medical opinion. 42 U.S.C. § 300aa-11(a)(1). On June 9, 2015, petitioner filed an expert opinion from Dr. David Axelrod, an immunologist, stating that petitioner's third Gardasil caused her a rash and lymphoproliferation, which resolved 23 days later. The Vaccine Act requires that petitioner's vaccine reaction last more than six months. 42 U.S.C. § 300aa-11((c)(1)(D)(i). Thus, petitioner's expert medical opinion does not support a vaccine reaction lasting more than six months. In addition, Dr. Axelrod notes that petitioner had symptoms (headache, boils, GERD, depression, etc.) both before and after the Gardasil vaccination without opining that Gardasil significantly aggravated these symptoms. Thus, petitioner's expert medical opinion does not support the allegation of significant aggravation. Although the undersigned issued an Order on June 9, 2015 that Dr. Axelrod submit a supplemental expert report addressing the deficiencies in his first report, he declined to do so, according to petitioner's status report filed July 8, 2015.

On October 8, 2015, petitioner filed a Motion for Decision Dismissing Her Petition, stating that "An investigation of the facts and science supporting her case has demonstrated to petitioner that she will be unable to prove that she is entitled to compensation in the Vaccine Program" and "to proceed further would be unreasonable and would waste the resources of the Court, the respondent, and the Vaccine Program." Pet'r's Mot. at 1.

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

FACTS

Petitioner was born on August 4, 1993.

On February 9, 2006, petitioner went to Amherst University Health Center where she told Dr. Barbara Stouter that she had had trouble sleeping at night for years and had headaches at school on many days. Med. recs. Ex. 15, at 516. She usually did not eat breakfast, but on that day, she ate breakfast and did not have a headache. Id.

On August 22, 2007, petitioner received her first Gardasil vaccination. Id. at 486.

On February 22, 2008, petitioner was at Kaleida Health, Women and Children's Hospital of Buffalo where she underwent an EEG given by Dr. Arie Weinstock. Med. recs. Ex. 14, at 277. She had a history of ADHD, anxiety, and depression, and was reported to zone out at school within the prior several months. Id. The EEG result was normal both when petitioner was awake and asleep. Id. She did not have any focal or diffuse epileptiform activity on EEG. Id.

On October 11, 2009, petitioner was in the Kenmore Mercy Hospital Emergency Department where she told Dr. Richard A. Kessler that, after a motor vehicle accident, she had neck pain and a possible muscle spasm. Med. recs. Ex. 25, at 781. She had a moderate degree of

scoliosis in her upper dorsal spine to the left. Id.

On October 29, 2009, petitioner complained of a headache in the occipital region up to her neck during a motor vehicle accident follow-up. Med. recs. Ex. 15, at 458.

On February 17, 2010, petitioner saw Dr. Lynn A. Amarante, complaining of skin boils and bumps on her arms that began one year previously. Med. recs. Ex. 27, at 794. She was on a number of drugs (Lithium, Clonapin, Ablify, Bentyl) and had a history of bipolar disorder. Id. She was allergic to penicillin. Id.

On February 18, 2010, petitioner returned to Dr. Amarante, with hidradenitis of the axilla (armpit), groin, and occasionally breasts. Id. at 792. Dr. Amarante prescribed Doxycycline 100 mg. and told petitioner to return in two months. Id. Petitioner also had facial inflammation which the antibiotic would also help. Id. Petitioner was to apply Clindamycin gel (another antibiotic) daily as well as a cream daily. Id.

On November 29, 2010, petitioner received her second Gardasil vaccination. Med. recs. Ex. 15, at 486.

From March 26 to March 28, 2011, petitioner was at BryLin Hospitals. Med. recs. Ex. 2, at 13. Dr. Christopher G. Martin wrote the discharge summary. Id. Petitioner had a lengthy history of bipolar disorder. Id. Over the past several weeks, she had been experiencing significant worsening of her mood. Id. She had episodes of depression as well as suicidal ideation. Id. She had a previous history of self-mutilation but had not been cutting herself for the prior two years. Id. She had a history of sleep apnea, but was not compliant with using CPAP. Id.

On April 12, 2011, petitioner received her third Gardasil vaccination. Med. recs. Ex. 15, at 486.

On April 17, 2011, she went to Kaleida Health Emergency Department where Dr. Thomas N. Kowalak noted that she had a rash, headache, increased sleeping, and black stools. Med. recs. Ex. 29, at 1546. Petitioner's mother was concerned that petitioner's rash was secondary to the drug Tegretol which petitioner had started about three weeks earlier for bipolar disorder. Id. Petitioner recently had a sore throat but no abdominal pain. Id. Petitioner was diagnosed with a rash consistent with a drug eruption or contact dermatitis. Id. Petitioner did not have any relief of her rash and itching after taking Benadryl. Id. at 1562. Her white blood count was a bit low at 3.5. Id. She was prescribed a Medrol Dosepak and told to continue Benadryl. Id. She was given an intramuscular injection of Solu-Medrol and told to stop taking Tegretol. Id. Dr. Kowalak's opinion was petitioner was probably having a drug reaction. Id. Notes from the emergency department state petitioner gave a history of starting Tegretol three weeks earlier and she started having side effects of headaches and increased sleeping. Id. at 1568. Petitioner's mother had obstructive sleep apnea and her father had bipolar disorder. Id. at 1580. Petitioner was five foot three inches tall and weighed 187 pounds. Id. at 1569.

On April 24, 2011, petitioner was diagnosed with a drug allergy to Tegretol. Id. at 1581.

Also on April 24, 2011, petitioner went to Kaleida Health Emergency Department and told Dr. Kristin D. Krueger she was allergic to penicillin and Tegretol. Id. at 1608. She complained of a rash. Id. Her mental health doctor changed her prescription to Geodon. Id. Petitioner was unsure if she was reacting to the Medrol Dosepak or to Geodon. Id. She said she had generalized body aches, abdominal pain, nausea, vomiting, and a low-grade fever that morning of 100.3 degrees, but no diarrhea. Id. However her last bowel movement was a few days previously. Id. She had no chest pain or shortness of breath, but felt her abdomen was bloated. Id. Her past medical history included obstructive sleep apnea, bipolar disorder, and anxiety. Id. She had weakness, fever, and fatigue, but denied headache. Id. She was positive for abdominal pain, bloating, nausea, and vomiting. Id.

On July 25, 2011, petitioner went back to Kaleida Health Emergency Department and complained of having a headache starting in March 2011. Id. at 1682. She also had generalized malaise and vomiting, and was initially thought to have lymphoma but was ultimately diagnosed with some unknown syndrome. Id. Dr. Michael J. Mineo wrote that petitioner had intermittent headaches since then which occurred several times a week and she felt foggy. Id. She denied a rash. Id. at 1683. On physical examination, petitioner did not cooperate. Id. Initially, she had zero out of five strength in her wrists. Id. Her examination abruptly changed and she had full normal strength in her wrists. Id. Her psychiatric mood was labile. Id. One moment, petitioner would be laughing and, the next moment, she would be angry and cursing. Id.

On October 28, 2011, petitioner underwent a brain MRI, which was normal. Med. recs. Ex. 7, at 161. She took an EEG from November 3 to 5, 2011, which was also normal. Id. at 162.

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 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 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 her April 12, 2011 Gardasil, she would not have had significant aggravation of her pre-existing hidradenitis suppurative lymphadenopathy and headaches, but also that her April 12, 2011 vaccination was a substantial factor in causing her purported significant aggravation. 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). In the instant action, none of petitioner’s medical records substantiate petitioner’s allegation that she had significant aggravation of her pre-existing complaints or that her alleged vaccine reaction lasted more than six months. Her expert Dr. Axelrod says her vaccine reaction lasted 23 days and he does not offer an opinion about significant aggravation. Given a chance to submit a supplemental expert report, Dr. Axelrod declined to do so.

The undersigned **GRANTS** petitioner’s Motion for a Decision Dismissing Her Petition and dismisses this case for petitioner’s failure to prove by a preponderance of the evidence the matters required in the petition and amended petition. 42 U.S.C. § 300aa-13(a)(1).

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: October 14, 2015

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

² Pursuant to Vaccine Rule 11(b), entry of judgment can be expedited by each party, either jointly or separately, filing a notice renouncing the right to seek review.