In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 12, 2015

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ELISSA CASCIO,	*	
	*	No. 14-107V
	*	
Petitioner,	*	Special Master Dorsey
	*	
v.	*	Dismissal; Pneumococcal
	*	Polysaccharide Vaccine;
SECRETARY OF HEALTH	*	Pneumovax; Vaccine Not
AND HUMAN SERVICES,	*	Covered; Failure to State a
	*	Claim for which Relief may be
Respondent.	*	Granted
	*	
* * * * * * * * * * * * * * * * * * *	*	

Rhett Gordon Lunceford, Smart, Schofield, et al., Murray, UT, for petitioner.
Gordon Elliot Shemin, U.S. Department of Justice, Washington, D.C., for respondent.

DISMISSAL DECISION[1]

I. Introduction

On February 6, 2014, Elissa Cascio ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program (the "Vaccine Act").[2] Ms. Cascio alleged that as a result of receiving two pneumococcal conjugate vaccines on February 9, 2011, she suffered from diabetes mellitus, chronic kidney disease, and serum sickness. Petition at 1-2. Because petitioner has been unable to provide preponderant evidence that she received a vaccine covered by the Vaccine Act, her petition is dismissed.

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-1 to -34 (2006) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

II. Factual Background

a. Medical Records

Ms. Cascio was born on June 27, 1958, and was 52 years old at the time she received the vaccination at issue in this case. In her petition, Ms. Cascio alleged that she received two (2) pneumococcal vaccinations on February 9, 2011. Petition ("Pet.") at 1. The medical records from this February 9, 2011 visit note that petitioner received "0.5 ml pneumococcal vaccine" in her left deltoid. See Medical Records from Salt Lake City VA Hospital at 244.[3] The record specifically states:

> Pneumococcal Vaccine:
> Patient received 0.5 ml pneumococcal vaccine at this encounter.
> Series: Complete
> Reaction: None
> Manufacturer and lot number: Merek & Co lot 1296Z exp 20 April 2012
>
> - IM in left deltoid
> Vaccine Information Statement for pneumococcal(4/16/10)reviewed,
> given to pt/SO and they had opportunity to ask questions: Yes
> Level of Understanding: Good
>
> /es/ NORMA RAE CUTTER, LPN
> LICENSED PRACTICAL NURSE
> Signed: 02/09/2011 09:18

Id. There is no reference on this visit note that two pneumococcal vaccines were given – only one.

On February 10, 2011, petitioner spoke with a nurse at the office of her primary care physician and reported that she had a localized reaction to the pneumococcal vaccine she received the day prior. The medical record states:

> Patient calling this RN to report a localized reaction to the pneumococcal vaccine. The patient describes 'My arm is swollen as big as a tennis ball and is black and blue where the shot went in' . . . . No other s/s of allergic type reaction at this time. This RN recommended that the patient come to the ED now for evaluation. The patient and her husband both declined stating 'we have to take two buses and it takes us two hours' . . . . Husband and patient report she is feeling a bit better since[] the onset of symptoms last night at 2300. Site is not currently red, is not inflamed and is not warm to the touch.

Id. at 232. Petitioner was advised to go to the emergency room ("ER") if

[3] Petitioner did not assign an exhibit numbers to the records that were filed on compact disc on August 11, 2014. The records were filed in two sets, designated by the Notice of Filing filed on August 5, 2014, as (1) Medical Records from Salt Lake City VA Hospital, and (2) Medical Records from St. George VA Community Based Outreach Clinic. The records will be cited accordingly.

symptoms of redness, inflammation or if the area around the shot became warm to the touch. Id.

Two days later, on February 11, 2011, petitioner presented to the ER at Salt Lake City Hospital with a chief complaint of an allergic reaction to "pneumonia vaccine," low blood pressure, a migraine, and an erythematous, circular patch on her left deltoid. See Medical Records from Salt Lake City VA Hospital at 169. The history of present illness states:

> [a] 52-year-old white female who had a pneumonia shot in the left deltoid 48 hours ago. Since then she has developed a migraine headache for 2 days. Her pulse has been high. She has had a low grade fever. She is quite distraught. . . . They felt a nodule under the skin where injection was done and today it has become red around the area . . . .
>
> Id.

Petitioner was assessed with an acute localized allergic reaction, acute migraine headache, and tachycardia. She treated with an IV, Benadryl, Bactrim, and discharged. She was told to return to the ER in two days for follow-up. Id. at 169-70.

On February 13, 2011, petitioner returned to the ER for the follow-up visit. The attending physician noted that petitioner had an allergic reaction to "a pneumococcal pneumonia shot in her left deltoid." See Medical Records from Salt Lake City VA Hospital at 163. The examination of her left arm showed "an area over the deltoid that has about a 3cm area of induration underneath this." Id. Petitioner was assessed with a local allergic reaction to an injection of pneumococcal vaccine. Id. The attending physician also noted that petitioner did not appear systemically ill, but recommended that she return in 48 hours for another follow-up visit. Id. at 164.

An addendum to petitioner's medical records dated February 14, 2011, states that petitioner reported that she was allergic to Latex and she felt this was the cause of her allergic reaction to the vaccine. See Medical Records from Salt Lake City VA Hospital at 232-33. It was noted that:

> [p]atient verbalizes frustration with the Blue Clinic staff in receiving this vaccine on Wednesday 9 February and reports she was not asked if she was allergic to any medications. Patient reports she was given the vaccine education sheet to review. Patient is going to return to the ED tomorrow for follow-up evaluation.
>
> Id. at 233.

Petitioner returned to the ER on February 15, 2011, for her follow-up visit. See Medical Records from Salt Lake City VA Hospital at 157. On observation, petitioner's left deltoid was slightly warm, tender, and indurated to "about 5 x 5 cm." Id. The attending physician noted that he did not feel that petitioner had an abscess or infection, but recommended that she continue her course of antibiotics. He noted that petitioner "looks to be doing well and is improving per

history and by examination." Id. at 158.

Three days later, on February 18, 2011, petitioner's husband called the ER's nurse telephone line to report that petitioner had a "golf ball size" area of swelling on her arm where she received the pneumococcal vaccine. See Medical Records from Salt Lake City VA Hospital at 155. On February 28, 2011, petitioner again presented to the ER with a chief complaint of "a lump the size of a ping pong ball in the left upper arm area. [Patient states] it is a reaction to her PNA shot she received 3 weeks ago." See Medical Records from Salt Lake City VA Hospital at 149. She was referred to the walk-in clinic for physical therapy treatment on her left deltoid. Id. at 144. Petitioner's medical records indicate that she had a continual reaction to the pneumococcal vaccine until April 2011. See Primary Care Preventive Maintenance Medical Records at 81.

b. Affidavit

In her affidavit, Ms. Cascio stated that she "had a pneumococcal conjugate vaccine given to [her] on February 9, 2011 at the VA Hospital in Salt lake City, Utah." Petitioner's Exhibit 1 at 1. She stated that after receiving the vaccine, she developed a migraine headache and low blood pressure. Ms. Cascio reported to the ER on February 11, 2011, because her left arm was "swollen up and became inflamed and red" at the injection site. Id. Ms. Cascio stated that to this day, her arm continues to have "a little, hard ball in it." Id. She further stated that "since the time of the vaccination," she has experienced concerns with diabetes, chronic kidney disease and serum sickness. Id. She also continues to experience flu-like symptoms that cause her to be "nonfunctional three (3) to four (4) times a week. Id. at 2. There is no reference by Ms. Cascio to two pneumococcal vaccines in her affidavit.

III. Procedural Background

The petition was filed on February 6, 2014. Medical records and a statement of completion were filed on March 11, 2014, but the records did not include a record of vaccination. Petitioner was granted additional time to request and file additional medical records and information to clarify the type of vaccination petitioner received on February 9, 2011.

Petitioner filed additional medical records on August 11, 2014. A status conference was held on January 6, 2015, to address the status of the medical record collection and to investigate whether the vaccine petitioner received was covered by the Vaccine Act. Respondent identified the medical record which documented the pneumococcal vaccine administered to petitioner, including the manufacturer and lot number of the vaccine. See Medical Records from Salt Lake City VA Hospital at 250. The undersigned requested that respondent further investigate and verify the vaccine petitioner received based on the lot number and manufacturer information, and to file a status report regarding her investigation. See Order filed Jan. 7, 2015, ECF No. 20.

On February 5, 2015, respondent filed a status report reporting the outcome of her investigation with the medical personnel at the Division of Vaccine Injury Compensation Programs (DVIC). Respondent confirmed that the vaccine petitioner received was, in fact, a

vaccine manufactured by Merck. Further, respondent verified that the only pneumococcal vaccination manufactured by Merck is the Pneumovax 23 vaccine, the adult pneumococcal vaccine, which is a vaccine not covered by the Vaccine Act. See Respondent's Status Report filed Feb. 5, 2015, ECF No. 21.

An Order to Show Cause was issued on February 23, 2015, ordering petitioner to provide evidence that she received a vaccine covered by the Vaccine Act or her petition would be dismissed. See Order to Show Cause issued Feb. 23, 2015, ECF No. 22. Petitioner filed several motions for enlargement which granted her six months of additional time to provide evidence disputing the medical records and respondent's investigation. Petitioner failed, however, to provide any refuting evidence.

IV. Applicable Legal Standards

The Vaccine Act provides that, in order to be eligible to file a petition, the vaccinee must have "received a vaccine set forth in the Vaccine Injury Table." Section 11(c)(1)(A). Cases concerning vaccines not included in the Vaccine Injury Table result in dismissals. See, e.g. Charette v. Sec'y of Health & Human Servs., No. 94-492V, 33 Fed. Cl. 488 (1995) (typhoid vaccine); Schmidt v. Sec'y of Health & Human Servs., No. 11-401V, 2011 WL 6148590 (Fed. Cl. Spec. Mstr. Nov. 21, 2011) (Pneumovax 23); Nilsen v. Sec'y of Health & Human Servs., No. 10-110V, 2010 WL 1753471 (Fed. Cl. Spec. Mstr. Apr. 6, 2010) (shingles vaccine); Silet v. Sec'y of Health & Human Servs., No. 04-1332V, 2004 WL 2677195 (Fed. Cl. Nov. 2, 2004) (hepatitis A vaccine not on Vaccine Injury Table at that time).

When medical records and affidavits contain discrepancies or contradictions, the "[m]edical records, in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Human Servs., 993 F.2d at 1525, 1526 (Fed. Cir. 1993). In the face of conflicting oral testimony and contemporaneous medical records, special masters may give greater weight to contemporaneous medical records. Id. Contemporaneous medical records are presumed to be accurate. Id. at 1528.

V. Discussion

There are two types of pneumococcal vaccines– a pneumococcal conjugate and a polysaccharide-vaccine. The pneumococcal conjugate vaccine is recommended for children and is expressly covered under Category XII of the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XII) (2011); see also 66 Fed. Reg. 28, 166 (May 22, 2001) ("Through this notice, pneumococcal conjugate vaccines are now included as covered vaccines . . . [on] the Table. The CDC only recommends pneumococcal conjugate vaccines to the Secretary for routine administration to children. Polysaccharide-type pneumococcal vaccines are not covered under the [Vaccine Act] or included on the Table."). Pneumovax 23 is a polysaccharide-type vaccine, and it is not on the Vaccine Injury Table. 42 C.F.R. § 100.3(a). See e.g., Amin v. Sec'y of Health & Human Servs., No. 13-300V, 2013 WL 3994322, at *2 (Fed. Cl. Spec. Mstr. July 29, 2013); Bundy v. Sec'y of Health & Human Servs., No. 12-769V, 2014 WL 348852, at *1-2 (Fed. Cl. Spec. Mstr. Jan. 8, 2014); Finley v. Sec'y of Health & Human Servs., No. 04-874V, 2004 WL 2059490 (Fed. Cl. Spec. Mstr. Aug. 24, 2004); see also National Vaccine Injury Compensation Program: Addition

of Pneumococcal Conjugate Vaccines to the Vaccine Injury Table, 66 Fed. Reg. 28, 166 (May 22, 2001).

To be entitled to compensation under the Vaccine Act, it is petitioner's burden to provide evidence to demonstrate that she "received a vaccine set forth in the Vaccine Injury Table." See 42 U.S.C. § 300aa-11(c)(1)(A). If it is determined that petitioner received only the Pneumovax 23 vaccine, her petition must be dismissed.

The petition alleges that Ms. Cascio received two pneumococcal conjugate vaccines on February 9, 2011. In her affidavit, however, Ms. Cascio repeatedly refers to the vaccine in singular form. For example, Ms. Cascio states that she received "a pneumococcal conjugate vaccine…. on February 9, 2011." In fact, Ms. Cascio's entire affidavit refers to the pneumococcal vaccine in the singular, evidence that she received just one vaccination.

In addition, all of the references to the pneumococcal vaccine in petitioner's medical records refer to the February 9, 2011 pneumococcal vaccine in singular form, showing that petitioner received only one vaccination. The record is replete with references to the pneumococcal vaccine in the singular form. There is no statement in any of the medical records which shows that petitioner received two pneumococcal vaccines on February 9, 2011. The only record that could possibly be interpreted to indicate that petitioner received two pneumococcal vaccinations on February 9, 2011, is petitioner's exhibit 2, pages 1-2, which contains a list of medications. The list contains separate entries for PNEUMO-VAC and PNEU-ADULT immunizations. Petitioner's Exhibit 2 at 1-2. But these entries do not contain the name of the manufacturer, the lot number, or the signature of the health care provider who administered the vaccine. The specific medical record that documents the vaccination lists the name of the nurse who administered the vaccine, Norma Rae Cutter, LPN, the type of vaccine administered, manufacturer and lot number, site of the administration, and the patient's level of understanding. See Medical Records from Salt Lake City VA Hospital at 244. This contemporaneous medical record documented by the licensed nurse, who administered the vaccine, is the best evidence of what occurred, and therefore, is given the most weight.

Moreover, the CDC guidelines show that it is more likely that Ms. Cascio received the pneumococcal polysaccharide-type vaccine. The CDC[4] recommends that the pneumococcal conjugate vaccine (PCV13) be given to all children younger than 5 years old, all adults 65 years or older, and people with certain risk factors. People ages 2 through 64 years old who are high risk of pneumococcal disease are recommended to receive the PV23 vaccine.[5] The CDC also states that PV23 is not be given with the PCV13, i.e., it is not recommended that a person receive both vaccines. Under the CDC guidelines, Ms. Cascio at 52 years of age, would have received PV23, the adult pneumococcal vaccine. It is highly unlikely that a licensed nurse would have ignored the CDC guidelines and administered both the child and adult pneumococcal vaccines to Ms. Cascio, especially when the nurse carefully documented the vaccine she administered, including the date, time and location of the injection. See Medical Records from Salt Lake City VA Hospital at 244.

[4] http://www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm#recommendations
[5] http://www.cdc.gov/vaccines/vpd-vac/pneumo/vacc-in-short.htm

In response to the Order to Show Cause that was issued on June 4, 2015, petitioner did not file any evidence, but instead requested that an investigation take place to determine which vaccine she received. The undersigned and respondent have already investigated this issue and resolved it. Further, the undersigned has afforded petitioner nearly a year and a half to investigate the circumstances surrounding her February 9, 2011 vaccination and to provide proof. Petitioner failed to provide any evidence. For all of these reasons, the undersigned finds that the vaccine received by Ms. Cascio February 9, 2011, was the adult pneumococcal 23 vaccine which is not covered under the Vaccine Act.

As stated above, an Order to Show Cause was issued affording petitioner a final opportunity to present evidence that she received a vaccine covered by the Vaccine Act was issued on June 4, 2015. Petitioner filed a response simply restating the information in her petition without providing additional evidence, and thus, petitioner has failed to provide preponderant evidence that she received a vaccine covered by the Vaccine Act. It is petitioner's burden to provide evidence to demonstrate that she "received a vaccine set forth in the Vaccine Injury Table," see 42 U.S.C. § 300aa-11(c)(1)(A). Thus, the undersigned must dismiss the petition.

VI. Conclusion

Because petitioner did not receive a vaccine covered under the Act, petitioner has failed to state a claim for which relief may be granted. Therefore, the undersigned must dismiss this petition. The petition is **DISMISSED**.

IT IS SO ORDERED.

s/Nora B. Dorsey
Nora B. Dorsey
Special Master