In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-437V
Filed: October 30, 2017
Not to be Published.

MARY BRODIE,	*	
	*	
Petitioner,	*	
	*	PPV/13 vaccine; myocardial infarction;
v.	*	stent insertion; no proof of causation;
	*	petitioner cannot find an expert; dismiss
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Renée J. Gentry, Washington, DC, for petitioner.
Claudia B. Gangi, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On March 27, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that Prevnar ("PPV/13") vaccine administered June 1, 2015 caused her myocardial infarction ("STEMI"). Pet. at ¶¶ 6 and 7.

Petitioner has eight risk factors for a clot in her right coronary artery:

1. age (she was 80 years old when she received PPV/13)
2. Type 2 diabetes
3. hypertension

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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

4. history of smoking (she stopped smoking in 1986)
5. hyperlipidemia (untreated as she refuses to take statins)[2]
6. brain mass, aneurysm
7. obesity
8. family history (her mother died from a stroke)

On July 23, 2015, petitioner filed a VAERS report[3] of her alleged vaccine reaction which she had filled out, asserting that onset was the same day as the vaccination, i.e., June 1, 2015. Med. recs. Ex. 1, at 1, 3. Petitioner complained that she immediately had intense pain spread in her arm. Id. at 3.

On May 31, 2017, the undersigned held a telephonic status conference with counsel, during which petitioner's counsel stated petitioner would try to find an expert in support of her allegations. The undersigned issued an Order that same day giving petitioner four months until September 29, 2017 to find an expert in support of her allegations or to file a motion or stipulation to dismiss.

On October 2, 2017, after the deadline for filing, petitioner moved for an enlargement of time until Monday, October 23, 2017 to file an expert report. The undersigned issued an Order that same day granting petitioner's motion for an extension of time until October 23, 2017 to file an expert report. That makes a total of five months of searching for an expert.

On October 23, 2017, instead of filing an expert report or moving to dismiss, petitioner's student attorney sent an e-mail to the undersigned's law clerk and to respondent's counsel stating, "We will not be filing an expert report today in the Brodie case (17-43V) because we will be filing a motion to dismiss after we receive the signed authorization from our client later in the week. Does the Respondent's counsel have any objection?" Matthew Chenoweth signed the e-mail. Respondent's counsel sent an e-mail to Mr. Chenoweth, with a cc: to the undersigned's law clerk, stating she had no objection.

On October 30, 2017, petitioner filed a Motion for Decision Dismissing Her Petition. She states that "she will be unable to prove that she is entitled to compensation in the Vaccine Program" and that "to proceed any further would be unreasonable. . . ." Pet'r's Mot. at 1. Furthermore, she states that to proceed any further would waste the resources of the court,

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[2] "Elevated levels of blood lipids are well documented risk factors for cardiovascular disease. Statins are the preferred class of drugs to lower elevated low density lipoprotein cholesterol (LDL-C)." R.H. Nelson, Hyperlipidemia as a Risk Factor for Cardiovascular Disease, 40 Prim Care 1:195-211, 195 (2013), published online at doi:10.1016/j.pop.2012.11.003; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3572442/ (last visited: May 16, 2017).

[3] VAERS is a passive reporting system. Anyone may file a VAERS report. Decisions have rejected attempts to prove causation based on VAERS reports. LaLonde v. Sec'y of HHS, No. 06-435V, 110 Fed. Cl. 184 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014); Analla v. Sec'y of HHS, 70 Fed. Cl. 552 (2006); Manville v. Sec'y of HHS, 63 Fed. Cl. 482 (2004); Williams-O'Banion v. Sec'y of HHS, No. 08-743V, 2014 WL 4050175 (Fed. Cl. Spec. Mstr. July 25, 2014).

respondent, and the Vaccine Program. Id.

The undersigned **GRANTS** petitioner's Motion for Decision Dismissing Her Petitioner and **DISMISSES** this case.

FACTS

Medical Records

Prevaccination

Petitioner has a prevaccinal history of anxiety. Med. recs. Ex. 2, at 24. On her visit June 1, 2015 to her personal care physician Dr. Alvin F. Young, she weighed 150.25 pounds and was 5'3" tall. Her blood pressure was 130/74. Id. at 25.

Postvaccination

On June 1, 2015, petitioner received Prevnar vaccine. Med. recs. Ex. 2, at 26.

On June 20, 2015, at 3:40 a.m., nineteen days after receiving Prevnar vaccine, petitioner was in the Emergency Department of ARMC-Athens Regional Medical Center. Med. recs. Ex. 3, at 54. She told Dr. Colin M. McKinney that she had a sudden onset of chest pain at midnight that night with associated diaphoresis, general malaise, and nausea. She reported feeling generally unwell for a couple of weeks after a Pneumovax shot. However, all of her symptoms got significantly worse that day. Id. Dr. McKinney diagnosed petitioner with STEMI (myocardial infarction). Id. at 55.

On June 22, 2015, Dr. Jared Griffis, a cardiologist, did a cardiac catheterization which showed a 99% thrombotic occlusion of the right coronary artery (culprit stenosis). Id. at 15. He inserted a bare metal stent. Petitioner tolerated the procedure well. She was ambulating without difficulty and did not have recurrent chest pain. Dr. Griffis tried to explain to petitioner that she needed to cut back her activity for at least a week or two. Petitioner was somewhat argumentative about that. She told Dr. Griffis she hates stents. Id.

The coronary angiography showed significant findings besides the focal thrombotic 99% stenosis in the distal vessel of the right coronary artery. Petitioner's left anterior descending artery was relatively small and was diffusely diseased up to 30%. Petitioner had diffuse 60% disease in the apical portion, which was very small. Her left circumflex coronary artery was small and diffusely diseased up to 40%. Her right coronary artery had diffuse wall irregularities in the proximal and mid segments up to 30%. Id. In other words, in addition to the 99% blockage of petitioner's right coronary artery, the remainder of the same artery was abnormal and her left artery was also abnormal with varying degrees of disease. Does petitioner believe that PPV/13 affected both her left and right coronary arteries, causing blockage in both? Does petitioner believe that a vaccine can cause blockage in both coronary arteries in 19 days?

On June 30, 2015, petitioner saw Dr. Griffis as an outpatient. Med. recs. Ex. 4, at 5. Dr. Griffis notes that petitioner "still insists that she had a heart attack because of her pneumonia shot." Id. It does not sound as if Dr. Griffis, her cardiologist, agrees with her. He further notes that petitioner continued to talk about issues she had had with medications in the past. She described having an allergy to ACE inhibitors (blood pressure medicine) and statins (to treat hyperlipidemia). She refused to restart either of them. She said she had an aspirin allergy but she had no recent issues with aspirin. (The EMTS gave her aspirin in the ambulance to the hospital.) She weighed 143 pounds. Her blood pressure initially measured 144/100. On recheck, it was 138/86. Petitioner was not interested in going to cardiac rehab. She was adamant about not doing cardiac rehab. Id.

On July 30, 2015, petitioner returned to Dr. Griffis. Id. at 4. He notes petitioner tolerated the insertion of the stent well. She had minimal damages. She was doing well and had no complaints. Because she refused statins but had hyperlipidemia, Dr. Griffis suggested she have dietary intervention to treat her hyperlipidemia. Id.

On December 4, 2015, petitioner saw Dr. Young, her personal care physician. Med. recs. Ex. 2, at 21. Petitioner told him she had a reaction following the flu shot in 2014, consisting of fever, a sore arm, and fatigue. She did not want another flu shot in 2015. Id. Overall, petitioner was doing well. Id. at 23.

Presumably to prove causation, petitioner filed the PREVNAR 13 Vaccine package insert as Exhibit 10. Nothing in this package provides proof of petitioner's allegations. On page 15 are references to serious adverse events during adult clinical studies, but they do not prove that Prevnar caused these serious adverse events. One person died due to cardiac failure three days after receiving placebo. A placebo[4] is not the vaccine. However, this person received Prevnar 13 and trivalent flu vaccine one month earlier. If one month is the appropriate temporal interval for Prevnar 13 and trivalent flu vaccine to cause cardiac failure, then petitioner's interval of 19 days is too short plus she did not receive trivalent flu vaccine.

In addition, the package insert notes that more than 30 days after receiving Prevnar 13, four people in the adult clinical studies died from cardiac disorders. This temporal interval is also too long compared to petitioner's 19-day interval. The point is that the package insert records serious adverse events. It does not provide any proof of causation from the vaccine. Mere temporal association is not sufficient to prove causation in fact. Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

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

[4] A placebo is "any dummy medical treatment." Dorland's Illustrated Medical Dictionary 1452 (32nd ed. 2012).

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 the Prevnar vaccination, she would not have had myocardial infarction, but also that Prevnar vaccine was a substantial factor in causing her TTP. 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 petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. The medical records do not support petitioner's allegations. She has not filed a cardiologist's expert opinion in support of her allegations.

Petitioner moves for a dismissal of her petition.

The undersigned **GRANTS** petitioner's 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.[5]

IT IS SO ORDERED.

Dated: October 30, 2017

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

[5] 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.