

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1221V

Filed: November 15, 2018

Not to be Published.

MARLO MAYLE,

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Petitioner,

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v.

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Influenza (“flu”) vaccine; right
sensorineural hearing loss; no
expert report; motion for ruling
on the record

SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Kevin A. Mack, Tiffin, OH, for petitioner.

Robert P. Coleman, III, Washington, DC, for respondent.

MILLMAN, Special Master

DISMISSAL DECISION¹

On September 8, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that an influenza (“flu”) vaccination she received on November 16, 2014 caused her right sensorineural hearing loss. Pet. Preamble.

Petitioner filed her medical records and affidavit, but not an expert report in support of her allegations.

On July 18, 2018, respondent filed his Rule 4(c) Report recommending against

¹ Because this unpublished decision contains a reasoned explanation for the special master’s action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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

entitlement. Respondent noted that petitioner's treating doctors did not support her allegations, although they noted anecdotal reports of hearing loss after flu vaccination. Resp't Rep. at 8. He also noted that petitioner has a history of mitral valve prolapse with mitral leaflet thickening and mitral regurgitation, which has been associated with sudden sensorineural hearing loss. Id.

On November 15, 2018, petitioner filed a status report stating, "After an extensive search, [p]etitioner has been unable to find a credible expert and respectfully request[s] a ruling on the existing record." S.R. at 1.

This is a causation in fact case. Petitioner's medical records do not support her allegations by a preponderance of the evidence and she has failed to file a medical opinion from an expert in support of her allegations. The undersigned finds petitioner has failed to make a prima facie case and **DISMISSES** this petition.

FACTS

On November 16, 2014, petitioner received quadrivalent flu vaccine. Med. recs. Ex. 1, at 1.

On January 6, 2015, petitioner saw Dr. John J. Hiestand, an internal medicine specialist, complaining of ringing in her right ear, seven weeks of fullness in her right ear, and a little muffling of sounds, all starting after she received a flu vaccination. Med. recs. Ex. 10, at 33. She denied she had congestion, but she cleared her throat frequently. Id. On physical examination, Dr. Hiestand found petitioner had mild nasal congestion. Id. at 34. His impression was that petitioner had serous otitis media.² Dr. Hiestand wrote in his notes, "I don't think flu shot had any connection to this." Id.

On February 16, 2015, petitioner saw Dr. Ellen Baxter, a specialist in ear, nose, and throat ("ENT"). Med. recs. Ex. 3, at 4. Petitioner complained of fullness and ringing in her right ear that began the day after she received a flu shot 13 weeks earlier. Id. An audio test showed petitioner's right ear was within normal limits through 2,000 Hz but then sloped to a moderately severe sensorineural hearing loss ("SSNHL"). Id. at 6. Petitioner's cranial nerves were intact on physical examination except for cranial nerve VIII. Id. Dr. Baxter's assessment was sudden right hearing loss, unilateral sensorineural hearing loss, and tinnitus.³ Id. at 7. She wrote, "I'm unsure if her flu shot caused this as there is no diagnostic test that can prove that. [H]owever, anecdotally, I have seen this frequently in my career, post flu shot." Id.

Other Documentation

On November 25, 2017, Dr. Hiestand wrote a letter to petitioner's attorney, stating when

² Serous otitis media is "chronic otitis media marked by serous effusion into the middle ear." Dorland's Illustrated Medical Dictionary 1351 (32nd ed. 2012) (hereinafter "Dorland's"). Otitis media is inflammation of the middle ear. Id. Serous is "pertaining to or resembling serum." Id. at 1699.

³ Tinnitus is "a noise in the ears, such as ringing, buzzing, roaring, or clicking." Dorland's at 1930.

he saw petitioner on January 6, 2015, “I did not think that her symptoms were connected to the flu shot.” Med. recs. Ex. 17, at 2. He also stated, “Sensorineural hearing loss has been associated with receiving a flu shot in some patients, although this remains an area of some uncertainty and controversy. . . . A flu shot would not cause conductive hearing loss. I cannot say one way or the other about influenza vaccine causing sensorineural hearing loss, but I am aware of the reported association reported anecdotally.” Id. He stated he supports others’ recommendation that petitioner avoid flu vaccination in the future. Id.

Medical Literature

On October 11, 2018, petitioner filed as exhibit 20 a case report: Claudia Kolarov et al., Bilateral deafness two days following influenza vaccination: a case report, HUM VACCIN IMMUNOTHER (Sept. 5, 2018), <https://doi.org/10.1080.21645515.2018.1509657>. The authors state that in over 90% of SSNHL cases, the cause is idiopathic. Id. at 2 (pagination done by counsel). However, inflammation of the eighth cranial nerve can be due to local hypersensitivity response and antigen-antibody reaction to various viruses and vaccines. Id. They state their case report describes the first adult patient to develop bilateral deafness after trivalent flu vaccination. The patient was 79 years old. Id. at 1. They review some other case reports of deafness after various vaccinations and state thimerosal might elevate intracellular calcium because it does that in guinea pigs. Id. at 5. But then the authors confess this is speculation since “the concentration of thimerosal in the vaccine is very low (0.05 mg), this effect is very unlikely.” Id. The authors admit that the subject of this case report might have had an undetected infection or disease, or her bilateral deafness “speculatively may be related to influenza vaccination.” Id.

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 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 flu vaccine, she would not have right sensorineural hearing loss, but also that flu vaccine was a substantial factor in causing her right sensorineural hearing loss. 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. Her treating doctors, Dr. Ellen Baxter, an ENT, and Dr. Hiestand, an internal medicine specialist, entertain doubts as to any causal connection between petitioner’s flu vaccination and her right sensorineural hearing loss although they are aware of anecdotal reports of a connection. This speculation does not satisfy the Althen criteria any more than does the case report in which Kolarov et al. speculates about a causal connection (Ex. 20). Petitioner has not filed a medical expert opinion in support of her allegations although she has done an extensive search for an expert.

The undersigned **DISMISSES** this petition for failure to make a prima facie case of causation of fact.

CONCLUSION

This case is now **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.⁴

IT IS SO ORDERED.

Dated: November 15, 2018

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

⁴ 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.