

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 13-275V

October 28, 2014

Not to be Published

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JUNG PARK, M.D.,

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Petitioner,

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v.

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Influenza (flu) vaccine; onset of unilateral sensorineural hearing loss two to three hours later; no expert in support of allegations; motion for ruling on the record; dismissal

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SECRETARY OF HEALTH  
AND HUMAN SERVICES,

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Respondent.

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Danielle A. Strait, Washington, DC, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

**MILLMAN, Special Master**

### DECISION<sup>1</sup>

On April 19, 2013, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that influenza (“flu”) vaccine administered on September 27, 2011, caused sensorineural hearing loss (“SNHL”) in his right ear within two or three hours of vaccination.

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<sup>1</sup> 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’s 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.

On September 13, 2013, the undersigned issued an Order setting a deadline of December 11, 2013 for petitioner to file an expert report in support of his allegations.

Petitioner made several motions for enlargement of time, which were granted. On May 27, 2014, the undersigned granted petitioner's fourth motion for enlargement of time, giving petitioner a deadline of July 28, 2014 to file an expert report.

On July 21, 2014, petitioner moved for an extension of time until September 26, 2014 to file an expert report. The undersigned held a telephonic status conference on July 22, 2014, during which petitioner's counsel mentioned that a neuro-otologist had not responded to her about the case, and her client would like to seek other counsel but did not have another attorney yet. Petitioner's counsel stated that her client did not give her authority to make a settlement demand.

On October 8, 2014, petitioner made a motion for a decision on the record. On that same date, petitioner filed a case report marked as Exhibit 9, consisting of a report of a case of sudden deafness in a young girl following H<sub>1</sub>N<sub>1</sub> vaccine.

On October 9, 2014, the undersigned held a telephonic status conference, during which petitioner's counsel stated her client would not settle his case and wanted to preserve his right to sue civilly.

On October 28, 2014, respondent filed her Rule 4(c) Report in response to petitioner's motion for a decision on the record. The undersigned's law clerk contacted petitioner's counsel, who stated that petitioner did not wish to file a reply.

The undersigned **GRANTS** petitioner's motion for a decision on the record and **DISMISSES** this case for failure to prove the allegations in his petition by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A).

## FACTS

Petitioner was born on January 15, 1950. Med. recs. Ex. 3, at 5.

On September 27, 2011, when he was 61 years old, he received flu vaccine. Med. recs. Ex. 1, at 1.

Also on September 27, 2011, petitioner saw Dr. Howard Stupak, an ear-nose-throat specialist, complaining of right sudden hearing loss that morning. Med. recs. Ex. 2, at 2. Dr. Stupak diagnosed petitioner with unilateral sensorineural hearing loss and tinnitus. Id. at 4.

## CASE REPORT

Petitioner filed Exhibit 9, a case report, as the only evidence in support of his allegations. Hsueh-Hsin Huang, M.D., et al., Bilateral sudden deafness following H1N1 vaccination, 143 Otolaryngology–Head and Neck Surgery 849 (2010). The authors state that acute loss of function of the cochleovestibular<sup>2</sup> nerve is a multifactorial disease. Id. at 849. The most common causes are vascular and viral agents, Ménière’s<sup>3</sup> disease, or neoplasm. Id. H<sub>1</sub>N<sub>1</sub> vaccine, used against influenza A, is newly developed and possibly associated with some neurological complications. Id. They discuss the case of a 17-year-old girl in Taiwan who developed sudden deafness in both her ears 14 hours after H<sub>1</sub>N<sub>1</sub> vaccination. Id. She also developed mild dizziness, nausea, and bilateral tinnitus. Id. She had moderate hearing impairment of 55 decibels in both ears. Id. The patient received corticosteroid, dextran, and vitamin B complex. Id. After six days of therapy, her hearing ability improved. Id. After one month, she had a hearing threshold of 30 decibels in both ears. Id. Since bilateral sudden hearing loss is a rare event clinically, the authors speculate that there might be a causal connection between the H<sub>1</sub>N<sub>1</sub> vaccination and the girl’s sudden hearing loss, but they admit that the mechanism of how this could occur from H<sub>1</sub>N<sub>1</sub> vaccine is unknown. Id. at 850. They propose a theory that this killed virus vaccine induced a latent autoimmune disease in the girl. Id. Since H<sub>1</sub>N<sub>1</sub> is, in the authors’ phrasing, a “novel” vaccine, and there have not been any other reports of vaccine-induced sudden hearing loss, the relationship between vaccine agents and neurological defects “has not yet been clearly established.” Id. They rely on the sequence of events in this case to attribute the young girl’s bilateral hearing loss and dizziness to labyrinthitis,<sup>4</sup> which the simultaneous occurrence of cochleovestibular symptoms corroborates. Id. They conclude the young girl may have had an adverse reaction to H<sub>1</sub>N<sub>1</sub> vaccine. Id.

## DISCUSSION

To satisfy his 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):

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<sup>2</sup> Cochleovestibular refers “to the cochlea and vestibule of the ear.” Dorland’s Illustrated Medical Dictionary 379 (32d ed. 2012).

<sup>3</sup> Ménière’s disease involves “hearing loss, tinnitus, and vertigo resulting from nonsuppurative disease of the labyrinth with edema.” Dorland’s, supra, at 539.

<sup>4</sup> Labyrinthitis is “inflammation of the internal ear; it may be accompanied by hearing loss or vertigo.” Dorland’s, supra, at 995.

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Althen, 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 influenza vaccination, he would not have sensorineural hearing loss in his right ear, but also that the vaccine was a substantial factor in causing his illness and, but for the vaccination, he would not have had SNHL. Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Although petitioner alleges that flu vaccination caused his SNHL, the medical records do not prove his allegation. Petitioner thus does not have medical record support for his allegation that that flu vaccine caused his unilateral SNHL. Petitioner did not file a medical expert report in support of his allegation. The Vaccine Act does not permit the undersigned to rule for petitioner based on his claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1) (2006).

All petitioner has filed purportedly in support of his allegations is Exhibit 9, a case report involving a 17-year-old girl in Taiwan who received a relatively new monovalent flu vaccine, experienced bilateral hearing loss, and recovered from her illness with corticosteroid treatment. Petitioner, a 61-year-old man, received trivalent flu vaccine, experienced unilateral hearing loss, and did not recover from his illness with corticosteroid treatment. The undersigned cannot credit this case report as fulfilling petitioner’s burden to satisfy the three prongs of Althen. The case report provides no explanation of a credible medical theory of how trivalent flu vaccine causes unilateral hearing loss (prong one), that trivalent flu vaccine caused petitioner’s unilateral hearing loss (prong two), and that a two- to three-hour onset after vaccination is a medically appropriate interval to connote causation from trivalent vaccine to unilateral hearing loss (prong three). The discussion in the case report is not sufficient to satisfy the three prongs of Althen.

Thus, petitioner has not made a prima facie case of causation.

Petitioner had a year, from September 2013 to September 2014, to find an expert to prove his case. He failed to do so. He has had “a full and fair opportunity to present” his case. Vaccine Rule 3(b)(2).

The undersigned **GRANTS** petitioner’s motion for a decision on the record and **DISMISSES** this case for petitioner’s failure to prove the allegations in his petition by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A).

**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.<sup>5</sup>

**IT IS SO ORDERED.**

October 28, 2014  
DATE

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

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<sup>5</sup> 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.