IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 06-670V
Filed: June 2, 2008

JANE DOE/16,	*	Not For Publication
Petitioner,	*	Influenza Vaccine, Sensorineural Deafness, Causation, Credibility of Expert Witnesses, Evaluation of Supporting Evidence, Timing
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Thomas Gallagher, Esq., Gallagher & Gallagher, Somerspoint, NJ, for petitioner
Ryan Pyles, Esq., U.S. Department of Justice, Washington, DC, for respondent

DECISION[1]

Vowell, Special Master:

On September 25, 2006, JANE DOE/16 ["JANE DOE/16" or "petitioner"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], alleging that an influenza vaccination she received on December 1, 2004, caused permanent hearing loss in her

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in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). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] Hereinafter, for ease of citation, all "§" references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

right ear. Petition, ¶¶ 3, 6, 9. JANE DOE/16's affidavit and various medical records[3] accompanied the petition; additional medical records were subsequently filed. After several delays, petitioner filed the report of a medical expert, Dr. Frederick Fiber, on May 21, 2007, as Petitioner's Exhibit ["Pet. Ex."] 7. On August 21, 2007, respondent filed a Vaccine Rule 4(c) report recommending that compensation be denied. The report of Dr. Thomas Willcox, filed as Respondent's Exhibit ["Res. Ex."] A, accompanied the Rule 4(c) report.

This case was originally set for a hearing on November 14, 2007, but was postponed until January 22, 2008, at the request of petitioner's counsel. JANE DOE/16 and Dr. Willcox testified in person; Dr. Fiber appeared by telephone. Post hearing briefs were received on April 4, 2008, from petitioner and April 7, 2008, from respondent. The record is now complete and the case is ripe for decision.

To be eligible for compensation under the Vaccine Act, a petitioner must either demonstrate a Vaccine Table[4] injury, to which a statutory presumption of causation attaches, or prove by a preponderance of the evidence that a vaccine listed on the Vaccine Table caused or significantly aggravated an injury. *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). JANE DOE/16 does not contend that she suffered a "Table" injury. Therefore, in order to prevail, she must demonstrate 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,* 418 F.3d at 1278. *See also*, *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

After considering the record as a whole,[5] including the testimony of petitioner and both medical experts, I find that petitioner received an influenza vaccination on December 1, 2004, that the vaccine was administered in the United States, that the influenza vaccine is a vaccine covered by the Vaccine Act, and that petitioner's condition has persisted for longer than six months. However, I hold that petitioner has failed to establish by preponderant evidence that the influenza vaccination caused her hearing loss. Therefore, I deny the petition for compensation.

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[3] The same medical test results often appear in more than one record. *See, e.g.*, brain MRI results at Petitioner's Exhibit ["Pet. Ex."] 2, pp. 31-32 and Pet. Ex. 3, pp. 6-7. In covering JANE DOE/16's medical history, citations are made to just one of the exhibits in which a particular record may appear.

[4] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

[5] *See* § 300aa–13(a): "Compensation shall be awarded...if the special master or court finds on the record as a whole..." *See also*, § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

I. Relevant Medical History.

There were no substantive disagreements between the parties concerning the facts of JANE DOE/16's vaccination, prior medical condition, medical treatment, and current diagnosis and prognosis. JANE DOE/16's testimony closely tracked the medical records; discrepancies largely concerned the dates of several visits. I find the following facts to be established by preponderant evidence.

JANE DOE/16 was born on January 5, 1938. Petitioner's Affidavit, ¶ 2. At the time she received the vaccination, she was 66 years old. Prior to the influenza vaccination, JANE DOE/16 suffered from a mild head tremor and torticollis, hypertension, hay fever, hypercholesterolemia, osteoporosis and osteopenia, and mitral valve prolapse. Pet. Ex. 3, pp. 20-31; Pet. Ex, 1, p. 2; Pet. Ex. 8, p. 14; and Pet. Ex. 16, p. 22.

JANE DOE/16 had received annual influenza vaccinations without ill effects, prior to the vaccination that is at issue in her petition. Transcript ["Tr."] at 27. The parties stipulated that JANE DOE/16 received an influenza vaccination on December 1, 2004. Joint Pre-Hearing Submission Concerning Issues in Dispute ["Joint Submission"]. Hearing testimony established that she was vaccinated at about 10:00 AM on that date. Tr. at 9. Within a few hours of receiving this vaccination, JANE DOE/16 experienced tinnitus, static, and a loss of hearing in her right ear. Joint Submission. JANE DOE/16 testified that these symptoms began at about 3:00 PM, while she was still at work. She began to experience vertigo that evening after dinner. Tr. at 10.

JANE DOE/16 went to the emergency department at Pascack Valley Hospital on the morning of December 4, 2004, three days after her influenza vaccination. Pet. Ex. 2, pp. 5-19; Tr. at 11-12. She had attempted to visit her internist over the preceding two days, but was too dizzy to make the trip. Tr. at 11. At the emergency department, she reported positional vertigo and vomiting after the vaccination (Pet. Ex. 2, pp. 7, 17), a three day history of vertigo (*id*., p. 7), and severe hearing loss in her right ear in the day after the vaccination (*id*., p. 17). The nausea and vomiting resolved in the 48 hours preceding the emergency department visit, but the hearing loss and vertigo persisted. *Id.*, p. 17. She denied any fever, chills, shortness of breath, skin rash, diarrhea, or headache. She had been taking Compazine and Bonine for the vertigo, Avapro[6] for her high blood pressure, and Fosamax[7] for her osteoporosis. Her neurological examination was normal and there were no signs of otitis media. *Id.*, pp. 17-18.

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[6] Avapro is the trade name for irbesartan, a medication used in hypertension. PHYSICIAN'S DESK REFERENCE ["PDR"] at 891-94 (61st ed. 2007).

[7] Fosomax is the trade name for alendronate sodium, used in prevention and treatment of osteoporosis. PDR at 1969-77.

Serologic testing revealed no signs of infection. She had a negative antibody test for both influenza A and B. Pet. Ex. 2, pp. 11-13. A head CT[8] revealed a subtle area of increased attenuation in the right thalamus, and could not exclude either a small focus of hemorrhage or dystrophic calcifications. *Id.*, p. 14. There was mild enlargement of the lateral third and fourth ventricles, mild cortical atrophy, and some very mild periventricular low density changes. *Id.*, p. 20.

The emergency room physician listed a number of differential diagnoses including: vertigo, labyrinthitis, neuroma, neuritis, cerebellar hemorrhage, and Meniére's disease. Pet. Ex. 2, p. 25. He recommended audiological testing and a referral to a specialist. *Id.*

On December 6, 2004, JANE DOE/16 saw Dr. John T. Nasr, a neurologist. She reported that she had developed an acute hearing loss in her right ear on the same day she received a flu shot, and had since experienced a gradually worsening sense of imbalance. Doctor Nasr noted head tremor, torticollis, and cautious tandem walking during examination of JANE DOE/16, but otherwise her neurological examination was normal. His impression was that the acute onset of JANE DOE/16's symptoms indicated either a vascular process or an infectious or inflammatory process. He noted that either an acute infarction of the inner ear or a viral infection could cause hearing loss and vertigo. He stated that the timing between the vaccination and the onset of JANE DOE/16's symptoms was too sudden for a vaccine-induced inflammatory process. He prescribed a steroid and Famvir.[9] Pet. Ex. 3, pp. 11-12.

The next day, JANE DOE/16 saw Dr. Jonathan Lesserson, an ear, nose, and throat ["ENT"] specialist. Audiological testing that day demonstrated that JANE DOE/16 had suffered a profound sensorineural hearing loss in her right ear. Pet. Ex. 1, p. 6; Pet. Ex. 4, p. 28.

JANE DOE/16 underwent a brain MRI and several MRA tests on December 13, 2004.[10] None of the studies revealed any evidence of hemorrhage or other vascular processes. Pet. Ex. 2, pp. 31-34. On December 14, 2004, another audiogram showed that her hearing loss had persisted. Pet. Ex. 1, p. 7; Pet. Ex. 4, p. 26. JANE DOE/16 also reported continuing dizziness and ambulatory difficulties. Pet. Ex. 4, p. 26.

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[8] A CT scan refers to a computed tomography scan of the brain, used to diagnose central nervous system disease, including tumors, aneurysms, and hemorrhages. It consists of a computerized analysis of x-rays of the brain. MOSBY'S LABS at 1095-96.

[9] Famvir is the trade name for famcilovir, an antiviral drug used primarily for the treatment of herpes and hepatitis B viral infections. PDR at 2211.

[10] "MRI" stands for "magnetic resonance imaging." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1178 (30th ed. 2003). "MRA" is an abbreviation for "magnetic resonance angiography." *Id.* at 1177.

JANE DOE/16 saw Dr. Nasr again on December 20, 2004. Her vertigo had improved, but the hearing loss persisted. His impression was that JANE DOE/16 had an "inflammatory process affecting the eighth [cranial] nerve." Pet. Ex. 3, pp. 8, 10.

On December 28, 2004, JANE DOE/16 saw Dr. Huang, an otolaryngologist.[11] Pet. Ex. 6, p. 43. In a letter to Dr. Lan, JANE DOE/16's primary care physician, Dr. Huang described the onset of JANE DOE/16's symptoms as a development of tinnitus and hearing loss on the afternoon of the day she received her influenza vaccination. Acute vertigo developed that evening. Upon awakening the next morning, December 2, 2004, JANE DOE/16 experienced severe vertigo with nausea and vomiting, and she felt completely deaf in her right ear. *Id*., p. 43.

Doctor Huang's examination documented mild left-sided and severe right-sided sensorineural hearing loss. He opined that she had experienced an "acute labyrinthine injury most likely secondary to the flu vaccine." He did not provide any basis for this opinion, other than JANE DOE/16's medical history. Doctor Huang noted that she had been treated appropriately with high dose steroids and Famvir, but that her hearing had not improved on that therapy. He did not believe her hearing was likely to improve. *Id.*, pp. 43-44.

JANE DOE/16 had an abnormal electronystagmography ["ENG"][12] examination on January 6, 2005, which demonstrated a right sided weakness in how her eyes, inner ears, and brain interacted to achieve balance. This weakness was consistent with "peripheral pathology." Pet. Ex. 4, p. 5. Two days prior to this testing, she called Dr. Gold's office to report that her hearing and balance had improved slightly. An audiogram supported her subjective assessment, demonstrating "definite improvement" in pure tones, and a speech recognition threshold at 70-75 decibels. This suggested to Dr. Gold that the hearing loss might be reversible, as the improvement suggested possible decrease in nerve edema. *Id*., p. 24. He recommended another course of steroids. *Id*.

On January 7, 2005, JANE DOE/16 saw another otolaryngologist, Dr. Jack Wazen. He recommended treatment by intratympanic steroid perfusion through a

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[11] During her testimony (Tr. at 18), JANE DOE/16 stated that she saw Dr. Huang on December 13, 2004, as well, but the medical records filed do not reflect a visit on that date. She did see Dr. Huang on December 13, 2005. Pet. Ex. 5, p. 2.

[12] An ENG is used to differentiate psychogenic vertigo from organic problems. It is also used to determine where the pathologic causes for vertigo originate: in the central nervous system (the cerebellum, brainstem, or eighth cranial nerve) or in peripheral areas (such as those in the vestibular-cochlear area of the inner ear). Kathleen D. Pagona & Timothy J. Pagona, MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS ["MOSBY'S LABS"](3d. ed. 2006) at 577. *See also,* DORLAND'S at 583 (diagrams reflecting the location of vestibular and cochlear areas of the inner ear).

device called the MicroWick,[13] which JANE DOE/16 began on January 10, 2005. Pet. Ex. 1, p. 2. Although she did well with the treatment, only slight hearing improvement was noted. *Id.*, pp. 4-5. Audiograms taken on February 23, 2004, and March 28, 2005, indicated that her hearing had not improved from the level measured on January 6, 2005.

By December, 2005, JANE DOE/16's balance had returned to normal and she was not experiencing any tinnitus, but her hearing loss persisted. Dr. Huang recommended against a hearing aid, noting that JANE DOE/16 was functioning well. Pet. Ex. 5, p. 2. At the hearing, JANE DOE/16 testified that she did not get a hearing aid because her insurance did not cover it. Tr. at 21.

Although she returned to work on January 18, 2005, JANE DOE/16 was unable to function at her previous level of efficiency, due to her hearing loss. She was frustrated and embarrassed because she could not keep up with the demands of her job, and elected to retire on March 31, 2005, at age 67. Tr. at 22-24.

II. Expert Opinions and Evidence on Causation.

A. Treating Physicians.

JANE DOE/16's hearing loss, vertigo, and tinnitus were evaluated by several treating physicians with different medical specialties. A neurologist, Dr. Nasr, opined that her hearing loss was the result of either a vascular or an infectious/inflammatory process. He did not believe that the hearing loss was caused by the influenza vaccine, as "[t]he symptom onset appears too acute for a vaccination-induced inflammatory process." Pet. Ex. 3, p. 12. An ENT specialist, Dr. Lesserson, attributed JANE DOE/16's profound sensorineural hearing loss to a "labyrinthine insult"[14] without opining on what caused that insult. Pet. Ex. 4, p. 28. The first otolaryngologist she saw, Dr. Huang, opined that JANE DOE/16's labyrinthine injury was "most likely secondary to the flu vaccine" but he did not provide any basis for his opinion, other than the temporal connection. Pet. Ex. 6, p. 43. The second otolaryngologist, Dr. Wazen, offered no opinion on causation, but apparently believed the injury to be inflammatory in nature, based on his steroid treatment of JANE DOE/16. Pet. Ex. 1, pp. 1-2. Dr. Gold, a medical doctor for whom no speciality is listed, felt that nerve edema, or swelling, might be the cause of the hearing loss, but offered no opinion on what caused the swelling. Pet. Ex. 4, p. 24.

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[13] MicroWick is a device for delivering medication directly to the inner ear. It involves the use of a small wick inserted through the eardrum. Ear drops are applied to the ear canal, and the wick transports them into the inner ear. Tr. at 19-20, 121-22.

[14] Labyrinthitis is an inflammation of the labyrinth area of the ear. DORLAND'S at 988 (definition)-989 (diagram).

B. Petitioner's Medical Expert.

1. Background and Qualifications.

Doctor Frederick Fiber's curriculum vitae and report were filed as Pet. Ex. 7. He graduated from medical school in Hungary, where he also did a residency in surgery and a second residency in otolaryngology. Tr. at 35-36. He completed surgical and otolaryngology residencies in the United States as well. Tr. at 36-37. After teaching for three years at the University of New Mexico School of Medicine and serving as the chief of otolaryngology for the Veteran's Administration in Albuquerque, he moved to Hawaii as a staff physician with Kaiser Permanente. Tr. at 36-37; Pet. Ex. 7, p. 2. He became a solo practitioner in ENT and head and neck surgery after returning to New Mexico in 1983. Pet. Ex. 7, p. 1; Tr. at 37. He is board certified in otolaryngology. Pet. Ex. 7, p. 2. He published two papers, both early in his medical career. *Id.*, p. 3. Two of his lectures dealt with treatment of vertigo; one in 1980 and the other in 1984. *Id*.

2. Expert Opinion, Testimony and Supporting Evidence.

The basis for Dr. Fiber's opinion on causation was not well elucidated in either his expert report or his testimony.[15] Doctor Fiber's one-page expert opinion summarized JANE DOE/16's symptoms and diagnoses following her influenza vaccination. He noted the absence of evidence for any infectious or vascular process that might have caused JANE DOE/16's injury. He succinctly opined that the flu vaccine "caused an inflammatory process to occur damaging the inner right ear resulting in a permanent hearing loss." Pet. Ex. 7, p. 9. He did not provide any further explanation and his report did not explain why he concluded an inflammatory process was present.

His testimony regarding the medical theory provided some additional details for his postulated mechanism of injury. He clarified that he did not believe the killed virus in the vaccine could directly provoke an illness. Tr. at 70. He testified that the influenza vaccine triggered an antigen reaction, which caused inflammation in a structure in the inner ear called the endolymphatic sac. This inflammation caused fluid to accumulate, which caused swelling that damaged JANE DOE/16's hearing. As the membranous

[15] Doctor Fiber testified telephonically. This presented some difficulties in that he did not have all of the exhibits available. This became especially apparent on cross examination and during my questions regarding his opinion and its basis. *See generally*, Tr. at 56-59 (Dr. Fiber having difficulty locating on cross examination an article he testified about on direct examination); Tr. at 64 (Dr. Fiber's attempt to testify about an internet search he was conducting while testifying); and Tr. at 75-76 (difficulties in questioning Dr. Fiber about references in Pet. Ex. 13). An additional problem with Dr. Fiber's testimony is that it was almost entirely presented as "yes" or "no" responses to leading questions by petitioner's counsel. While the rules of evidence do not apply to Vaccine Act proceedings and thus there is no prohibition against leading one's own witness, testimony is far more persuasive when presented by the witness rather than the attorney.

part of the labyrinth swelled, it compromised the blood supply to the inner ear. This would be an immunologic (autoimmune) reaction, triggered by the killed virus in the vaccine, causing inflammation. Tr. at 45-46; 70-71.

Doctor Fiber explained that the endolymphatic sac is a filtering structure for the inner ear that "helps clearing up the metabolic debris from the ear, after which the inner ear fluid joins brain fluid." Tr. at 44. When the fluid is not cleaned up rapidly or something obstructs that process, the fluid accumulates in the cochlea, creating hydrops. *Id.* Hydrops is an accumulation of the endolymph in the organ of Corti. This could be the result of an inflammatory or post-inflammatory process. Tr. at 44-45. Doctor Fiber acknowledged that the mechanism of injury with endolymphatic sac swelling that he described was associated with Meniere's disease,[16] and that none of the specialists who saw JANE DOE/16 diagnosed her as having Meniere's disease. Tr. at 51.

In support of Dr. Fiber's opinion on causation, petitioner filed three medical journal articles, a website printout, and a vaccine information sheet.[17] Pet. Ex. 10-14. After the hearing, petitioner filed Pet. Ex. 17, an abstract of a medical journal article. These references will be discussed, *infra*.

Doctor Fiber testified that he first became aware of a connection between hearing loss and influenza vaccines based on the reported experiences of one of his patients. He did not provide details regarding the timing between this patient's vaccinations and the patient's hearing difficulties, the results of any audiological testing, or the apparently reversible nature of the patient's hearing loss and vertigo. Tr. at 39.

He based his opinion that the influenza vaccine could cause hearing problems on Pet. Ex. 13, a document entitled "International Vaccination Newsletter." This is a document Dr. Fiber "found on the internet." Tr. at 62. The URL found in the lower left hand corner of the document indicates that it is a printout from a website found at

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[16] Meniere's disease symptoms include hearing loss, tinnitus, and vertigo, caused by labyrinthine edema. It is also known as "endolymphatic hydrops, labyrinthine hydrops, and recurrent aural vertigo." DORLAND'S at 538. According to Dr. Willcox, who has published several articles on this condition, Meniere's disease presents as a cyclic or fluctuant hearing loss. Tr. at 119-20.

[17] The only exhibit not discussed in testimony was Pet. Ex. 12, a study of streptococcus pneumoniae and influenza virus vaccines and ear infections in chinchillas. This was unsurprising, given that the study drew no connection between sudden hearing loss and influenza vaccines and actually demonstrated a protective effect of influenza vaccines against otitis media (ear infections) in chinchillas. *Id.*, pp. 2-3. Petitioner's counsel's statement (Tr. at 72) appears to indicate that he was unaware that he had filed this exhibit. Conversely, counsel's statement may have pertained to other articles in Dr. Fiber's possession, but not filed as exhibits. In any event, I attach no weight to this article because it lacks relevance to this case.

http://www.whale.to.[18] The article itself does not list an author. Respondent's Trial Exhibit ["Res. Tr. Ex."] 1 is a printout from the same website, that identifies the author as Dr. Kris Baublomme, a Belgian medical doctor and homeopath, who asserts that:

> The vaccination lobby shamelessly takes all the children of this world as hostages to still their greed for money and power. They relentlessly abuse our compassion for the weaker and our concern about health to promote their giga-business. No matter what. No matter how many more vaccine victims will suffer death or side-effects. No matter how many financial resources this strategy devours at the expense of essential social investments like housing and employment. No matter what. Shocking!

Res. Trial Ex. 1.

The "International Vaccination Newsletter" consists of two parts. The first is a polemic asserting that influenza vaccines do not prevent influenza. The second contains summaries of case reports of post-vaccination illnesses. The decades-old references are apparently European medical journal case reports.

A portion of the article is marked by hand drawn brackets. Page 3's bracketed text references a case of encephalitis[19] following an influenza vaccine with "central disturbance of the N. Vestibularis." The citation is to a 1978 German medical journal article. Doctor Fiber testified that this case study indicates that the influenza vaccine can cause problems with the ears. Tr. at 40. Leaving aside the issues of the age of the reference and the lack of any connection to more recent influenza vaccines[20] administered in the United States, there is no evidence that JANE DOE/16 had encephalitis. Tr. at 74. Encephalitis itself may cause hearing loss. Tr. at 78. Further, based on the ENG testing performed, JANE DOE/16's injury was based in the

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[18] This website (last visited May 1, 2008) describes its mission as "mostly a medical politics and anti-vaccination site, the Big Brother and (his) Mind Control sections were included to show the wood from the (medical) trees and to see where Tyranny (eg wars, famine, atheism, poverty, droughts, killer hurricanes, drugs, crime, most disease fear, etc) really comes from, causing most folk to think God doesn't exist! 'Whale' is a tribute to our larger brained mammals." It appears from the configuration of the website, Pet. Ex. 13 itself, and Res. Tr. Ex. 1 that Pet. Ex. 13 is not a medical journal article published elsewhere and merely linked to this website, as the article contains no medical journal citation or pagination.

[19] Encephalitis is an inflammation of the brain. DORLAND'S at 608. Symptoms include altered consciousness, mild lethargy, motor weakness, accentuated tendon reflexes, and occasionally tremors. More serious cases may involve confusion, stupor, and coma.

[20] Unlike many other vaccines, the composition of the influenza vaccine administered in the U.S. changes annually.

peripheral, rather than the central, nervous system . Pet. Ex. 4, p. 5.[21] This summary of a case report is thus of limited relevance to JANE DOE/16's case.

Doctor Fiber also testified about two other case reports briefly mentioned in Pet. Ex. 13. The first concerned a case of vertigo identified as occurring five days after vaccination. The second was a case of nystagmus and vertigo that occurred within moments of vaccination. The article provides no further details about the two cases. Tr. at 41-42. The timing between vaccination and injury in these two case reports does not coincide with the timing between vaccine and injury in JANE DOE/16's case. Doctor Fiber testified that he did not read the underlying case reports mentioned in the website article and had no further details concerning those cases. Tr. at 78.

Doctor Fiber next addressed Pet. Exs. 10 and 11, two case reports of hearing injuries following hepatitis B vaccinations. He testified that these two case reports established that a hearing loss attributed to a vaccine can occur on the same day as the vaccination. Tr. at 43. The medical theory proposed by Dr. Fiber to link the influenza vaccination to JANE DOE/16's hearing loss was the same theory proposed in Pet. Ex. 10 and 11, hydrops of the inner ear presenting as sudden hearing loss, nausea, vomiting, and possible permanent hearing impairment. The hearing loss discussed in Pet. Ex. 10 began eleven hours after vaccination and was attributed to a lesion on cranial nerve VIII, not hydrops. *Id.*, pp. 1, 3. The case report in Pet. Ex. 11 concerned fluctuant hearing loss attributed to hydrops, with the patient experiencing full recovery of hearing. *Id*., p. 2.

Doctor Fiber next addressed the issue of timing. A portion of his testimony regarding timing was difficult to understand, primarily due to the nature of the question posed to him. Apparently relying on the timing in the case reports in Pet. Exs. 10 and 11, he believed that sudden sensorineural hearing loss ["SSNHL"] could occur on the same day the vaccine was administered. Tr. at 46-47. He believed that an adaptive immune system response could occur in less than 12 hours, but acknowledged that petitioner's exhibits did not address the timing of an adaptive immune response. Tr. at 71-72. Petitioner was offered the opportunity to supplement the record with additional documentary evidence. However, the only additional exhibit filed included no references to the time frame for an adaptive immune response to a vaccine stimulus. Tr. at 136; Pet. Ex. 17.

On cross examination, Dr. Fiber acknowledged that he found no medical literature, other than the International Vaccine Newsletter, linking the influenza vaccine to sudden hearing loss. The peer-reviewed medical literature related to hearing loss and vaccines all concerned vaccines other than the influenza vaccine. Tr. at 50, 52.

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[21] Respondent's expert, Dr. Willcox, testified that JANE DOE/16's injury was a peripheral rather than a central one. Tr. at 117-18.

He agreed that Pet. Ex. 14, a Food and Drug Administration information sheet[22] on the Fluzone influenza vaccine, did not mention audiological problems as a possible adverse event temporally or causally associated with the vaccine. Tr. at 66-67.

Petitioner's Exhibit 17, filed after the hearing, is an abstract of a medical journal article provided by Dr. Fiber. The abstract indicates that the article is a review of the literature regarding the role viruses may play in the initiation and development of autoimmune diseases and the mechanisms for that role. This abstract does not provide sufficient detail to determine its relevance, if any, to petitioner's case.

C. Respondent's Medical Expert.

1. Background and Qualifications.

Doctor Thomas Willcox's curriculum vitae was filed as Res. Ex. B.[23] He graduated from the University of Pennsylvania Medical School, where he performed his internship and a residency in otolaryngology and head and neck surgery. He did a fellowship in otology, neuro-otology, and skull-based surgery at the Ear Research Foundation in Sarasota, FL. Tr. at 82-83; Res. Ex. B. After completing his fellowship, he returned to Pennsylvania, where he is currently an associate professor and director of the hearing center at Thomas Jefferson University. He is board certified in otolaryngology. *Id.* In addition to his academic, teaching, and research responsibilities, he maintains an active clinical practice. Tr. at 84. He has published over 30 medical journal articles, primarily dealing with diseases of and injuries to the ear and various head and neck surgical issues. Res. Ex. B.

2. Respondent's Expert Report and Testimony.

Doctor Willcox's report summarized JANE DOE/16's relevant medical history. As he explained in later testimony, JANE DOE/16 had several risk factors for developing SSNHL.[24] These included her age (the risk of SSNHL increases with age) and a medication she was taking (Avapro), which has been linked to hearing abnormalities. Tr. at 89, 129-30. Given that her hypertension and hypercholesterolemia predisposed her to vascular problems, Dr. Willcox testified that infarction, an interruption of the blood supply causing cell death, is a more likely cause

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[22] Petitioner's Exhibit 14 is a Food and Drug Administration print out regarding the 2004-2005 influenza vaccine known as Fluzone. None of the possible adverse effects listed include sensorineural hearing loss. *Id.* at 7-8.

[23] Respondent failed to number the pages of this exhibit.

[24] Doctor Willcox testified that SSNHL is a decrease in hearing of greater than 10-15 decibels that occurs over a period of hours and involves three contiguous frequencies. Tr. at 87-88. Vertigo and nausea may occur in SSNHL. Tr. at 91.

for her hearing loss than the influenza vaccine. Tr. at 92-93.

Other known causes of SSNL include tumors, syphilis, noise trauma, head trauma, certain medications, antibiotics, and chemotherapy. Tr. at 87-88. Viral infections and vascular compromise of the labyrinthine area of the ear, intracochlear membrane rupture, and immune-mediated inner ear disease are all postulated etiologies for SSNHL. Res. Ex. A, p. 3. Although viruses are postulated causes for SSNHL, the influenza vaccine contains killed virus, which cannot cause a viral infection. Doctor Willcox also opined that there are no plausible mechanisms by which an influenza vaccination can cause vascular compromise or membrane rupture. *Id*.

In his testimony and expert report, Dr. Willcox detailed several factors that led to his unequivocal conclusion that the influenza vaccine did not cause JANE DOE/16's deafness:

First, the influenza vaccine is administered seasonally, prior to or during the influenza "season." If the vaccine caused SSNHL, he would expect to see a clustering of cases of SSNHL around the same time. He sees between two and four patients per week with this condition and has not noted any seasonal variability. There is no evidence to suggest that SSNHL is clustered during the vaccine season. Tr. at 87-88, 94.

Second, if the influenza vaccine could cause SSNHL, it is likely that a temporal connection between vaccine and hearing loss would have been previously noted in case reports. He contrasted the number of case reports concerning the measles, mumps, and rubella vaccine's association with sudden hearing loss (over 100) with the total lack of such case reports with regard to the influenza vaccine. Given the millions of influenza vaccines administered annually, Dr. Willcox found the lack of even one case report to be quite compelling. Tr. at 107-08. As he put it, JANE DOE/16's case would be the first case in "the whole history of reported medicine in millions of vaccinations." Tr. at 111.

Third, he opined that the timing between vaccine and onset of symptoms did not support a hypersensitivity reaction. Accepting JANE DOE/16's report of hearing problems beginning approximately five hours after her vaccination, he noted that she displayed no signs of an immediate hypersensitivity reaction (anaphylaxis), which typically occur within seconds to minutes of vaccination. Res. Ex. A, p. 3.

The clinical picture did not supply any evidence of a delayed hypersensitivity reaction or autoimmune reaction either. These reactions typically do not occur until 48-72 hours after antigen exposure because of the time required for an adaptive immune response. *Id*. When seen in the emergency department within this time frame, JANE DOE/16's testing for influenza viral antigens was negative, indicating no delayed hypersensitivity reaction to the influenza vaccine. Based on the lack of any

leukocytosis[25] or lymphocytosis[26] in the serologic testing done during the emergency department visit, he concluded that there was no evidence of any inflammatory process, autoimmune or otherwise. *Id*. He acknowledged, however, that a subacute inflammatory response could have been present, but that this was only a possibility. Tr. at 125.

Doctor Willcox concluded that there was no plausible mechanism by which the influenza vaccine could have caused JANE DOE/16's hearing loss in the time period involved. Tr. at 112. There were no objective markers pointing towards inflammation and the time frame of the hearing loss did not fit with either an immediate hypersensitivity reaction or a delayed hypersensitivity reaction. The adaptive immune system, including any autoimmune reaction, could conceivably react in less than 48 hours, but to see such a reaction in five hours would be very uncharacteristic because of the time required for cell sensitization to occur and the adaptive immune system to react. Tr. at 124-25.

Fourth, Dr. Willcox questioned Dr. Fiber's reliance on the case studies in Pet. Exs. 10 and 11, as they involved a different vaccine and different clinical presentations. The influenza vaccine is a killed virus vaccine; the hepatitis B vaccine is a recombinant DNA vaccine. In Dr. Willcox's words, comparing the influenza vaccine to the hepatitis B vaccine would be comparing "apples and oranges." Tr. at 95-96. He used a drug analogy to further illustrate this point, stating that all antibiotics cannot be impugned because one causes an adverse reaction. Tr. at 126.

He also noted that the case report in Pet. Ex. 11 concerned the histopathological condition underlying Meniere's disease and the case report in Pet. Ex. 10 concerned a lesion in the retrocochlear area involving the auditory nerve. He found them inapplicable to JANE DOE/16's case, as she did not have Meniere's disease and did not have a retrocochlear hearing loss. Tr. at 96-97. Cases dealing with the etiology of a central hearing loss would be of limited probative value in evaluating the etiology of JANE DOE/16's loss. Tr. at 117-18. Meniere's disease presents with fluctuant episodes of vertigo and hearing loss followed by recovery. The non-episodic nature of JANE DOE/16's hearing loss ruled out Meniere's disease. Tr. at 120. Although she experienced some recovery of hearing, the loss stabilized and has not otherwise changed. Tr. at 121. The normal MRI and MRA findings suggest that there is no neurologic cause for JANE DOE/16's hearing loss. Tr. at 133.

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[25] Leukocytosis is an elevated level of white blood cells seen with strenuous exercise, hemorrhage, fever, infection, or other inflammatory processes. DORLAND'S at 1021. JANE DOE/16's leukocyte levels were within normal limits. Pet. Ex. 2, p. 31.

[26] Lymphocytosis is an elevated level of lymphocytes in the blood. DORLAND'S at 1078. Lymphocytes are white blood cells that play a major role in the body's response to infection. They exist in two forms, B cells and T cells. *Id.* at 1077. JANE DOE/16's lymphocyte levels were within normal limits. Pet. Ex. 2, p. 31.

In summary, Dr. Willcox concurred with Dr. Nasr's opinion regarding possible non-vaccine causes for JANE DOE/16's sudden hearing loss and, likewise, agreed with him that the timing between vaccination and hearing loss was inappropriate for Dr. Fiber's postulated autoimmune reaction.

IV. Legal Standards to be Applied.

A. In General.

Petitioner must establish each of the three *Althen* factors: (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. 418 F.3d at 1278. Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006).

The medical theory factor does not require petitioner to establish identification and proof of specific biological mechanisms, as "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. The petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a "substantial factor" in causing the condition and was a "but for" cause are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). *See also, Pafford v. Sec'y, HHS,* 451 F.3d 1352, 1355 (Fed. Cir. 2006) (petitioner must establish that vaccinations were a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners may not be required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect...." *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y*, *HHS* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see, Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden).

When a petitioner alleges an "off-Table" injury, eligibility for compensation is established when, by a preponderance of the evidence, petitioner demonstrates that she: (1) received a vaccine set forth on the Vaccine Injury Table; (2) received the vaccine in the United States; (3) sustained an illness, disease, disability, or condition caused by the vaccine (or experienced a significant aggravation of an illness); and (4)

the problem has persisted for more than six months.[27] Vaccine litigation rarely concerns whether the vaccine appears on the Table, the situs for administration, or whether the symptoms have persisted for the requisite time. In this case, the focus, as in most vaccine litigation, is on the issue of whether the injury alleged was caused by the vaccine; all of the other requirements of the Vaccine Act were established.

The special master determines the reliability and plausibility of the expert medical opinions offered and the credibility of the experts offering them. Not all evidence carries equal weight with a trier of fact. A medical opinion on causation may be based on factually incorrect medical histories or it may be offered by someone without the necessary training, education, or experience to offer a reliable opinion. An expert's opinion may be unpersuasive for a variety of reasons.

Courts, whether they deal with vaccine injuries, medical malpractice claims, toxic torts, or accident reconstruction, must base their decisions on reliable evidence. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594-96 (1993). *Daubert* provides a useful framework for evaluating scientific evidence in Vaccine Act cases. *Terran v. Sec'y, HHS*, 41 Fed. Cl. 330, 336 (1998), *aff'd* 195 F.3d 1302, 1316 (Fed. Cir. 1999), *cert. denied, Terran v. Shalala*, 531 U.S. 812 (2000). *See also*, *Ryman v. Sec'y, HHS*, 65 Fed. Cl. 35, 40 (2005) (special master performs gatekeeping function when he "determines whether a particular petitioner's expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon").

The Vaccine Act clearly contemplates that the special masters will weigh the merits of the evidence presented in making entitlement decisions. Special masters are not bound by any particular "diagnosis, conclusion, judgment, test result, report, or summary," and in determining the weight to be afforded to these matters, "shall consider the entire record...." § 300aa–13(b)(1). Respondent may challenge the factual underpinnings of a causation opinion, the opinion itself, or both. Special masters weigh the evidence found in the medical records (*see, e.g., Ryman*, 65 Fed. Cl. at 41-42); consider evidence of bias or prejudice on the part of a witness, affiant, or expert (*see, e.g., Baker v. Sec'y, HHS*, No. 99-653V, 2003 WL 22416622, *33-34 (Fed. Cl. Spec. Mstr. Sept. 26, 2003)); weigh opposing medical opinions and the relative qualifications of experts (*see, e.g., Epstein v. Sec'y, HHS*, 35 Fed. Cl. 467, 477 (1996) and *Lankford v. Sec'y, HHS*, 37 Fed. Cl. 723, 726-27 (1997)); examine medical literature, studies, reports, and tests submitted by both sides (*see, e.g., Sharpnack v. Sec'y, HHS*, 27 Fed. Cl. 457 (1993), *aff'd,* 17 F.3d 1442 (Fed. Cir. 1994)); and may consider a myriad of other factors in determining the facts of the case and the mixed questions of law and fact that arise in causation determinations. Special masters decide questions of credibility, plausibility, reliability, and ultimately determine to which

[27] Section 300aa–13(a)(1)(A). This section provides that petitioner must demonstrate "by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)..." Section 300aa–11(c)(1) contains the four factors listed above, along with others not relevant to this case.

side the balance of the evidence is tipped. *See Pafford*, 451 F.3d at 1359 ("Notably, this court accords great deference to a Special Master's determination on the probative value of evidence and the credibility of witnesses"). As noted in *Althen* and *Grant*, a persuasive medical theory is one supported by reputable medical or scientific evidence. *Althen*, 418 F.3d at 1278; *Grant*, 956 F.2d at 1148. *See also*, *Daubert*, 509 U.S. at 594-96 and *Terran*, 41 Fed. Cl. at 336 (*Daubert*'s framework for evaluating scientific evidence applicable to Vaccine Act cases).

In an off-Table case, if the special master concludes that petitioner's evidence of causation is lacking, then the burden never shifts to respondent to demonstrate the "factors unrelated" as an alternative cause for petitioner's injury. *See*, *Bradley,* 991 F.2d at 1575 (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed) and *Johnson v. Sec'y, HHS*, 33 Fed. Cl. 712, 721-22 (1995), *aff'd,* 99 F.3d 1160 (Fed. Cir. 1996) (in an idiopathic disease claim, the special master may nonetheless conclude that petitioner has failed to shift the burden to respondent to prove a factor unrelated).[28] If a petitioner fails to establish one or more of the *Althen* factors, then the petitioner has failed to establish causation. By challenging any of *Althen's* three causation factors through cross-examination, introduction of medical literature, contrary testimony of well-qualified experts, or by some other method, respondent may stymie petitioners' efforts to establish causation without the necessity of establishing an alternate cause. Because I conclude that petitioner has not met her burden of proof on causation, respondent's obligation to demonstrate an alternate cause is not triggered.

B. Applying *Althen*.

1. *Medical Theory.*

Doctor Fiber's testimony that the influenza vaccine triggered an autoimmune hypersensitivity reaction supplies petitioner's medical theory. Whether it is a reliable medical theory is another matter entirely. An on-line search of medical databases, such as PubMed and Medscape, is qualitatively different from an open-source search. The former will yield results related to indexed and peer-reviewed medical literature; the latter may access sources with questionable reliability.

2. *Logical sequence of cause and effect.*

[28] If the respondent were limited to presenting the matters set forth in § 300aa-13(a)(1)(B)–proving by a preponderance of the evidence that the petitioner's condition is due to a factor unrelated to the vaccine–any petitioner with a disease for which medical science has not yet discovered a cause would be at a distinct advantage in Vaccine Act litigation. Section 300aa–13(a)(1)(B) indicates that respondent may not rely upon "idiopathic, unexplained, unknown, hypothetical, or undocumentable" causes as a "factor unrelated."

Doctor Fiber relied on his medical theory and the timing to link the vaccination to the disease. He did not point to anything in JANE DOE/16's medical history, examination, or test results that linked his theory of swelling in the endolymphatic sac to her condition. Swelling in the endolymphatic sac can cause Meniere's disease, but JANE DOE/16's persistent hearing loss is inconsistent with the fluctuant hearing loss present in Meniere's disease. Further, there was no evidence introduced that influenza vaccine can cause Meniere's disease.

The lack of support in medical literature for influenza vaccine causation of SSNHL is not fatal to JANE DOE/16's causation claim. If a vaccine can cause a particular injury, someone must be the index case. However, the sheer number of influenza vaccines administered in the U.S. annually without any reports of hearing loss (Dr. Willcox testified that in 2006, over 50 million influenza vaccines were administered, and Dr. Fiber conceded that "millions" are administered annually), coupled with the difficulties inherent in the medical theory and timing in her case (discussed below), suggest that the interrelationship between vaccine and injury here is coincidental, not causal.

3. *Proximate temporal relationship*.

Doctor Fiber based his opinion that five hours was an appropriate time frame for the injury on two case reports involving a different vaccine, different mechanisms for injury, and different clinical presentations. Neither case study involved the same medical theory of an autoimmune hypersensitivity reaction and neither involved a time period as short as five hours. As the Federal Circuit stated in *Althen*: "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." 418 F.3d at 1278 (*citing Grant*, 956 F.2d at 1149). In this case, the temporal relationship can be considered "proximate" only in that the injury followed the vaccination. Doctor Willcox's testimony that the timing was too long for anaphylaxis and too soon for a delayed hypersensitivity reaction is corroborated by Dr. Nasr's opinion. Doctor Fiber conceded that he was unable to find any support beyond Pet. Exs. 10 and 11. As noted earlier, neither of those case studies supports that a delayed hypersensitivity response can occur in five hours time.[29]

4. *Discussion*.

[29] I have decided this case solely on the basis of the information contained in this record. I am aware, however, that there is a substantial body of information concerning the adaptive immune system and the time required for it to respond to a stimulus. When timing is an issue and two experts advance opposing opinions, it would behoove the parties to produce evidence supporting their expert's conclusions. In this case, there are ample reasons to credit Dr. Willcox's testimony about the response time rather than that of Dr. Fiber. I note that the time required for the adaptive immune response to occur was recently addressed in *Shepperson v. Sec'y,* 05-1064V, 2008 U.S. Claims LEXIS __ (Fed. Cl. Spec. Mstr. April 30, 2008).

Petitioner's case presents two weaknesses. The first is the interrelationship between *Althen's* first two factors. The second is the problem of timing.

This court is frequently confronted by two expert witnesses with diametrically opposed opinions. That is certainly the case here. In deciding which opinion to credit, the court may look to relative qualifications of the two experts; the extent to which the opinions are buttressed or contradicted by other evidence in the case, including those of treating physicians; and support or lack thereof in the medical literature, bearing in mind that petitioner bears the burden of establishing causation by a preponderance of the evidence. A theory is only a theory, until there is some evidence that the theory is at work in the case.

Doctor Willcox and Dr. Fiber are both board-certified in otolaryngology. However, Dr. Willcox's clinical practice actually involves treating two to four patients a week with JANE DOE/16's condition. His publications, including book chapters and research papers, are more extensive, more current, and more directly related to SSNHL and other conditions, such as Meniere's disease, referenced in his testimony. Because I did not have the benefit of observing Dr. Fiber in person, I do not base my opinion of relative credibility on demeanor, but I note that Dr. Fiber seemed unprepared to address questions related to one of his principal references, Pet. Ex. 13.[30]

Petitioner's Exhibit 13 itself is of questionable reliability. It appears from Res. Tr. Ex. 1 that the author is a frequent contributor to a website that bills itself as "anti-vaccine" and there is no evidence that it is a peer-reviewed publication. It is clear that a petitioner cannot be *required* to supply confirmation of medical plausibility by submitting peer reviewed medical literature. Stated differently, medical literature of any type may not be required as a condition precedent to finding vaccine causation. *See Althen*, 418 F.3d at 1279, 1281 (discussing the Federal Circuit's rejection of the *Stevens* test, which required such evidence as a condition precedent to finding causation). However, when medical literature is submitted as evidence, the type of medical literature submitted may be weighed and evaluated in determining what weight should be accorded to that evidence. The Supreme Court has noted:

> [S]ubmission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

[30] The fax machine header information appearing at the top of the article indicates that he supplied the article to petitioner's counsel.

Daubert, 509 U.S. at 593-94. When an expert places reliance on documents such as Pet. Ex. 13, the weight that may be accorded that expert's opinion is not enhanced.

Additionally, the *Reference Manual on Scientific Evidence*, Federal Judicial Center, 2000 (2d ed.), notes that, in determining medical causation, "[c]ausal attribution based on case studies must be regarded with caution," largely because they lack controls and thus do not provide the level of information or detail found in epidemiologic studies. *Id*. at 475.

Capizzano indicates that the opinions of treating physicians are significant evidence in deciding questions of causation. *Capizzano*, 440 F.3d at 1326-27. In JANE DOE/16's case, two treating physicians addressed the issue of causation. Doctor Nasr considered the vaccine as a possible cause, but rejected it due to the acute onset of the injury. Doctor Huang's statement that JANE DOE/16 experienced a labyrinthine injury "most likely secondary to the influenza vaccine" fails to provide the basis for his opinion. Without information regarding the basis for his opinion, I do not accord it the same weight I accord Dr. Nasr's contrary opinion.

In summary, there is a dearth of reliable evidence logically or causally linking JANE DOE/16's influenza vaccination to SSNHL. This leaves a *post hoc, ergo propter hoc*, analysis that is insufficient to establish causation.

Because I have concluded that petitioner has failed to meet her burden of proof, I need not address whether respondent has produced sufficient evidence of an alternate cause–a "factor unrelated" to the vaccine. *Johnson,* 33 Fed. Cl. at 721-22.

CONCLUSION

Petitioner has not demonstrated by a preponderance of the evidence that her condition was either caused in fact or significantly aggravated by the influenza vaccination she received on December 1, 2004. She has thus failed to establish entitlement to compensation and the petition for compensation is therefore DENIED.

In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.[31]

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Special Master

[31] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.