# In the United States Court of Federal Claims
## OFFICE OF SPECIAL MASTERS

No. 08-625V
Filed: August 31, 2010

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| DONNA DONICA, | ) | PUBLISHED |
| Petitioner, | ) | Causation-in- fact; Influenza (Flu) Vaccination; Vertigo; Inner Ear Disorders |
| v. | ) | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | ) | |
| Respondent. | ) | |

Sean F. Greenwood, Houston, TX, for Petitioner.
Ann D. Martin, United States Department of Justice, Washington, D.C., for Respondent.

**DECISION**[1]

**Lord**, Chief Special Master.

## I. Introduction and Overview

On August 26, 2008, Donna Donica ("Petitioner") filed this case under the National Childhood Vaccine Injury Act ("Vaccine Act" or "Act").[2] Petitioner alleged the

[1] As provided by Vaccine Rule 18(b), each party has fourteen days within which to request the redaction "of any information furnished by that party (1) that is 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." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of timely objection, the entire document will be made publicly available.

[2] The National Vaccine Injury Compensation Program comprises 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-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

influenza vaccination she received on October 27, 2006, caused her to suffer vertigo and other related inner ear disorders.[3]

The Vaccine Act created the National Vaccine Injury Compensation Program ("Vaccine Program") under which compensation may be paid for vaccine-related injury or death. 42 U.S.C. § 10(a); Walther v. Sec'y of Dep't of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). Pursuant to the Vaccine Act, petitioners may be compensated for injuries caused by certain vaccines. See generally §§ 10 to 34. To receive compensation, a petitioner must prove that either: 1) a "Table Injury"– that is, an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) an "off-Table" injury that was actually caused by or "caused-in-fact" by a vaccine. See §§ 13(a)(1)(A), 11(c)(1); Shalala v. Whitecotton, 514 U.S. 268, 270 (1995). In this case, Petitioner alleged that she suffered an off-Table injury.

To prove an off-Table claim, a petitioner must provide evidence, in the form of medical records or reliable medical opinion, to establish "(1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury." Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

After carefully evaluating and weighing all of the evidence, I find that Petitioner has not satisfied her burden of making a prima facie case under Althen. Specifically, Petitioner has not presented evidence demonstrating a medically appropriate "proximate temporal relationship between the vaccination and the injury." Althen, 418 F.3d at 1278. Respondent has demonstrated that the onset of Petitioner's alleged vaccine related injuries was too soon after the administration of her vaccination for the vaccine to have been the cause of her injuries.

Accordingly, Petitioner has not presented a prima facie case of entitlement and the Petition must be denied.

## II. Facts and Background

### A. Medical Record

Petitioner is a 52-year old nurse with some pertinent medical history prior to her vaccination. Petitioner's Exhibit ("Pet'r Ex.") 1 at 7, Tr. 143.[4] Petitioner received

[3] Petitioner's alleged vaccine related injuries include, but are not limited to, the following: vertigo or specifically benign paroxysmal positional vertigo, hearing loss, and vestibular weakness in the left inner ear, and viral labyrinthitis (collectively referred to as "vertigo and related inner ear injuries" or simply "inner ear injuries.")

[4] When citing to a particular page in the record, I use the page number assigned by the

treatment for fatigue, dizziness, and generalized weakness in July of 2004. Pet'r Ex. 1 at 20. Petitioner was treated for chest pain and lightheadedness in February of 2006. Id. at 18. In March 2006, Petitioner was treated for fatigue; the medical records at that time noted that Petitioner "doesn't feel right." Id. at 17. On October 19, 2006, one week before she received her 2006 influenza vaccination at issue in this case, Petitioner saw her primary care physician, Dr. Julia DeHoyos, for a routine checkup. Pet'r Ex. 10 at 16. Dr. DeHoyos' records indicate Petitioner did not feel well at that time and had throat pain. Id.

Petitioner received an influenza vaccine on the morning of October 27, 2006, at her workplace in New Braunfels, Texas. Pet'r Ex. 10 at 14; Pet'r Ex. 9. Petitioner sought medical attention from Dr. DeHoyos' office that same day at 1:20 p.m. Pet'r Ex. 1 at 14. Dr. DeHoyos' records indicate that Petitioner reported she received a flu vaccination at work and later that morning she felt dizzy, "spinning head," experienced an upset stomach and threw up five to six times over a period of one to two hours. Id. Dr. DeHoyos' records indicate Petitioner appeared ill and tired. Id. Petitioner also suffered mild sinus symptoms. Id. Petitioner was assessed with vertigo and nausea/vomiting and given Phenergan at Dr. DeHoyos' office. Pet'r Ex. 10 at 15. Dr. DeHoyos released Petitioner to go home with prescribed medication to treat her symptoms, and instructed her to eat a bland diet, rest and follow-up the following week if she did not improve. Id.

Petitioner returned to Dr. DeHoyos' office on October 30, 2006, with complaints of dizziness with movement and the sensation her head was spinning around. Pet'r Ex. 10 at 12. She was assessed with persistent vertigo. Id. at 13. [5] Magnetic resonance imaging (MRI) was performed on October 31, 2006, and assessed as normal. Pet'r Ex. 1 at 27.

Petitioner sought treatment from an otolaryngologist, Dr. Charles Lano, on November 1, 2006. Pet'r Ex. 1 at 58. Dr. Lano's evaluation was normal with the exception that Dix Hallpike maneuver testing was positive on the right side. Id.[6] Dr.

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court's electronic filing system, or the PDF document number in the case of exhibits filed on compact disk. When citing to the hearing transcript, I cite to the page number provided on the actual transcript.

[5] Vertigo is defined as "1. A sensation of spinning or whirling motion. . . . 2. Imprecisely used as a general term to describe dizziness." STEDMAN'S MEDICAL DICTIONARY 1958 (27th ed. 2000).

[6] Dix Hallpike Maneuver is defined as: a "[t]est for eliciting paroxysmal vertigo and nystagmus in which the patient is brought from the sitting to the supine position with the head hanging over the examining table and turned to the right or left; vertigo and nystagmus are elicited when the head is rotated toward the affected ear." STEDMAN'S MEDICAL DICTIONARY 1060 (27th ed. 2000).

Lano's impression was right benign paroxysmal positional vertigo (BPPV) and allergic rhinitis. Id.[7] Petitioner saw Dr. Lano again on November 8, 2006 for a follow-up visit for her BPPV. Pet'r Ex. 2 at 5. At that time, Dr. Lano indicated her condition had improved/resolved. Id. On November 15, 2006, however, Petitioner telephoned Dr. Lano's office complaining of dizziness and was provided medication refills. Id. at 6. Petitioner had a follow-up visit with Dr. Lano on November 29, 2006. Id. at 7. She reported that her symptoms were better, but not gone. Id. Petitioner also noted that she felt drunk when she walked. Id. Dr. Lano's impression was dizziness and sinusitis. He prescribed an antibiotic. Id.

On December 7, 2006, Petitioner saw Dr. Gerlyn Friesenhahn for a neurological evaluation. Pet'r Ex. 1 at 56 -57. Dr. DeHoyos referred Petitioner to Dr. Friesenhahn to evaluate her vertigo. Id. at 56. Dr. Friesenhahn's impression was that Petitioner had "complaints of movement-induced vertigo following a flu vaccine consistent with peripheral labyrinthine cause of vertigo." Id. at 57. Dr. Friesenhahn noted Petitioner's neurological examination was otherwise normal. Id. Dr. Friesenhahn did not believe her complaints were of a neurological etiology. Id. However, Dr. Friesenhahn noted Petitioner wished to have a further evaluation by a neurotologist and she recommended Dr. Charles Syms. Id.

Petitioner received a comprehensive examination from Dr. Syms on March 7, 2007. Pet'r Ex. 2 at 11-18. This examination revealed Petitioner had hearing loss in the left ear, which Dr. Syms described as consistent with "absent high-frequency outer hair cell function on the left." Id. at 17. Dr. Syms' additional diagnoses were viral labyrinthitis on the left and uncompensated peripheral vestibulopathy. Id. at 18. Dr. Syms recommended Petitioner receive a full vestibular and inner ear work-up and then see him for a follow-up visit. Id. at 17-18.

Petitioner began vestibular rehabilitation and physical therapy in April 2007. Pet'r Ex. 4 at 19-44. On April 27, 2007, Petitioner saw Dr. Syms, who recorded that Petitioner's symptoms persisted. Id. 46-47. Dr. Syms advised treatment could take three or four months before any significant improvement. Id. at 46. Dr. Syms'

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[7] Benign paroxysmal positional vertigo is defined as "a recurrent, brief form of positional v.[ertigo] occurring in clusters; believed to result from displaced remnants of utricular otoconia." STEDMAN'S MEDICAL DICTIONARY 1958 (27th ed. 2000).

Benign positional vertigo is defined as "brief attacks of paroxysmal v.[ertigo] nystagmus that occur solely with certain head movements or positions, e.g., with neck extension; due to labyrinthine dysfunction." Id.

Allergic rhinitis is defined as "r[hinitis] associated with hay fever." Id. at 1566.

Rhinitis is defined as "[i]nflammation of the nasal mucus membrane." Id.

impression was Petitioner suffered endolymphatic hydrops, central and peripheral vertigo and loss of hearing. Id. at 45-46. Dr. Syms advised Petitioner she should see improvement in her condition with adequate treatment. Id. Dr. Syms recommended a sodium and caffeine restricted diet, prescription medication, and Klonopin. Id. at 45. Petitioner also met with her physical therapist on April 27, 2007 and was discharged with a home exercise program to be continued daily for three months. Id. at 48.

Petitioner consulted with Dr. Lance Jackson (Petitioner's expert in the instant proceeding), a neurotologist, in December 2007. Pet'r Ex. 5 at 3-7.[8] Dr. Jackson noted Petitioner reported having daily dizziness, but that she also experienced episodes of true vertigo. Id. at 3. Her hearing loss at this time had progressed bilaterally. Id. Petitioner indicated she could only drive short distances because of her condition. Id. In a letter to Dr. DeHoyos dated December 19, 2007, Dr. Jackson indicated his impression of Petitioner's injuries: "1) Benign paroxysmal positional vertigo. . . . 2) Left vestibular weakness. 3) Asymmetric sensory hearing loss with apparent progression of the hearing loss in her left ear. This could represent endolymphatic hydrops." Id. at 6. Dr. Jackson recommended vestibular/balance rehabilitation therapy, a low sodium and caffeine diet, and the use of valium. Id. at 7.

Thereafter, Petitioner continued to seek treatment from Dr. Jackson, as well as vestibular therapy from physical therapists at the Ear Institute of Texas. See e.g. Pet'r Ex. 12 at 1-35.

### B. Petitioner's Testimony

Petitioner testified on December 3, 2009, that she has worked as a nurse for 33 years. Tr. at 143. In 2006, Petitioner indicated she began a new job as a medical review nurse with The Scooter Store. Tr. at 144. Petitioner testified she received an influenza vaccination at her workplace on October 27, 2006, at approximately 8:05 in the morning. Id. at 144. Petitioner stated at about 8:35 she felt flushed. Id. As the day went on, Petitioner testified, she felt worse and went home sick at 10:30. Id. at 144-145. After she left her place of employment, Petitioner testified, she began to vomit profusely, was unable to drive, and called her husband to take her home. Id. at 145. Petitioner sought medical care from her primary care physician, Dr. DeHoyos, that afternoon. Id. at 146. Petitioner testified Dr. DeHoyos indicated Petitioner was having a reaction to her vaccination, performed an examination, and ordered an MRI. Id. at 146-

[8] I note there are different spellings of Dr. Jackson's specialty, neurotology. For consistency, I will utilize the spelling used by Dr. Jackson and the Otology & Neurotology Journal.

Neurotology is defined as "[t]he branch of medicine concerned with the nervous system related to the auditory and vestibular systems." STEDMAN'S MEDICAL DICTIONARY 1211 (27th ed. 2000).

147.

Petitioner testified she continued to feel ill and returned to see Dr. DeHoyos for the MRI on October 31, 2006. Tr. at 147. The MRI was normal and Petitioner testified Dr. DeHoyos referred her to Dr. Lano, an ear, nose, and throat doctor, that same day for an evaluation. Id. Petitioner testified that Dr. Lano indicated she "had a reaction to the flu vaccine," gave her steroids, and advised it could take two weeks or six months for her symptoms to subside. Id. at 148. Petitioner testified both Dr. DeHoyos and Dr. Lano described her symptoms as severe vertigo. Id. Thereafter, Petitioner testified Dr. Lano referred her to a neurotologist, Dr. Syms, who treated her for seven or eight months. Id. at 150. Petitioner felt Dr. Syms' treatment was not effective and she went back to see Dr. Lano, who referred her to Dr. Jackson for an evaluation. Id. Throughout this time period Petitioner testified she "could not walk a straight line . . . was nonfunctional at home." Id. at 151. She was able to go to work, but her husband had to drive her. Id.

Petitioner testified Dr. Jackson attributed her symptoms to the flu vaccine. Id. at 152. Petitioner further testified she remains able to drive only short distances, cannot clean her home, can no longer walk for exercise due to balance issues and must instead ride a stationary bicycle. Id. [9]

### C. Expert Testimony

#### 1. Lance Jackson, M.D.

Dr. Lance Jackson is a practicing otologist and neurotologist. Tr. at 6.[10] He has practiced in his specialty for nine years. Id. at 8. He is the founder and director of the Ear Institute of Texas. Pet'r Ex. 8, Curriculum Vitae of Lance E. Jackson, M.D., F.A.C.S., filed November 19, 2008 at 26. Dr. Jackson is also an Assistant Clinical Professor in Otolaryngology at the University of Texas Health Science Center at San Antonio. Id. Dr. Jackson serves as the Director of Otolaryngology at the Spine Hospital of South Texas and as an Otologist for employees at Sea World of San Antonio. Id. Dr.

[9] Some of the notations in the records of Petitioner's treating physicians indicate that Petitioner's symptoms began after she received her influenza vaccination. These notations appear to be recitals of information Petitioner supplied to her treaters by way of history. See e.g., Pet'r Ex. 1 at 14, 56, 58. Similarly, some of the medical records list "flu vaccine" as an "allergy." See e.g., Pet'r Ex. 1 at 8, 10; Pet'r Ex. 5 at 3. I find that none of Petitioner's treating physicians, other than Dr. Jackson, actually ascribed the cause of her complaints to her vaccination.

[10] Otology is defined as "[t]he branch of medical science concerned with the study, diagnosis, and treatment of diseases of the ear and related structure." STEDMAN'S MEDICAL DICTIONARY 1288 (27th ed. 2000).

Jackson is board certified in otolaryngology. Id. at 27.[11] Dr. Jackson is a reviewer for Otology & Neurotology Journal, and is the author or coauthor of multiple journal articles and book chapters within his specialty. Id. at 28-33.

Dr. Jackson has treated patients with vertigo, which he described as "a symptom that is a sensation of motion." Tr. at 10. Dr. Jackson testified Petitioner came to him with complaints of dizziness in December of 2007 and he found her symptoms consistent with vertigo. Id. at 11-12. Dr. Jackson summarized his opinion in this matter as follows:

> Ms. Donica suffers from a significant left vestibular weakness and has also been treated for BPPV. These conditions can be caused by viral affects on the inner ear producing a labyrinthitis. Considering the onset of Ms. Donica's symptoms shortly after her influenza vaccination on October 27, 2006, I believe that the vaccination likely triggered the onset of Ms. Donica's dizziness disorders.

Affidavit of Lance Jackson, M.D., F.A.C.S. filed August 26, 2008 (attached to Petition), Pet'r Ex. 7 ("Jackson Aff.") at 3. Dr. Jackson further discussed his opinion that Petitioner's influenza vaccine was the cause of Petitioner's vertigo in his second affidavit. See Affidavit of Lance Jackson, M.D., F.A.C.S. filed November 19, 2008, Pet'r Ex. 8 ("Supp. Jackson Aff."). Dr. Jackson indicated he diagnosed Petitioner with vestibular weakness and displaced crystals in the inner ear (BPPV). Id. at 2. Dr. Jackson stated that, through diagnostic testing, he ruled out common causes of vertigo or vestibular weakness, Meniere's disease and tumors affecting the cochlear nerve. Id. at 1-2. He opined he "did not know the cause of the vestibular weakness" but elaborated, "a common cause of vestibular weakness is an inflammation or viral infection of the inner ear. Given the close proximity in time between the influenza injection and the onset of vertigo, it is therefore likely that the inactivated virus in the influenza vaccine caused the vertigo." Id. at 2. As support for his conclusion, Dr. Jackson pointed to the lack of an alternative cause in Petitioner's medical record, a study published in 2004 finding vertigo in 2-3% of senior citizens post flu vaccination, and the package insert from the influenza vaccinations indicating dizziness as a side effect. Id. at 2. See discussion of Petitioner's medical evidence infra at 11-13, 15-16.

Dr. Jackson testified that, through testing, he determined Petitioner suffered BPPV and "a very significant weakness of her inner ear on the left side, in the vestibular function of the inner ear on the left side." Tr. at 16.[12] Dr. Jackson opined "when

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[11] Otolaryngology is defined as "[t]he combined specialties of diseases of the ear and larynx, including the upper respiratory track and diseases of the head and neck, tracheobronchial tree, and esophagus." STEDMAN'S MEDICAL DICTIONARY 1288 (27th ed. 2000).

[12] Dr. Jackson testified petitioner's BPPV has largely resolved; however, she is responding more slowly to treatment of her vestibular weakness than the average sufferer from

somebody has the acute onset of symptoms with those two findings together and the absence of fluctuating hearing loss, a viral labyrinthitis is the most - - would be the most common etiology of that, of those two conditions together." Id. at 16-17. Dr. Jackson later clarified his theory of vaccine causation and opined as to two possible mechanisms by which Petitioner's flu vaccination could have caused her injuries. Dr. Jackson opined

> [t]hat [the influenza] vaccine introduced inactivated viral particles to her body, and that [the viral particles were] systematically absorbed and circulated through the body. . . . And most likely the inner ear on the left side was exposed to those viral particles for some reason, and it produced either an immune or inflammatory response in the inner ear on the left side, or possibly reactivated a latent virus within the inner ear on the left side.

Id. at 41; see also id. at 35, 38-39. As to the first possibility, Dr. Jackson explained why one might see an immune response in one ear but not the other:

> [W]e don't entirely understand that, because it is very common. But it would have to do with somehow the viral particles entered the inner ear, because usually the inner ear is somewhat like the central nervous system, it's largely isolated from the circulatory system. So somehow the viral particles entered one ear and possibly not the other.

Id. at 39. As to why the reactivation of a virus might affect one ear and not the other ear, Dr. Jackson again testified, "somehow . . . the inner ear was exposed to those viral particles on one side and not the other." Id. Dr. Jackson explained these are theories, unproved hypotheses, because one cannot culture the inner ear in living humans. Id. at 40.

Dr. Jackson further opined that two hours (the time period alleged in the Petition) was an appropriate time period for the reaction to occur: "the particles are going to be absorbed relatively quickly" and in the case of a latent virus, he opined such a virus could be activated quickly. Id. at 41. When asked if he had an immunological basis for the two hour time period for the reaction Dr. Jackson testified "[t]he immune system can react pretty quickly to a particle. If the antibodies are already present, those antibodies could react quickly. . . . I can't tell you whether it's five minutes or eight hours. . . . if your body is exposed to an antigen, your immune system will react to it." Id. at 42-43.

Dr. Jackson concluded, based on the above as well as the literature discussed infra at 11-13, 15-16, that Petitioner's influenza vaccination more likely than not was the cause of her injuries.

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the disorder. Tr. at 19-20. Nonetheless, he testified her prognosis for recovery is reasonably good. Id. at 20.

### 2. Burton Zweiman, M.D.

Dr. Burton Zweiman is an immunologist. He was Co-Chief and later Chief of the Allergy and Immunology Section, Department of Medicine at the University of Pennsylvania School of Medicine from 1969-1998. Respt.'s Ex. B, Curriculum Vitae of Burton Zweiman, M.D., at 3. Currently, Dr. Zweiman serves as an Adjunct Professor of Pathology and an Emeritus Professor of Medicine and Neurology at the University of Pennsylvania School of Medicine. Id. He is board certified in internal medicine, has a sub-specialty board in allergy and immunology, and a special competence in diagnostic laboratory immunology. Id. Dr. Zweiman is the author of textbook chapters on autoantibodies, immune complexes, and allergic reactions. Id. at 41-45; Respondent's Expert Report filed May 8, 2009, Respt.'s Ex. A ("Zweiman Report") at 2-3. Dr. Zweiman also is the author or co-author of a large volume of medical journal articles in immunology, Respt.'s Ex. B at 7-26, and sits on multiple editorial boards. Id. at 4. Additionally, Dr. Zweiman has performed research in the field of neuroimmunology, specifically investigating "possible autoimmune mechanisms in the pathogenesis of disorders of the nervous system." Zweiman Report at 3.[13]

Dr. Zweiman opined that Petitioner's influenza vaccination was not the cause of her vertigo. Tr. at 76. Dr. Zweiman based his conclusion on the relevant medical literature, his knowledge of immune responses in general and the body's immune response in particular to vaccines. Id. Dr. Zweiman further testified it was extremely unlikely a significant amount of vaccine component could actually get into the inner ear to cause the reaction hypothesized by Dr. Jackson. Id. at 86. Relying on a report from the Institute of Medicine, Dr. Zweiman testified that, even if a minuscule amount was able to get into the inner ear, there was no evidence to support a "direct neurotoxic effect or an immune response within the inner ear" resulting from the influenza vaccination. Id. at 99, 87.

Dr. Zweiman testified in detail, see infra discussion at 16-17, that it was not biologically plausible for Petitioner's vertigo to have been caused by an immune response to the influenza vaccination within the timeframe alleged. Tr. at 77. He stated that two hours was too short a time for Petitioner to have experienced an immunological response, other than an anaphylactic reaction, to her influenza vaccination. Id. at 89-92. Dr. Zweiman testified it would take a minimum of 12 to 24 hours, and likely much longer, for an immunological response to a vaccination to have manifested with symptoms of vertigo. Id. at 92.

[13] Dr. Zweiman conceded he is not an expert in inner ear disorders and does not clinically treat patients with inner ear disorders. Tr. at 99-104.

## III. DISCUSSION

### A. Petitioner's Burden of Proof to Demonstrate Causation-In-Fact

Petitioner must show that but for her vaccination she would not have been injured, and that the vaccination was a substantial factor in bringing about her injury. Shyface v. Sec'y of Dep't of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Mere temporal association is not sufficient to prove causation in fact; a petitioner must present a medical theory that is supported either by medical records or by the opinion of a competent physician. Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant, 956 F.2d at 1148 (medical theory must support actual cause).

The preponderance of evidence standard under the Vaccine Act requires proof that a vaccine more likely than not caused the vaccinee's injury. Althen, 418 F.3d at 1279. Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove her case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

Once the petitioner has met the initial burden of proof, "the burden shifts to the government to prove '[by] a preponderance of the evidence that the petitioner's injury is due to factor unrelated to the . . . vaccine.'" De Bazan v. Sec'y of Dep't of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citations omitted). If the petitioner fails to establish a prima facie case of causation, however, the burden does not shift. Doe 11 v. Sec'y of Dep't of Health & Human Servs., 601 F.3d 1359, 1357-58 (Fed. Cir. 2010).

In evaluating whether a petitioner has presented a legally probable medical theory, "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324. Assessing the reliability of expert in opinion in Vaccine Act cases can be challenging, because often there is little supporting evidence for the expert's opinion. See Althen, 418 F.3d at 1280 (noting that the "field [is] bereft of complete and direct proof of how vaccines affect the human body"). Consequently, most expert opinion will be an extrapolation from existing data and knowledge. The weight to be given to an expert's opinion is based in part on the size of the gap between the science and the opinion proffered. Cedillo v. Sec'y of Dep't of Health & Human Servs., -- Fed. 3d. --, 2010 WL 3377325, *6 (Fed. Cir. 2010(quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)). A special master is not required to

rely on a speculative opinion that "'is connected to existing data only by the ipse dixit of the expert.'" Synder, 88 Fed. Cl. at 745, n.66 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

### B. Analysis

#### 1. Could Vaccination Have Caused Petitioner's Injuries? – Prong 1

Under Althen Prong 1, a petitioner must set forth a biologically plausible theory explaining how the vaccine received by the petitioner could cause the injury complained of. See, e.g., Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009). This requirement has been interpreted as "can the vaccine(s) at issue cause the type of injury alleged?" Pafford, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Evidence should be viewed by the preponderance of the evidence standard and "not through the lens of the laboratorian." Andreu, 569 F.3d at 1380. Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must be sound, reliable, and reputable—in other words, the theory need not be scientifically certain, but it must have a scientific basis. See Andreu, 569 F.3d at 1379-80.

Petitioner presented two theories from Dr. Jackson to establish causation. Dr. Jackson opined Petitioner's influenza vaccination caused her to experience "an immune response to the viral particles in the inner ear" or alternatively "activated other live viruses within the inner ear." Tr. at 35; see also id. at 38-39, 41, supra at 8.

Dr. Zweiman responded that it was "very unlikely" vaccine particles or antigens could get into Petitioner's ear. Tr. at 78-79, 86. Dr. Zweiman testified further that if the vaccine antigen were able to get into the inner ear, there was no evidence it could cause damage. Id. at 86-87.

As support for the contention that influenza vaccination can cause vertigo, Dr. Jackson cited an article by Chen et al. Jackson Supp App at 2 citing Pet'r Ex. 14, Y. Chen et al., Influenza and pneumococcal vaccination of the elderly in Taiwan, 22 VACCINE 2806 (2004) ("Chen"). Chen conducted annual post vaccination telephone interviews with elderly vaccinees in Taiwan between 1999 and 2002 in an effort to survey adverse events. Id. at 3.[14] The authors found two to three percent of the elderly vaccinees reported vertigo, in addition to other adverse reactions, post influenza vaccination. Id. at 4.

[14] The study included interviews with 492 elderly influenza vaccinees in 1999, and 450 elderly influenza vaccinees in each of the subsequent years. Chen at 4. Although Dr. Jackson was uncertain as to when the vaccinees in this study were interviewed, Tr. at 23-24, Chen indicated interviews were conducted one week after the patients received influenza vaccinations. Chen at 3.

Dr. Zweiman identified several weaknesses in Petitioner's reliance on the Chen study, which was retrospective and not controlled. Zweiman Report at 4. A study that is not controlled does not compare participants receiving a particular treatment against a control group not exposed to the treatment. The scientific community recognizes the limitations of retrospective, uncontrolled studies in that they do not reveal true incidence rates. Further, the interviews with the elderly vaccinees were telephonic and the vertigo was self-reported. Id. at 4; Chen at 3. Without a medical assessment, it is unclear if the individuals suffered true vertigo. Dr. Zweiman indicated he performed a search of the medical literature and did not find any controlled study that found increased vertigo subsequent to influenza vaccination. Id. at 5.

Further, Dr. Zweiman pointed out that vertigo is a common symptom in all individuals, but particularly the elderly. Zweiman Report at 4. As support for this point, Dr. Zweiman cited literature that found the one-year prevalence of vertigo is 4.9% for all adults, and almost 9% for adults over 70 years old. Id. citing Respt.'s Ex A, Attachment ("Att") 2, Neuhauser HK, Epidemiology of vertigo, 20 Curr Opin Neurol, 40 (2007) ("Neuhauser") at 10. Neuhauser reported the incidence of newly manifested vertigo to be 1.4% for all adults in a given year. Id. Dr. Zweiman opined that if the prevalence of vertigo in adults over 70 was nearly double that of all adults, then cases of newly manifested vertigo for all adults over 70 should correspond to 2.5-3% of the elderly population. Zweiman Report at 4. Chen found the same incidence rate post vaccination in the elderly in Taiwan. Chen at 4. Further, Dr. Zweiman cited to a 2008 review that reported, "dizziness and vertigo occur frequently in aging." Zweiman Report at 4 quoting Respt.'s Ex A, Att 3, Katsarkas, Dizziness in aging: the clinical experience, 63 Geriatrics 18 (Nov. 2008) at 17.

Dr. Zweiman concluded "it is quite likely that the vertigo described in this report from Taiwan was unrelated to the prior influenza immunization and may well have occurred randomly." Zweiman Report at 5.

Additionally, Dr. Jackson and Petitioner relied upon an article by Pyykko et al. to further support Dr. Jackson's theory that "when exposed to viral antigens, people can develop inner-ear disturbances, such as BPPV." Petitioner's Post Hearing Brief ("Pet'r Post-Hr'g Br.") at 3 citing Pet'r Ex. 17, L. Pyykko et al., Do viruses cause inner-ear disturbances?, 70 ORL 32 (2008) ("Pyykko" ); Tr. at 28. Petitioner posited, "the influenza vaccine contains antigens or the viral particles which produce responses similar to what [she] experienced." Id.

Pyykko examined patients with inner ear disease in comparison to a control group to examine a possible association between viral infection and inner ear disease. Pyykko at 1. The authors found titers for the following viruses significantly elevated as compared with the control group: varicella zoster virus (VZV), Coxsackle virus B5 (CBV5), influenza B virus, and respiratory syncytial virus (RSV). Id. The authors noted

a correlation was not found between hearing loss and viral titers. Id. The article concluded "VZV, CVB5, and influenza B virus may be the main causes of SSHL [sensorineural hearing loss], vestibular neuritis, and Meniere's disease." Id. at 7.

Dr. Zweiman pointed out in his testimony that Pyykko discussed the influenza virus (not the vaccine, which does not contain live virus). See Tr. at 80. Further, Dr. Zweiman noted Pyykko concluded there was no evidence in the medical literature that reported '"influenza virus internalization in the cochlea,' which is the major structure in the inner ear." Id. at 80 citing Pyykko at 3. Dr. Zweiman elaborated that this information is significant because, while evidence of other viruses, such as herpes, has been found in the inner ear, influenza footprints never have been identified there. Id. at 80-83. Dr. Zweiman explained the influenza virus is distinct from the herpes virus as "[h]erpes viruses have the capacity to replicate in a very low-lying way in tissues." Id. at 81. Respondent argued, "the Pyykko article does not support even a tenuous connection between Petitioner's flu vaccination and her inner ear disturbance." Respondent's Post Hearing Brief ("Respt.'s Post-Hr'g Br.") at 18.

I find persuasive Dr. Zweiman's testimony that the medical literature provides weak support, if any, to Dr. Jackson's theory of possible vaccine causation in this case.

Dr. Jackson, however, is a well-qualified expert in inner ear disorders, and I respect his opinion, even if it is not supported by medical literature. Dr. Zweiman testified that the scenario posited by Dr. Jackson was unlikely. Tr. at 78-79, 86. Vaccine injuries in general are regarded as unlikely, however, so Dr. Zweiman's testimony does not advance the analysis materially.

I do not conclude, based on this record, that the evidence preponderates one way or the other. Because it is clear that Petitioner has not satisfied Prong 3 of the Althen test, it is not necessary to rule on Prong 1 in this instance. See infra at 14-17.

### 2. Evidence of a Logical Sequence of Cause and Effect – Prong 2

The second prong of Althen requires a petitioner to prove "'a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury.'" Andreu, 569 F.3d at 1374 (quoting Althen). Under Prong 2 of Althen, petitioners are not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific of medical communities to establish a logical sequence of cause and effect . . . ." Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Capizzano, 440 F.3d at 1325-26; Andreu, 569 F.3d at 1375-1377 (treating physician testimony).

Dr. Jackson presented Petitioner's case under Prong 2. He has treated the Petitioner since 2007 and examined her on numerous occasions. Dr. Jackson's testimony was coherent and reasonable. I place reliance on Dr. Jackson's opinion, as it is grounded in his subject matter expertise in inner ear disorders, as well as his knowledge as Petitioner's treating physician.

Respondent did not offer the testimony of an inner ear expert, nor has Dr. Zweiman examined and treated Petitioner. While personal examination and treatment of a petitioner is not required of an expert witness, in some cases it may provide additional support for an expert's testimony.

In this case, if Petitioner had satisfied Prong 1 and Prong 3, Dr. Jackson's testimony would support the conclusion that there was a logical sequence of cause and effect between Petitioner's vaccination and her injury, under Prong 2 of Althen.

### 3. Petitioner's Evidence of Appropriate Timing – Prong 3

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. Pafford, 451 F.3d at 1358. A temporal relationship between receipt of a vaccine and the alleged onset of symptoms, without more, however, is insufficient to establish a causal relationship in a cause-in-fact case. Grant, 956 F.2d at 1148. What constitutes an appropriate temporal association is a question of fact and will vary with the particular theory of causation advanced. Id.; de Bazan, 539 F.3d at 1352.

Dr. Jackson testified that Petitioner reported that the symptoms of her vertigo and related inner ear injuries began within two hours of her influenza vaccination. Tr. at 12.[15] Dr. Jackson testified that two hours was a "medically appropriate time period" for either of his two posited theories. Tr. at 41-42. When questioned as to the basis for his assertion, Dr. Jackson testified "[t]he particles are going to be absorbed relatively quickly, and if there is, for example, a latent virus within the inner ear, I think that could be activated quickly." Id. at 42. Upon further questioning, Dr. Jackson was asked if he could point to an article, study, or immunological principle to support his opinion as to a medically appropriate time period. Dr. Jackson responded:

> [t]he immune system can react pretty quickly to a particle. If the antibodies are already present, those antibodies could react quickly. I can't give you a - - I can't tell you whether it's five minutes or eight hours. I can tell you if your body's exposed to an antigen, your immune system will react to it.
>
> . . .

[15] Petitioner testified at hearing that she began to experience symptoms within 30 minutes. Tr. at 144.

> [W]hen you are exposed to a virus, your body doesn't want to wait three days to respond to it. It wants to respond pretty quickly.

Tr. at 42-43.

Dr. Jackson relied upon the Fluzone (influenza virus vaccine) package insert and numerous reports from the Vaccine Adverse Event Reporting System (VAERS) as evidence to support this aspect of Petitioner's claim. Pet'r Ex. 8 at 4-19; Pet'r Ex.13. The Fluzone package insert indicated that "dizziness" was reported post vaccination, but did not indicate an appropriate time period for the reaction. Pet'r Ex. 8 at 10.

The total VAERS reports Petitioner submitted consist of 1,595 pages. See Pet'r Ex. 13. Petitioner specifically indicated thirteen of the pages as relevant to this matter. See Amended Exhibit "B" – Petitioner's Exhibit List at 1 filed November 10, 2009. At hearing, Petitioner designated a second subset of these reports as relevant, as they "contain reports of dizziness." Tr. at 64; Pet'r Ex. 13(a). I note the thirteen pages Petitioner initially designated as relevant contain reports of vertigo. Dr. Jackson testified the VAERS reports "show[ed] that there can be a temporal correlation, but it's a relatively low number." Tr. at 59.

Dr. Jackson's explanation for why two hours was an appropriate time period for the onset of either medical theory proposed was vague and unclear. He stated that two hours was an appropriate time period for an immunological response under the causation theories he presented, but did not present a well-reasoned explanation for the basis of his opinion.

Dr. Zweiman pointed out that the Fluzone Package Insert and the VAERS data are unreliable evidence, since this information cannot be verified. Tr. at 95-97. The Fluzone Package Insert indicated that because the vaccine's post-approval reported adverse advents "are reported voluntarily from a population of unknown size, it is not always possible to reliable estimate their frequency or establish a causal relationship to vaccine exposure." Pet'r Ex. 8 at 10. Likewise, VAERS reports can be filed by anyone and there is no mechanism to control their accuracy or reliability. Tr. at 95-97. The United States Court of Federal Claims has recognized the limited utility of VAERS data in establishing causation under the Act. Analla v. Sec'y of Health & Human Servs., 70 Fed. Cl. 552, 558 (2006) (citations omitted).

Further, while Dr. Jackson testified that VAERS data was evidence of a temporal relationship, he did not explain how the VAERS data establishes an appropriate temporal relationship. I find the VAERS data did not provide any indication of a time period in which, given "the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The VAERS data simply provided reports of adverse events subsequent to vaccination.

Additionally, as Respondent noted the Fluzone Package Insert and the VAERS reports in Petitioner's Exhibit 13(a) reported the adverse event of "dizziness." Respt.'s Post-Hr'g Br. at 13. The broad symptom of dizziness, as Dr. Jackson testified, does not equate with the specific symptom of vertigo. See Tr. at 25.

In addition, Dr. Jackson is a neurotologist, not an immunologist. Dr. Zweiman, on the other hand, is a board-certified immunologist with over forty years of practice in the field of immunology. He testified that the temporal model for onset posited by Dr. Jackson is not possible in this case. Id. at 77. Dr. Zweiman explained that after receiving an influenza vaccination, multiple events occur. Tr. at 87. First, over several days the vaccine components are processed by the body to "present the antigen to certain cells within the immune capacity." Id. at 88. Next, if it is the body's first exposure to the vaccine, it will take several weeks before "there is a significantly expressed immune response against that particular vaccine, in this case influenza." Id. However, if the body has been previously exposed to the vaccine a "boost in the level of antibodies that are present against the particular vaccine components" occurs within several days. Id. Dr. Zweiman conceded that if an individual has previously received a vaccination, the immune response shortens or is faster after each subsequent vaccination – "to a point." Id. at 121-122. But he explained

> [t]he lag period really doesn't get that short. What happens [after subsequent vaccination] is you get - - frequently you get a more robust antibody response, the levels go up. But . . . it does not get to a point where it would be within 12 hours or something like that.

Id. at 122. Dr. Zweiman opined that if the influenza antigen were somehow able to get into the inner ear, as posited by Dr. Jackson, "it would take at least 12 to 24 hours and likely longer before you see an inflammatory cell reaction that would be sufficient in degree to make itself known as symptoms like vertigo." Id. at 92. Dr. Zweiman testified that the only type of immunological response that could occur within two hours of receipt of the vaccine is an anaphylactic type response. Tr. at 90, 92. He explained that an anaphylactic response occurs when

> the protein, in this case the influenza virus protein, and the antibody interact on the surface of a particular type of cell called a mast [cell] . . . . This interaction leads to an immediate activation of the mast cell and release of a number of what we call the vasoactive components within the mast cell. And that's what causes those immediate manifestations.

Tr. at 92. Dr. Zweiman testified such manifestations include: "breaking out in hives, an asthmatic sort of respiratory problem, maybe swelling of the tongue or the windpipe or the trachea, occasionally in shock." Id. at 90. Dr. Zweiman and Dr. Jackson agreed Petitioner did not experience an anaphylactic reaction to her influenza vaccination. Id. at 60, 90.

Dr. Zweiman's testimony regarding the time period for a medically appropriate immunological response is more persuasive than Dr. Jackson's testimony. While Dr. Jackson is a well-qualified neurotologist, he is not an immunologist and has no special training or experience in immunology or vaccine science. Dr. Jackson was unable to address how or why, with any specificity or scientific support, two hours was a medically appropriate time period for a post-vaccination immunological response. In contrast, Dr. Zweiman's testimony presented a complete and cogent explanation of the reasons why, based on principles of immunology, two hours was too short a time period for the onset of Petitioner's alleged vaccine-related injury.

Based upon all the evidence presented in this matter and for the reasons discussed above, I find Petitioner has not established by preponderant evidence that two hours is a medically appropriate time period for the onset of her vertigo and related inner ear disorders. As stated in de Bazan, "we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." de Bazan, 539 F.3d at 1352 citing Pafford, 451 F.3d 1352, 1358; Althen, 418 F.3d at 1281 (equating "proximate temporal relationship" with "medically-acceptable temporal relationship").

## IV. CONCLUSION

Based on the entire record, Petitioner has not presented a prima facie case of vaccine causation-in-fact. Therefore, Respondent is entitled to judgment.

For the foregoing reasons, Petitioner's Petition for compensation is **DISMISSED**. In the absence of a motion for review, the Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

s/ Dee Lord
Dee Lord
Chief Special Master