

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

Filed: April 28, 2020

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ALICE LAWLER,

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UNPUBLISHED

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Petitioner,

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No. 18-719V

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v.

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Special Master Nora Beth Dorsey

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SECRETARY OF HEALTH  
AND HUMAN SERVICES,

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Dismissal Decision; Influenza (“Flu”)

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Vaccine; Bell’s Palsy.

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Respondent.

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Danielle A. Strait, Maglio, Christopher & Toale, LLP, Seattle, WA, for petitioner.

Robert P. Coleman, III, U.S. Department of Justice, Washington, DC, for respondent.

**DECISION**<sup>1</sup>

**I. INTRODUCTION**

On May 22, 2018, Alice Lawler (“petitioner”) filed a petition under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”),<sup>2</sup> 42 U.S.C. § 300aa-10 et seq. (2012) alleging that as a result of receiving an influenza (“flu”) vaccination on September 23, 2016, petitioner suffered from Bell’s palsy. Petition at 1-2. Respondent argued against compensation. Respondent’s Report (“Resp. Rept.”) at 2 (ECF No. 13).

<sup>1</sup> Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in 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 to -34 (2012). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

After carefully analyzing and weighing the evidence presented in this case, in accordance with the applicable legal standards, the undersigned finds petitioner failed to provide preponderant evidence that the vaccine she received caused her Bell's palsy. Therefore, this case must be dismissed.

## II. PROCEDURAL HISTORY

Petitioner filed for compensation under the National Vaccine Injury Compensation Program on May 22, 2018. On May 24, 2018, petitioner filed medical records. Petitioner's Exhibits ("Pet. Exs.") 1-7. On March 4, 2019, respondent filed his Rule 4(c) Report, recommending against compensation. Resp. Rept. at 2.

In his Report, respondent asserted that petitioner did not allege a Table injury, and thus, she is not entitled to the presumption of causation afforded under the Table. Resp. Rept. at 5. Respondent further stated that to prove causation, petitioner must provide evidence of a medical theory connecting the vaccines to the injury, a logical sequence of cause and effect, and a temporal association between the vaccines and the injury. *Id.*; see Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Respondent also contended that "[p]etitioner's medical records alone fall short of establishing causation-in-fact, as petitioner's medical providers offered only faint support for petitioner's claim that the vaccine could have caused her Bell's palsy." Resp. Rept. at 5.

Respondent further argued petitioner had not provided a medical theory, expert report, or scientific literature causally linking her flu vaccination with her alleged injury. Resp. Rept. at 6. Respondent maintained, "[a]bsent a persuasive medical or scientific theory establishing that these vaccinations can cause Bell's palsy, petitioner cannot satisfy Althen prong one." *Id.* Moreover, petitioner's workers' compensation claim was denied because of her inability to prove that the vaccine caused her condition, further undermining the scientific validity of her claim. *Id.* at 5-6. Additionally, respondent asserted petitioner's viral infection, for which she was treated shortly after receiving the flu vaccination on September 23, 2016, provides an alternate cause of her Bell's palsy. *Id.* at 6.

On March 12, 2019, the special master at the time held a status conference and ordered petitioner to file a status report by April 12, 2019 and proposed a deadline for her expert report for June 28, 2019. Non-PDF Scheduling Order dated Mar. 12, 2019. On April 12, 2019, petitioner filed a status report stating that she secured an expert and expected to file an expert report by June 28, 2019. Pet. Status Rept., filed Apr. 12, 2019 (ECF No. 14). Petitioner then filed three motions for extension of time to file an expert report. Pet. Motion ("Mot.") for Extension of Time (ECF No. 15); Pet. Mot. for Extension of Time (ECF No. 17); Pet. Mot. for Extension of Time (ECF No. 18). On September 3, 2019, the special master filed an Order granting petitioner's third motion for extension of time stating, "[p]etitioner's Expert Report shall be filed on or before 10/3/2019. Because [p]etitioner will have had nearly six months to file an expert report, no further extensions of time shall be permitted." Non-PDF Scheduling Order dated Sept. 3, 2019.

The case was reassigned to the undersigned on October 2, 2019. On October 3, 2019, petitioner filed a supportive letter from petitioner's treating physician, Dr. Christina Klemme, and two articles of medical literature. Pet. Exs. 8-10. Petitioner also filed a status report stating no additional evidence in her case would be filed. Pet. Status Rept., filed Oct. 3, 2019 (ECF No. 21).

On October 16, 2019, petitioner filed a motion for Ruling on the Record, stating that petitioner filed all relevant medical records on May 24, 2019 and filed a supportive opinion from her primary care doctor on October 3, 2019. Pet. Mot. for Ruling on the Entitlement ("Pet. Mot.") at 1. Petitioner considered the evidentiary record closed and did not intend to file additional medical records, testimonials, or medical expert evidence. *Id.* at 3. Petitioner's motion contained no analysis of the Althen prongs or statement that petitioner satisfied her burden of proof by preponderant evidence and is entitled to compensation.

On October 28, 2019, respondent filed his response to petitioner's motion renewing the request that compensation be denied and that the case be dismissed. Resp. Response to Pet. Mot. for Ruling on the Record ("Resp. Response") at 2. Respondent highlighted that "none of petitioner's other treating physicians offered an opinion of causation" other than Dr. Klemme, who "indicated that she thought that it was possible that a vaccine could cause Bell's palsy." *Id.* at 6. Respondent opined that Dr. Klemme's belief of a "possible" association of a causal link between a vaccine and an alleged injury does not meet the statutory standard of proof set out in Moberly v. Secretary of Health & Human Services, 592 F.3d 1315, 1322 (Fed. Cir. 2010). *Id.* at 6 n.3. Respondent also emphasized that Dr. Klemme's opinion letter stated, "there ha[ve] been case studies that link Bell's palsy with an influenza vaccination," but she did not cite any such studies. *Id.* (internal citations omitted).

Respondent then addressed the medical literature submitted by the petitioner. See Resp. Response at 6-7. Petitioner's first article, Bardage et al.,<sup>3</sup> studied individuals who have received Pandemrix, a particular version of the flu vaccine. *Id.*; Pet. Ex. 9. However, petitioner did not provide any evidence that she received Pandemrix, or explain how this article supported her claim of a vaccine-induced injury. Resp. Response at 7. Petitioner's second article, Greco et al.,<sup>4</sup> noted that the cause of Bell's palsy is unknown, reviewed case reports on flu vaccine recipients, and suggested an immunological mechanism can cause Bell's palsy. Pet. Ex. 10 at 1, 4. Neither petitioner nor Dr. Klemme offered an explanation of how this article supports petitioner's claim. Resp. Response at 7.

Respondent continued to rebut petitioner's claim by citing the findings of the Institute of Medicine's ("IOM") review of the epidemiologic and mechanistic evidence linking the flu

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<sup>3</sup> Carola Bardage et al., Neurological and Autoimmune Disorders After Vaccination Against Pandemic Influenza A (H1N1) with a Monovalent Adjuvanted Vaccine: Population Based Cohort Study in Stockholm, Sweden, 343 *BMJ* 1/23 (2011).

<sup>4</sup> A. Greco et al., Bell's Palsy and Autoimmunity, 12 *Autoimmunity Rev.* 323 (2012).

vaccine to Bell's palsy.<sup>5</sup> Resp. Response at 7. Respondent cited the IOM's conclusion that the "evidence favors rejection of a causal relationship between inactivated influenza vaccine and Bell's palsy." Id.

Finally, respondent suggested petitioner's viral infection, which she was diagnosed with a week after receiving the flu vaccination, provides an alternative cause for petitioner's Bell's palsy. Resp. Response at 8. Respondent may introduce evidence of an alternate cause to rebut petitioner's theory of causation, and the special master is authorized to consider that evidence in determining whether petitioner has met her burden of proving a prima facie case. See Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 865 (Fed. Cir. 1992). Finally, respondent posited that "[a]ccording to medical personnel at DICP, a viral infection, which was ongoing at the time petitioner received the vaccination, is a known cause of Bell's palsy." Resp. Response at 9.

On October 30, 2019, petitioner filed a Reply to respondent's response. Pet. Reply to Resp. to Pet. Mot. for Ruling on Entitlement ("Pet. Reply"). Petitioner first addressed the authority of Dr. Klemme's letter as a medical opinion as defined in 42 U.S.C. § 300aa-13(a)(1)(B). Pet. Reply at 2. Petitioner provided evidence in the form of a medical opinion and defers to the Court the weight to accord Dr. Klemme's opinion. Id. Petitioner then stated that respondent did not introduce any evidence regarding an alternative cause to the alleged injury. Id. at 3. Respondent cited medical literature not filed with the Court and provided conclusory argumentation, not evidence. Id. at 3-4. Petitioner concluded her reply by citing a number of cases compensated by the Program of Bell's palsy following receipt of a flu vaccination to demonstrate the general validity of petitioner's claim. See id. at 5-6.

On January 21, 2020, the undersigned issued an Order asking respondent to file an expert report. Scheduling Order dated Jan. 21, 2020 (ECF No. 27). On March 24, 2020, respondent declined to file an expert report and asked that the evidentiary record be closed. Resp. Status Rept., filed Mar. 24, 2020 (ECF No. 28). On March 25, 2020, the undersigned issued an Order closing the evidentiary record. Order dated Mar. 25, 2020 (ECF No. 29).

This matter is now ripe for adjudication.

### **III. FACTUAL SUMMARY**

#### **A. Factual Background**

On September 23, 2016, petitioner, age fifty-nine, received a flu vaccination in her left arm. Pet. Ex. 1. On October 1, 2016, petitioner was treated by James Winde, M.D., for "mild dermatophytosis and chronic hearing problems from about a week ago when she got her flu shot

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<sup>5</sup> See Comm. to Review Adverse Effects of Vaccines, Inst. of Med., Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2011). This book was not filed into evidence by respondent.

she's had adenopathy in the anterior cervical chain and significant hearing problems.”<sup>6</sup> Pet. Ex. 3 at 4-5. Dr. Winde diagnosed petitioner with bilateral ear infections with significantly swollen and reddened tympanic membranes, fluid behind the ear, and associated hearing loss. Id. Dr. Winde treated petitioner's condition with oral steroids, pseudoephedrine, and nasal rinses. Id.

On October 6, 2016, petitioner was treated by Christina Klemme, M.D., a family medicine physician, for facial droop, which began the previous day, and continuing ear problems. Pet. Ex. 4 at 35-39. Petitioner was preliminarily diagnosed with Bell's palsy versus stroke. Id. at 35. Dr. Klemme prescribed antiviral and antibiotic medication, and referred petitioner for a brain CT scan. Id. at 35-39. The CT scan was unremarkable. Id. at 40.

Petitioner returned to Dr. Klemme on October 13, 2016, and Dr. Klemme noted that petitioner had filed a workers' compensation case, claiming that the vaccine administered on September 23, 2016 caused her Bell's palsy. Pet. Ex. 4 at 24-27. Dr. Klemme noted that “[t]here is definitely a possibility that influenza vaccine can cause [B]ell's palsy.” Id. at 24. It was also noted that petitioner's Bell's palsy should continue to improve. Id. at 26.

On October 18, 2016, petitioner visited a physician assistant, who noted that after steroid and antiviral treatment, petitioner's condition had improved, but she continued to experience slightly worse left-sided facial swelling, tightness, and left eye dryness. Pet. Ex. 4 at 20-23. Petitioner, a dental assistant, requested a note that she “avoid direct patient care for now due to eye strain, dryness.” Id. at 21.

On October 19, 2016, petitioner was seen again by Dr. Klemme, who noted that petitioner was feeling better, but that her hearing still felt as if it were “under water,” and she continued to have jaw pain and blurred vision. Pet. Ex. 4 at 16-19.

On December 2, 2016, petitioner was seen by Tony Bartley, M.D., for left ear sensitivity, who recorded that petitioner was “reassured that her hearing is completely normal. Told her that there was no guarantee that there would be complete resolution of the facial deficit caused by the Bell's palsy. As mentioned she does feel this is improving.” Pet. Ex. 4 at 12-15.

On January 19, 2017, petitioner was seen by Dr. Klemme, who noted that petitioner's symptoms improved with herbal supplements and acupuncture, although she continued to experience some facial weakness. Pet. Ex. 4 at 8-11. On April 11, 2017, petitioner visited Keith Johnston, O.D., for mild changes in vision and a complaint that her eyes were tiring more quickly over the past six months. Pet. Ex. 2 at 8-14, 109-16. Dr. Johnston recommended ocular lubricants and prescribed new glasses. Id. Petitioner was also noted to have been diagnosed with dry eye initially in March 2014. Id.

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<sup>6</sup> Dermatophytosis is a superficial fungal infection caused by a particular fungus in the keratinized tissues (e.g., skin, hair, nails). Dorland's Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=13381&searchterm=dermatophytosis> (last accessed April 20, 2020).

On June 8, 2017, petitioner was seen by Dr. Klemme for concerns about esophageal reflux, and petitioner indicated that she felt that her swallowing and speaking was slower and her voice was no longer stable. Pet. Ex. 4 at 62-64. Dr. Klemme noted that petitioner was upset that her workers' compensation claim was denied. Id. Petitioner also noted that she was undergoing acupuncture treatments that were helping her swallowing symptoms, and she continued to use herbal supplements to help the nerves on her face. Id. On July 10, 2017, a modified barium swallow test was performed, which did not reveal any evidence of aspiration. Pet. Ex. 6 at 12.

On October 6, 2017, petitioner was seen by Dr. Klemme because petitioner wanted to discuss her Bell's palsy and because she was "still having issues with L&I [worker's compensation] closing her case." Pet. Ex. 4 at 65-69. As petitioner explained, the workers' compensation case was denied because the cause of her Bell's palsy could have been her eczema or her ear infection. Id. Petitioner noted that she was unable to sing, and still experienced mild residual neurologic deficits. Id. Petitioner did not want a letter from Dr. Klemme's office for her workers' compensation case because she did not believe it would offer strong enough support for her contention that her symptoms were caused by the vaccination. Id. She also declined the opportunity to see a neurologist. Id.

#### **B. Dr. Christina Klemme's Letter**

On October 3, 2019, petitioner filed a letter from Dr. Klemme. Pet. Ex. 8. Dr. Klemme's letter consists of a paragraph containing petitioner's history, and it concludes with a two sentence opinion. The letter states,

This letter is written in support for Mrs. Alice Lawler in regards to her development of Bell's [p]alsy after receiving an influenza vaccination on 9/23/2016 at her place of employment. Mrs. Lawler afterwards had visited an urgent care clinic and was diagnosed with an ear infection and prescribed a Medrol Dosepack and antibiotic on 10/1/2016. Five days later, she presented to my clinic with facial drooping and to follow up on the ear infection. There was no vesicular rash. After testing and examination it was noted that her ear infection had resolved and she had Bell's [p]alsy. She was advised to stop her antibiotics and start treatment for Bell's [p]alsy. She was treated for this and had improvement.

Per UpToDate,<sup>7</sup> there ha[ve] been case studies that link Bell's [p]alsy with an influenza vaccination. Therefore having a side effect of Bell's palsy, although rare and unfortunate, can happen.

Id.

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<sup>7</sup> UpToDate is a physician's "point of care" resource that provides "evidence-based pathways related to specific clinical questions." Pet. Reply at 2 n.3.

### C. Additional Medical Literature

Also, on October 3, 2019, petitioner submitted two medical journal articles to support the causal link between the flu vaccine and Bell's palsy. The study conducted by Bardage et al. reviewed the safety considerations of Pandemrix, a particular version of the flu vaccine, as a response to the pandemic caused by influenza A (H1N1). Pet. Ex. 9. Over a period of eight to ten months the authors examined the risk of neurological and autoimmune disorders, such as Bell's palsy, in people vaccinated against the pandemic H1N1 with Pandemrix compared with those who remained unvaccinated. Id. at 1. The study concluded there was a small risk for Bell's palsy with the Pandemrix vaccination, but these risks only materialized among high risk groups who were likely to have earlier comorbidity. Id. at 5. Petitioner did not provide evidence that she received the Pandemrix vaccination and has offered no explanation of the relevance of this article to her claim.

The second article, authored by Greco et al., reviewed the current medical knowledge of the etiopathogenesis of Bell's palsy, including viral infection or autoimmunity. Pet. Ex. 10. The article states, "[t]he aetiology of Bell's palsy is unknown, but viral infection or autoimmune disease have been postulated as possible pathomechanisms." Id. at 3. Pertinent to this case, the article provides, "[i]n Bell's palsy and GBS, a viral infection or the reactivation of a latent virus may provoke an autoimmune reaction against peripheral nerve myelin components," leading to facial paralysis. Id. However, this assertion was based on a review of herpes viruses. The article also addresses the appearance of Bell's palsy after intranasal administration of the flu vaccine in children. Id. at 4. However, petitioner did not provide evidence that she received an intranasal flu vaccination and has offered no explanation of the relevance of this article to her claim.

### D. Petitioner's Affidavit

In her affidavit, the petitioner stated that she received a flu vaccination on September 23, 2016. Pet. Affidavit ("Aff.") at ¶ 1. On or about September 26, 2016, she felt a strange sensation in her left ear and wondered if she was getting an ear infection. Id. at ¶ 3. Her symptoms became painful and she had a ringing sound in her left ear. Id. at ¶ 4. On October 1, 2016, she visited a walk-in clinic to have her ears examined. Id. at ¶ 6. During that visit, her doctor told her she had an ear infection and gave her antibiotics. Id.

On October 5, 2016, she noticed her left eye did not shut all the way. Pet. Aff. at ¶ 7. Petitioner's pain in her left ear still bothered her. Id. On October 6, 2016, she visited her regular doctor and had a CT scan. Id. at ¶ 8. During that visit, the petitioner was diagnosed with Bell's palsy and prescribed prednisone, an anti-viral, and told to discontinue the antibiotics. Id.

On October 8, 2016, petitioner stated that her facial droop was more noticeable, her face and lips felt numb and weak, and she had difficulty eating. Pet. Aff. at ¶ 10. Petitioner also experienced blurred vision from her left eye and had issues with swallowing. Id. Throughout the rest of 2016 and into early 2017, petitioner stated she had little improvement in her Bell's palsy. Id. at ¶¶ 11-16. Petitioner's Washington Workers Compensation claim was denied for the vaccine related-injury that her work required. Id. at ¶ 18. At the time petitioner signed the

affidavit on November 17, 2017, she still had mild facial weakness, an abnormal sensation with swallowing, and left facial weakness that affected her speaking and singing voice. *Id.* at ¶ 19.

#### IV. LEGAL AUTHORITY AND ANALYSIS

##### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” *Rooks v. Sec’y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly*, 592 F.3d at 1322 n.2. In particular, petitioner must prove that that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Id.* at 1321 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B).

##### B. Diagnosis

The Federal Circuit has made clear that “identifying [the petitioner’s] injury is a prerequisite” to the *Althen* analysis. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010); see *Althen*, 418 F.3d at 1280. However, it is not necessary to diagnose an exact condition. The Federal Circuit has explained “the function of a special master is not to ‘diagnose’ vaccine-related injuries, but instead to determine ‘based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner’s] injury.’” *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). “[T]he Special Master [is] not required to perform an *Althen* analysis . . . ‘in the absence of a showing of the very existence of any specific injury of which the petitioner complains.’” *Lasnetski v. Sec’y of Health & Human Servs.*, 696 F. App’x 497, 506 (Fed. Cir. 2017) (quoting *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011)).

##### C. Causation

To receive compensation under the Program, petitioner must prove either: (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was caused by a vaccination. See

§§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because petitioner does not allege that she suffered a Table injury, she must prove that a vaccine caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and her injury (“Althen Prong One”); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury (“Althen Prong Two”); and (3) a showing of a proximate temporal relationship between the vaccine and her injury (“Althen Prong Three”). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Thus, petitioner must provide a reputable medical or scientific explanation for her theory, although the explanation need only be “legally probable, not medically or scientifically certain,” it must be “sound and reliable.” Boatmon v. Sec’y of Health & Human Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); Knudsen, 35 F.3d at 548-49. Petitioner cannot establish entitlement to compensation based solely on assertions. Rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material contained in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A).

## **D. Analysis**

### **i. Diagnosis**

As described above, in order to be entitled to compensation under the Vaccine Act, a petitioner must show a vaccine-related injury. Here, there is no real dispute as to diagnosis. In her petition, the petitioner alleges that she suffered from Bell’s palsy. The medical records state that Bell’s palsy was a differential diagnosis. On October 6, 2016, petitioner was treated by Dr. Klemme and was preliminarily diagnosed with Bell’s palsy versus stroke. Pet. Ex. 4 at 35. Subsequently, petitioner underwent a brain CT scan, which was unremarkable. Id. at 40.

Petitioner returned to Dr. Klemme on October 13, 2016 and was told her Bell’s palsy should continue to improve. Pet. Ex. 4 at 24-27. This was evidenced by petitioner’s October 18, 2016 visit with a physician’s assistant who noted that after steroid and antiviral treatment, petitioner’s condition had improved. Id. at 20-23. Petitioner continued to report improvement to her care providers on October 19, 2016, December 2, 2016, and January 19, 2017. Id. at 8-11, 12-15, 16-19.

Of note, on October 6, 2017, petitioner had a follow up appointment with Dr. Klemme to discuss her Bell’s palsy, and because she was “still having issues with L&I [workers’ compensation] closing her case.” Pet. Ex. 4 at 65-69. As petitioner explained, the workers’ compensation case was denied because the cause of her Bell’s palsy could have been her eczema or her ear infection. Id.

Based on her review of the petitioner's medical records, and the statements in the records made by petitioner's treating physicians, the undersigned finds petitioner suffered from Bell's palsy. However, there is no evidence that petitioner sustained a vaccine-related injury.

**ii. Althen Prong One: Petitioner's Medical Theory**

Under Althen Prong One, petitioner must set forth a medical theory explaining how her vaccines could have caused her alleged injuries. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation must be informed by a "sound and reliable medical or scientific explanation." Knudsen, 35 F.3d at 548; see also Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Here, Dr. Klemme noted that "[t]here is definitely a possibility that influenza vaccine can cause [B]ell's palsy." Pet. Ex. 4 at 24. Petitioner also submitted a supportive letter from her treating physician Dr. Klemme. Pet. Ex. 8. The entirety of Dr. Klemme's medical opinion states, "[p]er UpToDate, there ha[ve] been case studies that link Bell's palsy with an influenza vaccination. Therefore having a side effect of Bell's palsy, although rare and unfortunate, can happen." Id. However, Dr. Klemme's supportive letter does not contain or discuss information about a medical theory that explains how the flu vaccine can cause Bell's palsy. And none of petitioner's other treating physicians offered any opinions regarding a medical theory.

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Human Servs., No. 08-209V, 2018 WL 3679843, at \*31 (Fed. Cl. June 22, 2018), review denied, decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Human Servs., No. 04-1717V, 2019 WL 2509626, at \*19 (Fed. Cl. May 24, 2019) (quoting Moberly, 592 F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

Dr. Klemme's letter is conclusory in nature and provides no evidence linking the flu vaccination to Bell's palsy. Without further medical explanation or analysis beyond the conclusion that Bell's palsy "can happen" after flu vaccination, Dr. Klemme's opinion is insufficient to provide a medical theory of causation. Dr. Klemme's opinion is analogous to the expert opinion given by Dr. Kendell in R.V. v. Secretary of Health & Human Services. See No. 08-504V, 2016 WL 3882519, at \*38-39 (Fed. Cl. Feb. 19, 2016), review denied, decision aff'd,

127 Fed. Cl. 136 (2016). The special master in R.V. found Dr. Kendall’s suggestion that a vaccine could cause sufficient oxidative stress to cause injury conclusory. Id. Furthermore, the special master found that Dr. Kendall “offered little reliable evidence—whether from her own experience or research, or a laboratory test or case study cited in her report—establishing that the flu vaccine could be so associated with [petitioner’s injury].” Id. Like Dr. Kendall, Dr. Klemme offers no evidence to support her assertion that Bell’s palsy is linked to the flu vaccine.

Additionally, possible theories or mechanisms are insufficient to establish causation by a preponderance of evidence. “Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.” LaCour v. Sec’y of Health & Human Servs., No. 90-316V, 1991 WL 66579, at \*5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); accord Burns v. Sec’y of Health & Human Servs., No. 90-953V, 1992 WL 365410, at \*6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff’d, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec’y of Health & Human Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also De Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008).

Dr. Klemme’s medical record notes the possibility that the flu vaccine can cause Bell’s palsy. However, a possibility is not sufficient to establish causation. See Garner v. Sec’y of Health & Human Servs., No. 15-063V, 2017 WL 1713184, at \*16 (Fed. Cl. Mar. 24, 2017), review denied, decision aff’d, 133 Fed. Cl. 140 (2017) (providing the petitioner’s expert provided conclusory reasoning for “possible” vaccine causation is “not sufficient”). Dr. Klemme opines that according to her research, articles of which are uncited in her opinion, studies link Bell’s palsy with a flu vaccination. Without evidence or further explanation of how Bell’s palsy can occur after the flu vaccination, Dr. Klemme’s theory of possibility is legally insufficient.

Furthermore, Dr. Klemme’s letter mentioned “case studies that link Bell’s palsy with an influenza vaccination,” but did not identify which case studies she was referring to. Pet. Ex. 8. Separately, petitioner filed two medical articles by Bardage et al. and Greco et al. Pet Exs. 9, 10. Neither petitioner nor Dr. Klemme offered an explanation of how the articles either relate or support petitioner’s claim. Therefore, the articles are unpersuasive as evidence in petitioner’s case.

Because Dr. Klemme’s letter is conclusory, and petitioner’s medical records do not provide a “sound and reliable” theory, but merely suggests a possibility of causation, the undersigned finds petitioner failed to provide preponderant evidence to support Althen Prong One.

**iii. Althen Prong Two: Logical Sequence of Cause and Effect**

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

Since there is no evidence of a theory of causation to support Althen Prong One, it follows that there is also no evidence to support a finding of a logical sequence of cause and effect to establish that the vaccine caused the petitioner’s Bell’s palsy. Although Dr. Klemme noted the fact that petitioner received the vaccine, she did not provide a logical sequence of cause and effect showing how the flu vaccine caused the petitioner to develop Bell’s palsy. Moreover, Dr. Klemme did not explain how petitioner’s clinical course or any medical facts support vaccine causation. There is no evidence in the record that petitioner’s other treating physicians expressed an opinion that the flu vaccine did in fact cause petitioner’s alleged injury here. Therefore, the undersigned finds that petitioner failed to prove Althen Prong Two.

**iv. Althen Prong Three: Proximate Temporal Relationship**

Under Althen Prong Three, petitioner must provide “preponderant proof that the onset of symptoms occurred within a time frame for which, given the understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” De Bazan, 539 F.3d at 1352. The acceptable temporal association will vary according to the medical theory advanced in the case. See Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that “a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury”), aff’d 475 F. App’x 765 (Fed. Cir. 2012).

On September 23, 2016, petitioner received a flu vaccination. Pet. Ex. 1. Thirteen days later, on October 6, 2016, petitioner presented to Dr. Klemme for facial droop, which began the previous day, and continuing ear problems. Pet. Ex. 4 at 35-39. Petitioner was preliminarily diagnosed with Bell’s palsy versus stroke. Id. at 35. Petitioner’s Bell’s palsy manifested twelve days after her flu vaccination. However, there is no statement or opinion by a treating physician or expert that the time frame between vaccination and her symptoms was medically appropriate to infer vaccine causation. Therefore, the undersigned finds that petitioner failed to provide proof of Althen Prong Three.

**V. CONCLUSION**

It is clear from the medical records that petitioner went through a period of illness and the undersigned extends her sympathy to her for the hardship she experienced. However, the decision in this case cannot be based upon sympathy for the petitioner but rather an analysis of the evidence.

For the reasons discussed above, the undersigned finds that petitioner has not established by preponderant evidence that she is entitled to compensation and her petition must be dismissed. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**

Nora Beth Dorsey  
Special Master