In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-651V
Filed: August 19, 2021
PUBLISHED

GINA KIDWELL, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Vasovagal Syncope; Table Injury; Presyncope; Causation-in-fact; Influenza Vaccine

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On May 18, 2017, petitioner, Gina Kidwell, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012)[2], alleging that she suffered an episode of syncope following her receipt of an influenza ("flu") vaccination on October 13, 2015. Petitioner was driving at the time of the alleged syncope and was involved in a motor vehicle accident, resulting, she further alleges, in injuries that persisted for more than six months.[3] Accordingly, petitioner alleges that her syncope, subsequent accident, and resulting injuries, were all caused by the flu vaccine.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 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 the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Throughout this decision, references to "§300aa" will refer to the relevant sections of the National Childhood Vaccine Injury Act.

[3] Petitioner is never more specific in her pleadings than to characterize her persistent symptoms as headache and unsteadiness in her walk. (ECF No. 1, p. 2; ECF. No. 46, p. 2.) However, her medical records reference her post-accident condition as post-concussion syndrome. (E.g. Ex. 5, pp. 21-22.) For ease of reference, this decision refers in some instances to petitioner's post-accident injuries as a post-concussion syndrome; however, as discussed below, the question of whether petitioner's post-accident condition represented a post-concussion syndrome is not reached.

Additionally, following a motion for reconsideration, petitioner was provided an opportunity to address whether she may have instead suffered a presyncope caused-in-fact by her vaccination. For the reasons set forth below, I conclude that petitioner is not entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists "vasovagal syncope" as a compensable injury if it occurs within one hour of administration of an influenza vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by a statutory "Qualifications and aids in interpretation" ("QAI"), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. § 300aa-14(a). To be considered a Table "syncope" petitioner must show that her injury fits within the following definition:

> Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent

syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

42 CFR § 100.3(c)(13).

Petitioner did not initially indicate in her petition whether she was pursuing her claim as a Table Injury. (ECF No. 1.) However, she later filed an amended petition asserting a Table Injury of vasovagal syncope. (ECF No. 46.)

Alternatively, if no injury falling within the Table can be shown, the petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Following a motion for reconsideration, petitioner has also contended in the alternative that she suffered presyncope that was caused-in-fact by her vaccination. (ECF No. 82; Exs. 32-33.) Because this is not a Table Injury, there is no causal presumption available for this alternative claim.

For both Table and Non–Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

II. Procedural History

As noted above, petitioner initiated this case on May 18, 2017, alleging that she suffered a syncopal episode that resulted in an auto accident and further injuries. (ECF No. 1.) She filed supporting medical records marked as Exhibits 1-11 on May 24, 2017. (ECF Nos. 7-8.) After an initial review, respondent requested further records and Exhibits 12-19 were subsequently filed over the course of several months. (ECF Nos. 16, 19, 22, 28.)

Respondent filed his Rule 4 report on October 15, 2018, recommending compensation be denied and the petition dismissed. (ECF No. 32.) Respondent noted the lack of a Table Injury allegation, but also disputed that petitioner suffered a syncopal episode and further contended that the timing of the event was unclear. (*Id*.) Petitioner subsequently filed a vehicle accident report (Ex. 20), an affidavit by petitioner (Ex. 21), and neuropsych records (Ex. 22). (ECF Nos. 35, 40, 43.) Petitioner filed an amended petition on April 8, 2019, specifically adding the allegation that she experienced a Table Injury of vasovagal syncope. (ECF No. 46.) On June 25, 2019, petitioner filed an expert report by neurologist Marcel Kinsbourne, M.D. (ECF No. 50; Ex. 23.)

On August 29, 2019, this case was reassigned to my docket. (ECF No. 53.) Respondent filed a responsive expert report by neurologist Peter Donofrio, M.D., on November 1, 2019. (ECF No. 55; Ex. A.) A video fact hearing was subsequently held on January 30, 2020. (ECF No. 62.) Petitioner was the only witness. (*Id*.) During the hearing, additional evidence was identified. Petitioner then filed her insurance claim relative to her auto accident (Ex. 25), an affidavit by her daughter regarding a separate falling incident discussed during the hearing (Ex. 26), updated primary care records by Dr. Connie Mercer (Ex. 27), and an affidavit by an eye witness to the auto accident (Ex. 28). (ECF Nos. 69, 73.)

Thereafter, I advised the parties that pursuant to Vaccine Rule 8(d) I intended to resolve this case on the basis of written submissions and set a briefing schedule requiring simultaneous briefs. (ECF No. 74.) Neither party objected; however, in a joint motion to amend the schedule, the parties advised of additional outstanding medical records and requested that their briefs be due after the filing of the outstanding records. (ECF No. 75.) Petitioner subsequently filed additional medical records marked as Exhibits 29-31. (ECF No. 76.)

On December 21, 2020, the parties filed simultaneous briefs in support of their respective positions. (ECF No. 77-78.) Petitioner filed a brief responding to respondent's brief on January 21, 2021. (ECF No. 79.) In her briefing, petitioner raised for the first time the suggestion that she could prevail in her claim even in the absence of evidence that she suffered a loss of consciousness. (ECF No. 78, p. 4.)

I initially issued a decision dismissing this case on March 16, 2021. (ECF No. 80.) I explained that petitioner did not suffer a Table Injury of syncope because there was not preponderant evidence that she lost consciousness. In further explaining why petitioner's expert, Dr. Kinsbourne, had not alternatively established causation-in-fact for a syncope occurring in the absence of a loss of consciousness, I noted, *inter alia*, that any suggestion that petitioner suffered vaccine-related presyncope had not been substantiated. Petitioner moved for reconsideration, seeking an opportunity to have Dr. Kinsbourne directly address presyncope, and filed a supplemental report by Dr. Kinsbourne. (ECF No. 82-83; Ex. 32.)

I subsequently withdrew the dismissal decision so that petitioner's argument could be considered and ordered respondent to file a response to petitioner's motion and a responsive report by Dr. Donofrio. (ECF No. 84.) Dr. Donofrio's supplemental report and supporting literature was filed on May 26, 2021, as respondent's Exhibit C. (ECF No. 86.) On June 21, 2021, I issued an order granting petitioner's motion for reconsideration so that petitioner's supplemental submission regarding presyncope could be considered and noted that a superseding decision would issue pursuant to Vaccine Rule 10(e)(3)(A)(ii). I explained that "reconsideration is granted on the basis of concluding the record was not sufficiently complete as of issuance of the March 16, 2021 dismissal decision. This order should not be construed as indicating whether the superseding decision will reach a different result."[4] (ECF No. 88, p. 2.) I also provided petitioner an opportunity to file a report by Dr. Kinsbourne responding to Dr. Donofrio's May 26, 2021 report. (*Id*.) Petitioner filed that report on August 6, 2021. (ECF No. 90; Ex. 33.)

This case is now ripe for a superseding decision resolving this case on the written record. In the discussion that follows (Section VI), sections A, B, and C remain substantially the same as they appeared in the initial, now withdrawn, decision dismissing this case. Section D, which addresses petitioner's cause-in-fact claim, has been replaced to reflect additional analysis prompted by the further evidence presented by the parties relating to presyncope. Additions were also made to Section E, which addresses proximate causation, based on further contentions included in the supplemental expert reports.

III. Factual History

A. Petitioner's prior medical history

Petitioner has a history of depression and hyperlipidemia. (Ex. 4, p. 1.) Petitioner was also previously evaluated for syncope. On June 12, 2012, petitioner visited the emergency room with multiple medical complaints including anxiety and syncope. (Ex. 15, p. 45.) Petitioner reported experiencing aura and then flashing lights. (*Id*.) On June 20, 2012, petitioner saw Dr. Ganesh Chari for further evaluation of her syncopal episode, where she reported that she saw flashing lights followed by nausea. (Ex. 12, p. 108.) Additionally, petitioner had a follow up appointment on July 18, 2012 for syncope. (*Id*. at 106.) According to petitioner there were no further syncopal episodes.

On May 20, 2013, petitioner visited Tampa Bay Optometric Group because she had issues with seeing "squares" followed by nausea and headache. (Ex. 12, p. 92.)

[4] Special masters "must determine that the record is comprehensive and fully developed before ruling on the record." *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012); *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993.)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2). The parties must have a full and fair opportunity to present their case and develop a record sufficient for review. *Id*.

Petitioner left a message for her primary care physician ("PCP"), Dr. Daniel Terrone that she experienced an episode where she saw squares in front of her eyes, lost her balance, and became nauseous. (Ex. 15, p. 93.) A couple of months thereafter in September, petitioner reported feeling dizzy and nauseated. She felt she was having problems with her inner ear, and requested seeing a specialist. (*Id.* at 99.)

Petitioner then established care with a new PCP, Dr. David Herndon, on January 6, 2015 and reported her inner ear problems. (Ex. 4, p. 1.) Petitioner reported that she felt slightly dizzy with some nasal drip. (*Id.)* On January 20, 2015, petitioner returned to see Dr. Herndon for pain management. (*Id*. at 10.) She reported nausea and ringing in her ear. Petitioner wanted to see an ENT specialist. (*Id*.) Dr. Herndon diagnosed petitioner with subjective tinnitus and referred her to a specialist for evaluation. (*Id*. at 12.)

On January 26, 2015, petitioner saw Dr. Michael Sakellarides with complaints of allergy to smoke, recent ringing in both ears, postnasal drip, and being lightheaded due to smoke. (Ex. 8, p. 3.) Petitioner was diagnosed with benign paroxysmal vertigo and referred for vestibular studies for dizziness and audiogram for ringing in ears. (*Id*. at 5.)

On October 13, 2015, petitioner saw Dr. Steven Willis regarding her back pain. (Ex. 4, p. 61.) And additionally, on the same day, petitioner visited Dr. Herndon for follow up. (*Id.* at 64.) Her vital signs were recorded at Dr. Herndon's office at about 3:43pm. (*Id*. at 65.) During this visit, petitioner was given the flu vaccine at issue in this case in her right deltoid. (*Id*. at 68.) The exact time of vaccination was not documented. She was 80 years old at the time.

B. October 13, 2015 auto accident

After departing Dr. Herndon's office, petitioner was involved in an auto accident. (Ex. 20.) According to the official Florida Traffic Crash Report, at approximately 4:30pm petitioner lost control of her vehicle, entered a parking lot to the right and collided with a parked car. (*Id*. at 2-3.) During the hearing, petitioner described the accident as follows: "I put my foot on the gas pedal. And then I'm going and all of a sudden, oh, my god, I thought my brakes aren't working. I kept – I thought it was the brakes. I kept my foot all the way down for the gas pedal. And I kept going, I said, I'm going to – there's trees all around me on both sides. I'm going to get killed. I know I'm going to die. After that I remember nothing else. Nothing." (Tr. 10-11.) Petitioner indicated the next thing she remembered was the airbag deploying. (Tr. 11-12.) She indicated that she fell to the ground when she initially exited the vehicle. (Tr. 12.) Petitioner repeated substantially the same description multiple times during the hearing. (Tr. 20, 45-46, 52-54.)

Following the accident, the most contemporaneous third-party observation of petitioner's state comes from the affidavit testimony of fact witness Timothy Skarka. (Ex. 28.) He was the individual who first helped petitioner out of the car following her accident. In relevant part he explained that "[a]fter she hit the car her foot was still on the gas. I ran over and opened the door and took her foot off the gas and turned the key

off. She did not get out of the car for a few minutes. She seemed confused. I suggested calling an ambulance because I thought she might have suffered a concussion. She said she was alright and did not want an ambulance." (*Id*. at 1.) Mr. Skarka did not indicate that he observed petitioner in a state of unconsciousness[5] and did not corroborate petitioner's recollection of falling over when she exited the vehicle. (*Compare* Ex. 28 and Tr. 11-12, 14.)

Pasco County Fire Rescue arrived at the scene by 4:39pm. (Ex. 14, p. 1.) Upon examination, they confirmed petitioner to be alert and oriented (x4) and recorded normal vital signs. (*Id*. at 3-4.) Petitioner reported that she had not experienced any loss of consciousness, voiced no medical complaints, and declined to go to the hospital. (*Id*. at 4.) The Florida Highway Patrol subsequently arrived on scene at 5:35pm. (Ex. 20, p. 1.) The officer indicated that petitioner was not distracted at the time of the accident, did not have obscured vision, and was "apparently normal" at the time of the accident. (*Id*. at 2.) He cited petitioner for careless driving. (*Id*.) Petitioner testified that following the accident she "felt fine" and "just wanted to go home." (Tr. 16.) It wasn't until she went home that she "fell on the bed [and] that was it," causing her to conclude the next day that she should go to the hospital. (Tr. 17.) Petitioner could not recall her interaction with Fire Rescue (Tr. 15-16); however, on cross-examination she acknowledged that she would have been truthful in speaking with them (Tr. 51-52).

C. Post-accident hospital visit

When she first reported for triage at the emergency department the next day, petitioner reported that she "felt disoriented while driving" and "snapped out of it when [the] airbag deployed." (Ex. 13, p. 22.) A handwritten intake form further records that she had a "'black' out before accident." (*Id*. at 23.) A further history indicates that she "got disoriented and doesn't remember speeding across 2 lanes and hitting a car on the other side" and further that she "couldn't see." (*Id*. at 14.) The initial clinical impression at the emergency department was syncope and closed head injury. (*Id.* at 21.) Petitioner was admitted for disorientation and possible syncope. (*Id.* at 33.) Petitioner was first evaluated by Dr. Mukeshumar Patel, who assessed her with sudden loss of vision with disorientation of unknown etiology. (*Id.* at 34.)

When petitioner reported for a neurology consultation with Dr. Rakesh P. Shah, she reported that she "was just driving back to her home, was in the car, knew that she was making a left turn, was just waiting for the traffic to just pass by, and then she suddenly lost her control, could not focus, could not see, and everything kind of foggy, slightly blacked out, and *without any loss of consciousness*. The patient just woke up after she hit another car in the apartment and the patient was kind of surprised herself, was giving all the answers appropriately to the state trooper . . ."[6] (Ex. 13, p. 36

[5] This is only to note that Mr. Skarka did not confirm any loss of consciousness. To the extent petitioner contends that she "woke up" when the airbag deployed (Tr. 11-12), the two accounts are not inherently in conflict.

[6] One could question the apparent inconsistency within this record – indicating no loss of consciousness immediately followed by reference to having "woke up." (Ex. 13, p. 36.) However, this is consistent with

(emphasis added).) Dr. Shah felt petitioner's description of not being able to see was "questionable" and concluded there were "no signs of syncopal episode." (*Id*. at 37.)

Importantly, although the emergency department histories also state that "[patient] states hit head on roof of car" and that she suffered a "head injury" (*Id.* at 22-23), petitioner subsequently acknowledged in testimony that she did not ever remember hitting her head and that she was told by others, most notably her husband, as an after-the-fact rationalization that she must have hit her head. (Tr. 17, 47-48, 61.) This was the reason she ultimately sought care. (Tr. 17.) Additionally, Dr. Shah noted that petitioner answered the state troopers questions "appropriately," but petitioner also testified that she was "dazed" and in "shock" as a result of the accident and, as noted above, Mr. Skarka likewise observed petitioner to seem confused in the moments after the accident. (Tr. 16, 65; Ex. 28, p. 1.) Petitioner further testified that Dr. Shah observed her to be "not acting right," contributing to the impression that she suffered a concussion. (Tr. 18-19.) Asked to review and confirm the history recorded by Dr. Shah, petitioner testified "I'm not sure," but also indicated "I might have said something." (Tr. 20.) Accordingly, it is very difficult to discern from the most contemporaneous medical records what statements reflect reliable, independent recollections of what petitioner experienced during her auto accident.

During the course of her one-day hospitalization, petitioner had various tests conducted, including a chest x-ray, EEG, ultrasound, which all had presented normal results. (Ex. 5, pp. 1-4.) Additionally, petitioner's neck, head, brain, and spine CT scans did not show any remarkable findings. (*Id.* at 7.) Petitioner was discharged from Medical Center of Trinity on October 15, 2015. (Ex. 13, p. 38.) Petitioner's discharge diagnosis was "sudden loss of vision with disorientation, unknown etiology, resolved." (Ex. 5, p. 7.)

D. Subsequent medical history

Petitioner was not seen by any doctor again until December 10, 2015, when she saw neurologist Indira Umamaheswaren, M.D. (Ex. 5, p. 21.) Petitioner's description of her alleged syncopal episode continued to evolve. Whereas she previously denied losing consciousness and described being "slightly blacked out," she described to Dr. Umamahesawaren experiencing everything becoming "white." (*Id*.) She was assessed with post-concussion syndrome and an episode of loss of awareness of unclear etiology, with a differential diagnosis being syncope versus seizures versus cardiac etiology. (*Id*. at 22.)

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the description elicited in the emergency department wherein petitioner described only disorientation followed by "snap[ping] out of it." (Ex. 13, p. 22.) During the hearing, petitioner similarly indicated that the airbag "woke me up" in the context of indicating that this was the "next thing I can remember" in the aftermath of having lost control of the vehicle. (Tr. 11-12.) It is also noteworthy that the record includes the characterization of petitioner as "slightly blacked out," further evidencing that Dr. Shah is attempting to capture a history being provided by petitioner that indicates something less than a complete blackout. (Ex. 13, p. 22.)

On January 14, 2016, petitioner returned to see Dr. Umamaheswaren for follow up regarding her post-concussion syndrome. (Ex. 5, p. 26.) Petitioner still had mild headaches and feelings of being off balance while walking. Petitioner was not feeling herself and had difficulty focusing. (*Id*. at 27.) Dr. Umamaheswaren advised that petitioner's symptoms could take months to resolve. (*Id*. at 28.) Petitioner returned for a follow up on June 30, 2016, complaining of similar symptoms as well as lack of energy. (*Id.* at 30.)

Petitioner first saw Dr. Tedodulo Mationg on March 10, 2016 with complaints of nausea, headache, sleep problems, and frequent urinary tract infections. (Ex. 11, p. 29.) Dr. Mationg advised petitioner to have a colonoscopy and encouraged her to follow up with her psychiatrist. (*Id*. at 31.) Dr. Mationg further assessed petitioner with generalized anxiety disorder. (*Id*. at 30-32.)

On August 22, 2016, through referral from Dr. Mationg, petitioner saw Dr. Krishna Ganti for left ear problems. (Ex. 9, p. 12.) Petitioner reported that she had a head injury over a year ago, but that there was no loss of consciousness ("no LOC"). She presented with several months of fullness, pain, and pressure feeling over her left ear. (*Id*.) Dr. Ganti suspected Meniere's disease or inflammatory labyrinthitis. (*Id*. at 13.)

Petitioner saw Dr. Ganti again on September 6, 2016 regarding her hearing loss. (Ex. 11, pp. 86-87.) Petitioner again reported that she had a car accident last year, where she was flustered and appeared confused, and although she could not provide more details, petitioner recalled having a concussion. (*Id.* at 86.) Although exam findings and test results suggested Meniere's disease or inflammatory labyrinthitis, at this visit, petitioner was diagnosed with sensorineural hearing loss and subjective tinnitus. (*Id*. at 87.)

Petitioner called Dr. John Pirrello's office on June 28, 2017, stating that she lost her eyesight and fell. (Ex. 15, p. 157.) Petitioner stated that she was not dizzy at the time of the fall and did not know how she fell but that she could not see. (*Id*.) Petitioner was subsequently seen by Theresa R. Haffner, ARNP, for her fall on June 30, 2017. (*Id*. at 159.) NP Haffner recorded that petitioner lost her footing and fell forward at a department store, and further that petitioner denied any head trauma and loss of consciousness. (*Id*.) Petitioner wanted to discuss her worsening anxiety. (*Id*.) Although fall precautions were discussed and there was a fall risk screening, no advanced care planning was needed. (*Id*. at 160-161.) Additionally, on July 20, 2017, petitioner called her PCP's office again to add that when she fell, her vision went black and after a moment she regained sight as if "someone turned the lights back on." (*Id*. at 170.) Petitioner also indicated that she had a panic attack earlier on the day of the fall that may have set off her temporary blindness.[7] (Ex. 15, p. 170.) Petitioner saw Dr. Pirrello on July 20, 2017 regarding abdominal pain, unrelated to her fall. (*Id*. at 171.)

[7] Petitioner's daughter, who was with her at the time of the fall, submitted an affidavit in which she averred that petitioner fell, but did not pass out. (Ex. 26.) The affidavit did not address whether petitioner separately experienced any loss of vision as reflected in her reports to physicians.

On October 22, 2019, petitioner reported to Dr. Shah that she was in a lot of stress, had mental confusion, and some issues with short-term memory loss. (Ex. 31, p. 6.) Dr. Shah ordered a brain MRI to look for any signs of memory loss or dementia. Petitioner saw Dr. Shah again on December 2, 2019 to discuss her brain MRI results. (*Id.* at 1.) Her MRI showed chronic periventricular white matter changes without acute ischemic stroke. (*Id*.) Compared with petitioner's August 28, 2016 MRI, there were extensive bilateral white matter T2 and FLAIR sequence hyperintensities and bilateral inflammation of her mastoids. (*Id*. at 3.) Petitioner was diagnosed with dementia, most likely vascular dementia. (*Id.* at 1.)

IV. Expert Opinions

A. Petitioner's expert, Marcel Kinsbourne, M.D., initial report

Dr. Kinsbourne explained that syncope results when there is a drop in blood pressure and diminution of perfusion of the brain. (Ex. 23, p. 2.) He indicated that "[a]mong the causes is emotional distress, associated with blood drawing or needle puncture in [the] course of vaccination. An emotional reaction to the needle, the pinprick or the association with blood can cause an exaggerated response of the vagus nerve, reducing the blood pressure." (*Id*.)

With regard to petitioner's own presentation, he opined "Ms. Kidwell had an unmistakable syncopal episode. Prominent among symptoms of syncope are feeling funny (probably dizzy), being confused and having blurry and tunnel vision. She lost control of her car. Her [primary care physician] had omitted the recommended 15 minutes of staying seated in the office after her vaccination." (*Id*. at 1.) Dr. Kinsbourne indicated that petitioner's medical records do not reflect any cardiovascular cause for her syncope nor any other syncopal episodes. (*Id*.) Dr. Kinsbourne did not address petitioner's post-concussion syndrome.

B. Respondent's expert, Peter Donofrio, M.D., initial report

Dr. Donofrio similarly described the mechanism of syncope as relating to insufficient blood flow to the brain, but stressed that it represents a form of transient loss of consciousness. (Ex. A, p. 5.) He identified vasovagal syncope in particular as being reflex-mediated in response to prolonged standing or emotional distress. (*Id*.) Dr. Donofrio explained that syncope has numerous causes in addition to the type of emotional distress highlighted by Dr. Kinsbourne, including orthostatic hypotension from dehydration or bleeding, adverse reactions to medication, dysautonomia, and can be secondary to a number of cardiovascular conditions. (*Id*.)

Dr. Donofrio disagreed that petitioner's October 13, 2015 "spell" constituted a syncopal event. (*Id.*) In reaching this conclusion he relied in particular on the fact that petitioner initially denied losing consciousness and also that her description of the event has been inconsistent. (*Id*. at 5-6.) Dr. Donofrio also suggested that other causes for petitioner's spell are evidenced in her medical records. (*Id*.) Additional spells occurring

on June 20, 2012, May 20, 2013, and July 20, 2017, as well as reports of "squares" in her vision, flashing lights, and nausea, are consistent with migraines. (*Id*. at 6.) Petitioner was also later diagnosed with Meniere's Disease in October of 2016. (Ex. A, p. 6.) Additionally, petitioner previously demonstrated bradycardia on August 23, 2015 and June 11, 2012. (*Id*.) Dr. Donofrio opined that the October 13, 2015 spell is consistent with bradycardia leading to loss of blood pressure and perfusion of blood to the brain. (*Id*.) Dr. Donofrio did not address petitioner's post-concussion syndrome.

C. Dr. Kinsbourne's supplemental report accompanying petitioner's motion for reconsideration

In his supplemental report, Dr. Kinsbourne confirmed that his description of Ms. Kidwell as experiencing symptoms of "feeling funny (probably dizzy), confused, and losing her vision" antecedent to her car accident did constitute a description of presyncope rather than syncope. (Ex. 32, p. 1.) He explained syncope as the end result of having fainted (or lost consciousness) whereas presyncope constitutes the preceding process of fainting. (*Id*. at 2.) Dr. Kinsbourne characterized petitioner's symptoms, i.e., presyncope, as "inherent to the process of fainting," but acknowledged that it is unclear whether Ms. Kidwell ultimately reached the endpoint of lost consciousness. (*Id.* at 2.)

However, Dr. Kinsbourne suggested that the question of whether petitioner lost consciousness "does not affect the interpretation of the episode of record since the crash that ensued became unavoidable when she lost control of the vehicle. She lost control when she became confused, she lost her vision and she depressed the accelerator pedal rather than the brake pedal and maintained pressured on the accelerator until she crashed." (*Id*.) Dr. Kinsbourne suggested that the fact that petitioner experienced her loss of control in the context of presyncope (which he characterizes as "not usually so sudden") explains why she was able to subsequently describe the process. (*Id*.) He indicated that "[p]resyncopal symptoms alert people that they are about to lose consciousness. They lie down in order not to lose consciousness. At the wheel of a moving car that is not an option, however." (*Id.* at 3.)

Dr. Kinsbourne acknowledged that Ms. Kidwell's age and medical history may have left her at greater susceptibility to fainting. (*Id*.) Additionally, whereas he indicated in his first report that petitioner had experienced no other episodes of syncope (Ex. 23, p. 1), he conceded in his supplemental report that there were two other episodes of syncope (Ex. 32, p. 3.) Nonetheless, he contended that "her episode of record was caused by her reaction to having been vaccinated and not by any other event." (Ex. 32, p. 3.)

With respect to Dr. Donofrio's report, Dr. Kinsbourne agreed that Ms. Kidwell's spells on June 29, 2012, May 20, 2013, and July 20, 2017, which included vision changes, were consistent with migraine, but indicated that Ms. Kidwell did not complain of headache prior to her accident and none of her treating physicians diagnosed the episode as relating to a migraine. (Ex. 32, at 4.) Conversely, Dr. Kinsbourne noted that petitioner's Meniere's disease could not explain her vision changes or disorientation at

the time of the accident. (*Id*.) Dr. Kinsbourne contended that there is no evidence to support bradycardia at the time of the accident or any evidence of basilar artery narrowing. (*Id*.)

D. Dr. Donofrio's supplemental report accompanying respondent's response to petitioner's motion for reconsideration

In his supplemental report, Dr. Donofrio stressed that Dr. Shah's initial post-accident differential diagnosis included suspicion of posterior segment transient ischemic attack ("TIA"). (Ex. C, p. 1 (citing Ex. 25, pp. 228-29.) Dr. Donofrio explained that TIA can likewise cause loss of vision, feeling funny, and confusion, and can do so with preserved consciousness. (*Id*. at 2.) TIA commonly lasts for only 10-20 minutes and leaves no neurologic deficit, meaning that a negative evaluation does not rule it out as a cause of petitioner's episode. (*Id*.) Dr. Donofrio stressed petitioner's advanced age and the fact that she had a narrowed basilar artery as contributing to the likelihood she experienced a TIA. (*Id*.) Whereas Dr. Kinsbourne had denied any evidence petitioner has a narrow basilar artery, Dr. Donfrio refuted that suggestion by citing petitioner's October 14, 2015 CT angiogram that demonstrated "diffusely diminished caliber" of the basilar artery. (*Id*. (citing Ex. 25, pp. 176, 280).)

Dr. Donofrio agreed that presyncope may be described as a prodrome of syncope, with symptoms including lightheadedness, general weakness, warmth, sweating, nausea, palpitations, or blurry vision, without a loss of consciousness. (*Id*. at 3.) It can last for seconds to minutes. (*Id*.) However, Dr. Donofrio indicated that it is error for Dr. Kinsbourne to imply that presyncope is the same as syncope or always leads to syncope. (*Id*. at 4.) Dr. Donofrio further stressed that the symptoms described by Dr. Kinsbourne of feeling funny, confused, and losing vision, are non-specific and that Dr. Kinsbourne was adding his own inference by interpreting "feeling funny" as dizziness. (*Id*.)

Dr. Donofrio charged Dr. Kinsbourne with speculation regarding the cause of petitioner's accident. He explained that vasovagal syncope physiologically represents a stressful event followed by a slow heart rate (bradycardia) and a drop in blood pressure. (*Id*. (citing Ex. A1 (Kidd)).) He explained that "other disorders could explain the petitioner's symptoms prior to her MVA, including panic attacks, migraine phenomena, seizures, Meniere's Disease, sinus bradycardia, and a TIA of the posterior circulation." (*Id*.)

E. Dr. Kinsbourne's final supplemental report

In his final report, Dr. Kinsbourne countered that "Dr. Donofrio maintained that what happened was any of a set of multiple different hypothetical medical events, all having in common that they are unconnected with vaccination but allegedly coincidental with the post vaccination hour. He implied any one of these hypothetical other events should be considered preponderant to the diagnosis of a syncopal process." (Ex. 33, p. 1.) Dr. Kinsbourne ultimately agreed that petitioner's narrowed basilar artery "might account for the prominence of visual changes" during petitioner's episode given that it

would point to already reduced blood flow. However, he maintained that this is better explained as a further consequence of a syncope-related drop in blood pressure and not as a stand-alone TIA. (*Id*. at 2.) Dr. Kinsbourne contended that "[v]asovagal presyncope/syncope is a well-recognized cause of traffic accidents, as the medical literature attests. The multiple possible causations that Dr. Donofrio suggested as alternatives are in contrast hypothetical, poorly documented and not seriously considered or follow up by treating physicians."[8] (*Id*. at 3.)

V. Party Positions

A. Petitioner's contentions

Petitioner contends that the record evidence is clear in demonstrating that petitioner experienced an auto accident within one hour of her influenza vaccination and that a causal presumption is therefore warranted under the Vaccine Injury Table. (ECF No. 78, p. 1.) Petitioner asserts that, consistent with syncope, she became confused and disoriented, which caused her to initially confuse the gas and brake pedals, and later passed out as her vehicle crossed traffic and ultimately collided with a parked vehicle. (*Id*. at 2.)

Petitioner contends that the subsequent medical records discussing petitioner's state at the time of the accident are "imprecise" and ultimately incorrect as far as any reference to there having been no loss of consciousness. (*Id*. at 3.) Petitioner further notes that the medical records contain no neurologic explanation for syncope. (*Id*.) Initially, petitioner also suggests that "[e]ven if the Special Master finds petitioner did not fully lose consciousness, Petitioner was clearly confused. Dr. Kinsbourne supports the event as a syncopal episode even without a total loss of consciousness."[9] (*Id*. at 4 (citing Ex. 23).) In moving for reconsideration and submitting supplemental expert reports, petitioner also effectively asserted an alternative claim that the same ultimate injuries occurred even in the absence of any loss of consciousness as a result of a vaccine-caused presyncope. (ECF No. 82; Exs. 32-33.)

Petitioner acknowledges that her testimony was affected by a failing memory, but contends that "even with that disability, the facts that are relevant to this case came through, again and again." (ECF No. 78, p. 5.) Petitioner also asserts that her "version of events is the only one that makes sense. A person who is conscious takes their foot

[8] In his final reported Dr. Kinsbourne cited as references "Mayo Clinic, Vasovagal Syncope" and "Whitledge JD, Ali N, Basit H, and Grossman SA (2021) NCBI Bookshelf, NIH." (Ex. 33, p. 4.) Petitioner did not file these materials; however, they are available online and I have reviewed them. *See* https://www.mayoclinic.org/diseases-conditions/vasovagal-syncope/symptoms-causes/syc-20350527, last accessed August 11, 2021, and https://pubmed.ncbi.nlm.nih.gov/29083783/, last accessed August 11, 2021. The latter was also filed by respondent accompanying Dr. Donofrio's supplemental report as Exhibit C, Tab 1.

[9] For the reasons discussed above, this would be inconsistent with a Table Injury regardless of Dr. Kinsbourne's endorsement. According to the QAI, vasovagal syncope "means loss of consciousness (fainting) and postural tone." 42 CFR §100.3(c)(13). I will separately address whether Dr. Kinsbourne's opinion could support an alternative cause-in-fact claim.

off the gas. They do not drive into a parking lot at 50 miles per hour and run into parked cars. Syncope is the only explanation for what we know happened." (*Id*. at 5.)

In response to respondent's contentions, petitioner further stressed that there is evidence in the contemporaneous medical records both that petitioner lost consciousness and that she suffered syncope. (ECF No. 79, p. 2.) Petitioner also stressed that she had no signs of dementia at the time of the accident, further explaining "[a]nyone might miss the brake pedal and accidentally hit the gas. However, everyone would take their foot off the pedal when they started accelerating instead of slowing down. The exception would be if someone had lost the ability to control their motor functions because they were suffering a syncopal event." (*Id*. at 3.)

B. Respondent's contentions

Regarding the Table claim alleged by petitioner, respondent first stressed that petitioner has not established the time of her vaccination, leaving it impossible for her to demonstrate that her alleged syncopal event occurred within one hour of vaccination. (ECF No. 77-1, p. 19.) He additionally contended that petitioner's medical records do not substantiate a syncope diagnosis, stressing the evidence that suggests there was no loss of consciousness. (*Id*. at 20.) To the extent petitioner's testimony and allegations contradict the medical records, respondent argues that petitioner's failing memory detracts from her credibility. (*Id*. at 21-22.)

Respondent argues that Dr. Kinsbourne's report is not credible with respect to a cause-in-fact claim because it relies on a diagnosis (syncope) that is not supported by petitioner's medical records. (*Id*. at 24.) Respondent also stresses that petitioner's treating physicians did not support vaccine-causation, noting that her primary care physician opined that her accident was "[l]ikely not from flu vaccine." (*Id*. at 24 (quoting Ex. 4, pp. 69-70).) Respondent further argues that any cause-in-fact claim would suffer the same limitation as her Table claim with respect to establishing the timing of the alleged injury. (*Id*. at 24-25.)

Finally, respondent also argues that in either event petitioner "has ignored potential alternative causes of her symptoms." (ECF No. 77-1, p. 25.) Specifically, respondent contends that petitioner's overall medical history suggests the October 13, 2015 episode is more likely to have been caused by a migraine phenomenon, Meniere's disease, or sinus bradycardia. (*Id*. (citing Ex. 23, p. 1; Ex. A, p. 6).)

VI. Discussion

A. The weight afforded petitioner's testimony

A critical threshold question presented in this case is how much weight to afford petitioner's testimony. Both parties acknowledge that petitioner's testimony was affected by failing memory. (ECF No. 78, p. 5; ECF No. 77-1, p. 21-22.) However, they disagree with respect to the specific circumstances of her dementia at the time of the hearing. While respondent stressed that petitioner was assessed as having dementia

two months prior to the hearing (ECF No. 77-1, n.3), petitioner replied that her dementia was "mild, early onset" and she has never been deemed incompetent or otherwise mentally unsound (ECF No. 79, p. 4).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 300aa-11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be trustworthy. *Cucuras v. Sec'y of Health & Human Servs.,* 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe v. Sec'y of Health & Human Servs.*, 95 Fed.Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"). Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974, 113 S.Ct. 463, 121 L.Ed.2d 371 (1992) (*citing United States v. United States Gypsum Co.*, 333 U.S. 364, 396, 68 S.Ct. 525, 92 L.Ed. 746 (1948) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight."); *but see Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382 (Fed. Cir. 2021) (holding that "[w]e reject as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions.").

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are,

themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy*, 23 Cl. Ct. at 733). Ultimately, a determination regarding a witness's credibility is often needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

During the hearing, petitioner repeatedly denied having a medical history consistent with what had been recorded in her medical records relative to multiple medical providers. (For example, *compare* Tr. 80 (denying panic attacks) and Ex. 15, pp. 159, 170; Ex. 27, pp. 7-9, 50-51; *compare* Tr. 76-77 (denying referral to psychiatrist) and Ex. 11, pp. 31-32, 38-39; *compare* Tr. 22-23 (denying migraines) and Ex. 12, pp. 92-95; *compare* Tr. 28-29 (denying Meniere's disease) and Ex. 9, pp. 12-13; Ex. 11, pp. 88-93.) Petitioner did not provide any reason for the discrepancies or explanation of why her medical records did not align with her recollections. However, she nonetheless purported to offer testimony regarding the details of encounters she acknowledged being unable to recall. (Tr. 17-18, 56, 62, 70-75.) Petitioner also offered some contradictory testimony regarding her prior health. (*Compare* Tr. 21-22 (indicating bloodwork is "always perfect") and Tr. 23 (acknowledging taking cholesterol medication).) A very notable example featured prominently in respondent's cross-examination. Petitioner testified clearly, and unprompted, on direct examination that she had never had a prior influenza vaccination. (Tr. 8.) She confirmed the same on cross-examination. (Tr. 37.) On further cross-examination, respondent presented petitioner with multiple consent forms and administration records for prior influenza vaccinations, which petitioner acknowledged signing. (Tr. 37-40.) Petitioner's utter surprise when presented these documents was obvious during the hearing and even remains discernable from the resulting transcript. (*Id*.)

My observation of the quality of petitioner's testimony regarding her own medical history is that it is clearly not reliable enough to overcome the weight typically allowed contemporaneous medical records. Accordingly, I do not credit any of petitioner's testimonial denials of relevant aspects of her medical history over what appears in her contemporaneously recorded medical records.[10] Petitioner's dementia diagnosis and her concession in her briefs that her memory was affected at the time of the hearing

[10] Notably, however, as noted in Section III C, above, even the contemporaneous histories petitioner provided after her accident are not entirely clear regarding what she could recall versus what she rationalized as the cause of her condition.

may help to further explain how petitioner's testimony came to be unreliable with respect to her medical history, but the quality of the testimony is apparent regardless of that explanation.

Importantly, however, this does not account for the whole of petitioner's testimony. Aspects of petitioner's testimony that relay affirmative recollections rather than negative recollections (i.e. denials) cannot easily be explained by mere memory loss. Moreover, petitioner persuasively stressed in her briefs that, even faced with advanced age and dementia, "a traumatic event like the car crash at issue is still indelibly imprinted in her mind." (ECF No. 79, p. 4.) In that regard, petitioner was very clear in testifying as to the affect the accident had on her. She testified that the memory of the accident caused her to experience ongoing fear that led her to stop driving. (Tr. 21, 67-68.) This is also supported by her reports to physicians. (*E.g.*, Ex. 5, p. 21.) Accordingly, petitioner's specific *affirmative* recollections will be weighed against the other record evidence on an individual basis.

B. Petitioner's auto accident likely occurred within one hour of vaccination

Respondent stresses that the exact time that petitioner was vaccinated is unclear. (ECF No. 77-1, p. 19.) While this is true – the vaccination record does not indicate the time of administration (Ex. 1) – there is sufficient circumstantial evidence to conclude that it is more likely than not that petitioner's alleged syncopal event (if it occurred) happened within one hour of her influenza vaccination.

The fact that petitioner's vaccine was administered during her primary care appointment at Dr. Herndon's office is well documented. (Ex. 1; Ex. 4, p. 68.) There is no evidence that petitioner was seen by anyone in Dr. Herndon's office prior to 3:43pm when her vital signs were first recorded. (Ex. 4, p. 65.) Emergency dispatch and accident report records confirm that petitioner's subsequent auto accident was reported between 4:32pm and 4:38pm, which is less than an hour after petitioner's medical appointment *likely began* based on the above-referenced time stamp.[11] (Ex. 14, p. 1; Ex. 20, p. 1.) Petitioner also stresses there is no evidence of record contradicting her assertion that the accident occurred within one hour of vaccination. (ECF No. 79, p. 4.)

Accordingly, even without knowing the precise time of vaccination, there is preponderant, albeit not definitive, evidence that petitioner's auto accident (immediately preceded by her alleged syncope) occurred within one hour of her vaccination.[12]

[11] Potentially consistent with this, petitioner believed her appointment was at 4:00pm or later and that her vaccination occurred after she was seen by her doctor. (Tr. 6-7, 41-42.) This arguably provides further evidence regarding the timing of petitioner's vaccination; however, the time stamp(s) on the medical record remain the best available evidence regarding the time she was actually seen. Notably, vital signs are typically taken at the beginning of an appointment so they may be considered during the encounter.

[12] The Vaccine Act instructs that the special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such

However, this does not necessarily mean that what petitioner experienced constituted Table Injury of vasovagal syncope.

C. There is not preponderant evidence that petitioner lost consciousness or suffered a Table Injury of vasovagal syncope

A difficult and fundamental issue in resolving this case is the fact that petitioner was alone at the time of her alleged syncopal event, has acknowledged being unable to remember key moments, and subsequently has not provided a consistent description of what actually happened inside her vehicle at the time of the accident. The beginnings of this inconsistency arise as early as the moments following the accident and it affects the medical histories she provided to physicians following her accident. Because petitioner bears the burden of establishing the factual circumstances of her claim (§ 300aa–13(a)(1)(A)), these difficulties prevent any finding by preponderant evidence that petitioner lost consciousness at or around the time of her accident. Accordingly, there is not preponderant evidence that she suffered a Table Injury of vasovagal syncope.

As explained in greater detail in Section III B, above, petitioner's contemporaneous account to first responders was that she did not lose consciousness, causing her to receive a traffic citation for careless driving. (Exs. 14, 20.) Moreover, the only witness on the scene did not confirm any loss of consciousness. (Ex. 28.) As reflected in Section III C, above, her subsequent reports to medical providers when hospitalized the next day were inconsistent in reporting whether she experienced a loss of consciousness. (Ex. 13, pp. 22, 36.) Additionally, the record as a whole reveals even those contemporaneous accounts to be a mix of recollection and after-the-fact rationalization.

To some extent this is understandable. If petitioner was, in fact, unconscious, she could not be expected to recall her own unconsciousness. Nor does it seem possible to meaningfully parse her later report of "loss of vision" or being "slightly blacked out" coupled with an inability to recall from a true loss of consciousness.[13] (*Id.* at 22, 36.) However, these explanations still remain inconsistent with petitioner's specific *denial* of having lost consciousness, made both to first responders and to her first post-accident neurologist, Dr. Shah, the latter of whom explicitly considered and

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symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." § 300aa-13(b)(2).

[13] During the hearing, I asked petitioner to compare what she experienced in her car on that day to another seemingly similar incident, but this did not help to resolve the issue. Petitioner's medical records reflect that in June of 2017, she momentarily lost her vision while shopping and fell down. (Ex. 15, pp. 157-159.) As with the October 2015 episode, she denied loss of consciousness or dizziness. (*Id*.) In describing this incident during testimony, petitioner confirmed that she was able to recall that "it went dark and I knew I was going to fall." (Tr. 80.) I asked petitioner to focus on the last moment she could recall before the auto accident and compare it to what she experienced when she fell down. She indicated it was "nothing like that, nothing." (Tr. 81.) I specifically asked petitioner if she could recall losing her vision after she saw the trees "whirring by." She could not recall. (*Id*.)

rejected the possibility that petitioner had experienced a syncopal event.[14] (Ex. 14, p. 4; Ex. 5, pp. 7-8.) To deny a loss of consciousness is to recall remaining conscious. Importantly, although she repeatedly disputed during the hearing any suggestion that she did not lose consciousness, petitioner could not disclaim the reports contained in either Dr. Shah's or the first responders' records. Upon review of this history contained in Dr. Shah's record, she indicated that she could not recall and "might have said something." (Tr. 20.) She also could not recall her interactions with the fire department at the accident scene but vouched for her truthfulness to them. (Tr. 51-52.) Petitioner again confirmed much later that she did not lose consciousness when she first saw Dr. Ganti in August of 2016. (Ex. 9, p. 12.)

Moreover, petitioner's hearing testimony confirms that she has a clear and cogent recollection of losing control of her vehicle, including her specific recollection of seeing trees pass by along the side of the road and of being afraid for her safety. (Tr. 10-12.) Additionally, contrary to her argument that unconsciousness is the only possible explanation for the accident, petitioner also specifically confirmed in testimony that she continued to depress the gas pedal "all the way" after losing control because she mistakenly believed she was pressing the brake pedal and the brakes were failing. (Tr. 10-11, 20, 54.) This testimony is not consistent with a loss of consciousness. In her earlier affidavit, petitioner had likewise not indicated any loss of consciousness. (Ex. 21, p. 1.)

Although petitioner testified that she could not recall what subsequently happened in the final moments before impact, without more, and especially in light of the above, this does not *a fortiori* suggest that she lacked consciousness due to syncope. She reasonably noted that "it happened so fast." (Tr. 54.) Petitioner described the events as "all hell br[eaking] loose" and also explained that she was "dazed" and in "shock" as a result of the accident. (Tr. 17, 56, 65.) Additionally, the only eyewitness available was concerned petitioner may have had a concussion and, indeed, she was later treated for post-concussion syndrome.[15] (Ex. 28; Ex. 5, pp. 20-23.) Petitioner also has a history of panic attacks. (Ex. 15, p. 170; Ex. 27, pp. 7-9.) Even without suspecting her subsequently diagnosed dementia, these are factors that could plausibly contribute to petitioner's failure to recall the final moments of her

[14] The fact that Dr. Shah discussed with petitioner whether she lost consciousness in the context of assessing whether she experienced syncope is significant because petitioner urges that petitioner's motivation should be considered in assessing her medical records. (ECF No. 79, pp. 1-2.) Specifically, petitioner argues that the first responder reports should be discounted because she denied losing consciousness on the day of the accident in an effort to avoid being hospitalized. (*Id.*) In contrast, by the time petitioner was seen by Dr. Shah she was already hospitalized and actively seeking medical treatment.

[15] Given that petitioner clearly recalls initially losing control of the vehicle before later being unable to recall subsequent events, this raises the question of whether a concussion and post-concussion syndrome could instead explain the entirety of her presentation, including her alleged momentary loss of consciousness and/or inability to remember the final moments of the accident. However, because this would require additional expert opinion regarding the nature of concussions and their effects, I do not reach that question.

accident that do not implicate any syncope-induced confusion or lack of consciousness. Considering the record as a whole, petitioner's lack of memory may be potentially consistent with a loss of consciousness, but it does not in itself provide preponderant evidence favoring petitioner's assertion that a loss of consciousness did occur.

D. Petitioner has not met her burden of proof with respect to any alternative cause-in-fact claim

Setting aside the question of whether petitioner lost consciousness as required by the specific requirements of the Vaccine Injury Table, petitioner also asserts that Dr. Kinsbourne's opinion supports her contention that she suffered a syncopal or presyncopal event caused-in-fact by her vaccination regardless of whether she experienced a loss of consciousness. Although petitioner is correct that a flu vaccine can cause syncope and presyncope, there are several issues relative to *Althen* prong two, requiring a logical sequence of cause and effect showing that petitioner's vaccination did cause her injury, that prevent petitioner from establishing any cause-in-fact claim by preponderant evidence.

Petitioner's burden under the first *Althen* prong is to provide, by preponderant evidence, "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). In that regard, Dr. Kinsbourne and Dr. Donofrio both agree that vasovagal syncope results from a loss of blood perfusion in the brain that can be brought about by, among other things, emotional stress. Dr. Kinsbourne's further suggestion that a needle injection can cause such stress appears to be sound and reliable insofar as the potential for syncope is factored into the standard of care when administering the flu vaccine. (*E.g.*, Ex. 10, p. 5.) While Dr. Kinsbourne was initially unpersuasive in applying the term "syncope" to any such episode regardless of whether a loss of consciousness occurred (Ex. 23), his supplemental reports adequately explain that presyncope can constitute the prodrome of syncope and represent the same physiologic process only incomplete (Ex. 32-33).

Dr. Donofrio stresses that syncope and presyncope are not synonymous and that it is speculative to suggest that vaccination could cause presyncope in the same manner as syncope (Ex. C, pp. 3-4); however, he acknowledges vasovagal syncope to stem from a stressful event leading to a slowed heart rate and a drop in blood pressure. (*Id*. at 4.) Although Dr. Donofrio observed that presyncope does not always lead to syncope, he did not explain why the physiologic process of lowered blood pressure would necessarily lead to a complete loss of consciousness in all instances where it was initially triggered by a vaccination. Dr. Donofrio's objection appears to be that presyncope as a concept is nonspecific and broader than what Dr. Kinsbourne discusses, but this concern speaks to the "did it" type of analysis under *Althen* prong two more so than the "can it" type of analysis under *Althen* prong one. Accordingly, petitioner has satisfied *Althen* prong one with respect to either syncope or presyncope.

The second *Althen* prong requires proof of a logical sequence of cause and effect connecting vaccination and injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). However, medical records and/or statements of a treating physicians do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

Initially, Dr. Kinsbourne, opined that what petitioner experienced was syncope, highlighting dizziness, confusion, and blurry or tunnel vision as "prominent" symptoms[16] without specific respect to a loss of consciousness and without specifically invoking presyncope. (Ex. 23, p. 1.) Petitioner then argued Dr. Kinsbourne's opinion supported a claim for syncope occurring with or without a loss of consciousness. (ECF No. 78, p. 4.) That specific framing is unpersuasive in that syncope necessarily refers to a loss of consciousness. (*E.g.*, Ex. 10, p. 5 (vaccine package insert characterizing syncope as fainting that "may be accompanied" by transient neurological signs such as visual disturbance); Ex. A, Tab 1, p. 1 (characterizing syncope as transient loss of consciousness that "is often preceded by" symptoms such as lightheadedness or blurred vision).) Therefore, because I concluded that there is not preponderant evidence petitioner lost consciousness, it would be impossible for petitioner to prove a cause-in-fact claim for syncope based on the facts of this case.

In his supplemental reports, Dr. Kinsbourne confirms that syncope and presyncope are not synonymous and contends that, in the absence of any loss of consciousness, petitioner's symptoms as he describes them remain consistent with presyncope. (Ex. 32, pp. 1-2.) He further contends that this does not change the analysis because presyncope is equally as capable of resulting in an auto accident. (*Id*. at 2.) However, regardless of whether presyncope would be likely to result in an auto accident, this more nuanced opinion by Dr. Kinsbourne remains unpersuasive in contending that the record evidence preponderates in favor of a vaccine-caused presyncope as a medical explanation for the events at issue.

There is no question in this case that it is impossible to know what exactly occurred in Ms. Kidwell's car on October 13, 2015. As described above, Ms. Kidwell was an inconsistent historian even in the hours and days immediately following the

[16] Dr. Kinsbourne's reference to tunnel vision would seem to be potentially inconsistent with petitioner's testimony that she observed trees passing by as she lost control. (Tr. 11, 13, 32, 46, 53-55, 64-65, 81.) This testimony might suggest intact peripheral vision. Dr. Donofrio also observes that Dr. Kinsbourne is taking an inferential step by equating petitioner's report of "feeling funny" as dizziness. (Ex. C, p. 4.)

accident and her initial hospitalization failed to reveal any etiology for the episode she described. The expert reports filed in this case further highlight this fundamental difficulty. Each expert comes to a different conclusion and each expert charges the other with speculation. (*E.g*. Ex. 32, p. 4; Ex. C, p. 4.)

Importantly, however, whereas a Table Injury of vasovagal syncope would have afforded petitioner a causal presumption that may have shifted the burden of addressing this uncertainty toward respondent in demonstrating the injury to be related to a factor unrelated to vaccination, a cause-in-fact claim for either syncope or presyncope requires petitioner to do the "heavy lifting" of affirmatively proving, *inter alia*, a logical sequence of cause and effect demonstrating petitioner's vaccination to have been the cause of her episode. *Hodges v. Sec'y of Health & Human Servs.,* 9 F.3d 958, 961 (Fed. Cir. 1993) (indicating that in the absence of a Table Injury, "the heavy lifting [of proving causation] must be done by the petitioner, and it is heavy indeed."); *see also Althen*, 418 F.3d at 1280 (clarifying that "heavy lifting" characterizes the preponderant evidence standard and not any heightened burden of proof.) In that context, the inherent difficulty in knowing what happened immediately prior to Ms. Kidwell's accident works against petitioner's claim. In all events a petitioner must prove by a preponderance of the evidence the factual circumstances surrounding her claim. 42 U.S.C. § 300aa–13(a)(1)(A). Dr. Kinsbourne is not persuasive in his attempt to find clarity in the situation. In fact, Dr. Kinsbourne's opinion seeks to emphasize the coincidental temporal association between petitioner's vaccination and auto accident while seeking to deny, dismiss, or minimize the confounding information available in petitioner's overall medical history. In effect, he seeks to have a causal presumption applied even in the absence of any Table Injury and even in the absence of any clear understanding of what actually occurred.

The first issue is that there is not preponderant evidence from petitioner's post-accident treatment records that petitioner's physicians felt her episode was explained by any syncopal process, whether syncope or presyncope. Of course, none of petitioner's treating physicians directly observed the episode in question; however, of all of the treating physicians, first responders, and experts who have evaluated this case, those who most contemporaneously and extensively evaluated petitioner in-person concluded on the whole that no syncopal process was implicated. *Accord Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras*, 993 F.2d at 1528.

As explained above, first responders observed petitioner to be alert and oriented with normal vital signs immediately after the accident and noted her to be "apparently normal." (Ex. 14, pp. 3-4; Ex. 20, p. 2.) The possibility of syncope was considered during petitioner's initial emergency department triage the next day (Ex. 13, p. 21), but she was subsequently seen by neurologist Dr. Shah who explicitly concluded there was

no evidence of syncope (*Id.* at 37). Dr. Shah made effort to record a nuanced history and not only confirmed that petitioner did not lose consciousness, but also noted her report of loss of vision to be "questionable." (*Id*. at 36-37.) Ultimately, syncope was not a part of petitioner's discharge diagnosis. (Ex. 5, pp. 7-8.)

Later, Dr. Umamahewswaran included syncope only as among a differential diagnosis also including seizure and cardiac event. (Ex. 5, p. 21.) Dr. Umamahewswaran's record is confusing in that she attached a diagnosis of "syncope" to the encounter, but in her assessment indicated that the episode of loss of awareness was of unclear etiology. (*Id.*) Her later records drop the encounter diagnosis of syncope while maintaining the assessment of a loss of awareness of unclear etiology. (*Id.* at 32.) On the whole, Dr. Umamahewswaran's treatment records reflect greater focus on petitioner's subsequent post-concussion syndrome than on the initial cause of her accident. Dr. Shah's encounter record appears to offer the most extensive consideration of whether the history provided by petitioner represented a syncopal event and that assessment was based on a more contemporaneous recollection than was available to Dr. Umamahewswaran. (Ex. 13, pp. 36-37.)

Dr. Donofrio is also correct to observe that the presyncope symptoms described by Dr. Kinsbourne are non-specific. "Presyncope can be challenging to evaluate in a healthcare setting because of its broad differential diagnosis . . ." (Ex. C, Tab 1, p. 4.) Petitioner's symptoms as described by Dr. Kinsbourne (feeling funny/dizziness, confusion, loss of vision) are also consistent in varying combinations with other disorders for which petitioner has established diagnoses, including migraine disorder, panic attacks, and Meniere's disease. (Ex. C, p. 4.)

Additionally, to the extent petitioner may have suffered some type of spell or episode, Dr. Kinsbourne's assessment offers only short shrift to the alternative condition most prominently considered by Dr. Shah. Dr. Donofrio highlights that after engaging with Ms. Kidwell's reported history, Dr. Shah considered the possibility of a TIA more strongly than syncope. Specifically, Dr. Shah's impression included "rule out any posterior segment transient ischemic attack versus _____no signs of syncopal episode." (Ex. 13, p. 37.) Dr. Donofrio explained that TIA presents with the same symptoms highlighted by Dr. Kinsbourne relative to presyncope, is also transient, and like presyncope, leaves behind no lasting evidence that it occurred. (Ex. C, p. 2.) Also, Dr. Kinsbourne ultimately acknowledges that petitioner's narrowed basilar artery could have contributed to her visual disturbance in the context of either syncope or TIA. (Ex. 33, p. 2.) Dr. Kinsbourne's only response with respect to the possibility of TIA is to dismiss it as an unlikely or unnecessary explanation due to the fact that petitioner had recently been vaccinated. (*Id.*)

In any event, even assuming *arguendo* petitioner did suffer a presyncopal episode, Dr. Kinsbourne is still not correct to automatically invoke petitioner's vaccination as the cause. "The etiologies of presyncope are diverse, ranging from the benign to the life-threatening." (Ex. C, Tab 1, p. 1.) Notably, presyncope can result from conditions and activities as commonplace as dehydration. (Ex. A, Tab 1, p. 1.) In fact,

one of petitioner's prior syncopal episodes reportedly occurred in the context of foregoing anything to drink for two hours. (Ex. 15, p. 49.) Dr. Kinsbourne is also unreasonably dismissive of petitioner's history of bradycardia. "Atypical cardiovascular causes of presyncope should be considered more closely in the elderly than in younger populations." (Ex. C, Tab 1, p. 2.) Moreover, syncope and presyncope are established sequela of bradycardia. (*See* Ex. A, Tab 4, p. 4 (Table 1).)

As Dr. Donofrio noted, petitioner's medical records confirm that bradycardia was previously confirmed by electrocardiogram on two separate occasions. (Ex. A, p. 1 (citing Ex. 12, p. 127 (August 23, 2010) and Ex.12, p. 111 (June 11, 2012).) Dr. Kinsbourne's own reliance materials (Whitledge, et al) stress that dysrhythmias are a common cardiac cause of syncope and presyncope and that bradycardia is the most common dysrhythmia. (Ex. C, p. 2.) Dr. Kinsbourne discounts this possibility on the basis that no bradycardia was recorded around the time of the accident (Ex. 32, p. 4); however, petitioner's resistance to being hospitalized following her accident necessarily means she did not receive a full evaluation until the day after her accident. Arrythmias can be infrequent and detectable only upon longer-term electrocardiogram study. (Ex. A, Tab. 1, p. 2.) As with TIA, Dr. Donofrio also stresses that petitioner's narrowed basilar artery would be a predisposing factor. (Ex. A, p. 6.) And, again, Dr. Kinsbourne acknowledges that this narrowing could explain petitioner's visual changes as a consequence of any drop in blood pressure. (Ex. 33, p. 2.)

Furthermore, petitioner's own medical history refutes Dr. Kinsbourne's suggestion that the temporal relationship between vaccination and "spell" should without more be viewed as a distinguishing characteristic of this episode. Although a definitive etiology is not captured by her medical records, petitioner has had spell-like episodes on a number of occasions. (*See e.g.*, Ex. 12, p. 156 (flashing lights); Ex. 12, pp. 92-95 (saw squares); Ex. 15, p. 99 (dizziness and nausea); Ex. 15, pp. 157-59, 170 (losing vision and falling).) She has previously been diagnosed as having had syncopal episodes unrelated to vaccination (Ex. 12, p. 106, 108; Ex. 15, pp. 45-46) and has a history of reported panic attacks which have been suspected as the cause of a separate episode similarly described as involving a visual blackout without loss of consciousness (Ex. 15, p. 170; Ex. 27, pp. 7-9). No specific recurrent trigger has been identified and there has been no pattern of any of these events occurring following vaccination. However, petitioner's medical records reflect that she has received prior vaccinations without apparent incident. (Ex. 12, pp. 12, 16.) In the context of this medical history, Dr. Kinsbourne's charge that it is Dr. Donofrio who is relying on "coincidence" is not persuasive. (See Ex. 33, p. 1.)[17]

Additionally, given that petitioner's theory of causation is predicated on the idea that a type of emotionally-mediated stress response to vaccination ultimately leads to a

[17] Specifically, Dr. Kinsbourne wrote "[i]n his supplemental report dated May 24, 2021, Dr. Donofrio maintained that what had happened was any of a set of multiple different hypothetical medical events, all having in common that they are unconnected with vaccination but allegedly coincidental with the post vaccination hour. He implied any one of these hypothetical events should be considered preponderant to the diagnosis of a syncopal process." (Ex. 33, p. 1.)

drop in blood pressure, it is notable that petitioner emphasized in her testimony regarding the appointment at which she was vaccinated that she "felt great going in, great coming out." (Tr. 12.) She also did not describe any subjective fear or discomfort with respect to vaccinations or injections. Again, the record shows that petitioner received multiple prior vaccinations without reported incident. (Ex. 12, pp. 12, 16.) Additionally, whereas the Vaccine Injury Table allows a causal presumption for events occurring up to one hour post vaccination, Dr. Kinsbourne identified the relevant precautionary period as being only 15 minutes. (Ex. 23, p. 1.) As discussed above, circumstantial evidence establishes that petitioner's accident necessarily occurred after no more than 49 minutes; however, the record evidence is inadequate to place the episode specifically within 15 minutes of vaccination. This is not necessarily dispositive of the temporal relationship (I do not reach the question of *Althen* prong three here), but further calls into question Dr. Kinsbourne's confidence in the fact of a preceding vaccination itself being so significant as to exclude of all other scenarios reasonably suggested by petitioner's medical history.

Finally, I note that when reviewing Dr. Kinsbourne's multiple submissions collectively, it becomes apparent that his review of petitioner's medical history suffers diminished credibility. In his first report, Dr. Kinsbourne flatly denied "any cardiovascular disease process that might be conducive to syncope" and further denied "any previously syncopal episodes." (Ex. 23, p. 1.) In his second report, Dr. Kinsbourne acknowledged generally that "Ms. Kidwell's age and medical history may suggest a slightly greater susceptibility to fainting than average." (Ex. 32, p. 3.) He also specifically acknowledged, contrary to his first report, that petitioner had had "at least two" prior episodes of vasovagal syncope. (*Id*. at 2.) However, in this report he continued to deny that petitioner had a narrowed basilar artery. (*Id*. at p. 4.) It was not until his third and final report that Dr. Kinsbourne finally conceded that petitioner had a narrowed basilar artery and that it may be relevant to assessing the vision changes she reported during her episode. (Ex. 33, p. 2.) At no point did Dr. Kinsbourne meaningfully discuss petitioner's history of bradycardia, dismissing it solely because it was not documented specifically at the time of the accident. (Ex. 32, p. 4; Ex. 33, p. 3.)

"Most near syncope diagnoses are presumptive, cannot be confirmed by standard criteria and may not be able to exclude cardiac conduction causes that have potentially life-threating consequences." (Ex. C, Tab 1, p. 3.) Therefore, "[a] *thorough history* and physical examination are critical part of the evaluation of syncope and focus on identifying underlying heart disease." (Ex. A, Tab 1, p. 2 (emphasis added).) Given the importance of patient history in assessing presyncope, Dr. Donofrio has reasonably raised aspects of petitioner's own medical history that are highly significant to assessing whether any syncope and/or presyncope occurred and, if so, which among the broad range of known etiologies best explains it. Dr. Kinsbourne is not credible in dismissing these concerns as mere "hypotheticals." Accordingly, petitioner has not met her burden of proof under the *Althen* test with respect to any cause-in-fact-claim based on either a syncopal or presyncopal event.

E. There is not preponderant evidence that petitioner's alleged syncopal episode caused her accident and post-accident symptoms

Regardless of theory – Table or cause-in-fact injury – petitioner must also establish that her injuries satisfy the Vaccine Act's severity requirement. § 300aa-11(c)(1)(D). In relevant part the Vaccine Act requires petitioner to demonstrate that the residual effects of her injury persisted for at least six months.[18] *Id*. Because syncope is a transient and generally harmless condition, it necessarily follows that petitioner must also somehow causally link her longer-term treatment for headaches and unsteady walking (characterized as post-concussion syndrome) to her initial episode in order to demonstrate a compensable injury.

Petitioner has neither alleged nor demonstrated that her longer-term symptoms were a direct sequela of her syncope (or presyncope), but rather contends that the persistent injuries she suffered were the result of trauma she experienced in the ensuing auto accident. Petitioner suggests, in effect, a causal chain in which her vaccination caused her syncopal or presyncopal episode which caused her accident which caused her post-concussion syndrome. However, petitioner's above-discussed testimony that she lost control of the vehicle due to pedal misapplication contradicts that framing of events and therefore raises an additional issue of proximate causation. In all events, petitioner must prove that her vaccination was a proximate cause of her injury or injuries. *Shyface,* 165 F.3d at 1352 (adopting the Second Restatement of Torts with regard to proximate causation in the Vaccine Program and determining a vaccine must be both a "but for" cause and a "substantial contributing factor"); *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1381 (Fed. Cir. 2012) (examining the Second Restatement of Torts with regard to superseding causes, but determining that such analysis is not necessary where the special master found no casual role for the vaccine). Even under a Table Injury approach, the causal presumption afforded petitioner would extend only as far as the vaccine's role in causing her alleged syncope, which is the specific injury included on the Table.

The core of petitioner's claim is her assertion that her "version of events is the only one that makes sense. A person who is conscious takes their foot off the gas. They do not drive into a parking lot at 50 miles per hour and run into parked cars. Syncope is the only explanation for what we know happened." (ECF No. 78, p. 5.) But this is belied by petitioner's own testimony. As noted above, petitioner was clear and cogent in testifying that the cause of the accident was her own misapplication of the gas pedal when she intended to apply the brakes. (Tr. 20, 81.) She further testified that she

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[18] Under the Vaccine Act, petitioner must have either:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 300aa-11(c)(1)(D).

kept her foot on the gas after losing control because she continued to believe it was the brake pedal. (Tr. 10-11, 46.) The eyewitness at the scene further confirmed that petitioner still had her foot on the gas after her vehicle came to a stop. (Ex. 28.) It is only the details occurring after she had already lost control of her vehicle that petitioner cannot recall. Contrary to syncope (or presyncope) being the "only explanation" of her accident, petitioner credibly described the cause of her accident as pedal misapplication. In fact, because syncope involves a loss of postural tone, Dr. Donofrio suggested that petitioner's continued contracting of muscles to continuously depress the gas pedal as observed by the eyewitness is not consistent with a syncopal episode. (Ex. C, p. 1.)

Petitioner's broader suggestion that syncopal confusion or a loss of consciousness are the only reasonable explanations for this type of accident is also not correct. Accidents due to sudden unintended acceleration are a well-known phenomenon and litigation involving that type of accident has explored many potential causes including design and mechanical defects as well as driver error. *See, e.g.*, *Bullock v. Volkswagen Group of America, Inc.*, 107 F.Supp.3d 1305, 1317 (M.D. Ga. 2015) (noting an expert's "opinion is directly relevant and would be helpful to the jury on the issue of causation—whether driver error, instead of design defect, caused the wreck."); *Buck v. Ford Motor Co.,* 810 F. Supp. 2d 815, 838 (N.D. Ohio 2011) ("Sero concluded that the cause of the sudden rapid acceleration could only be one of two explanations: 'either the driver mistakenly put 'pedal to the metal' or the cruise control system electronically failed.' Sero then proceeded to rule out driver error as a potential cause. To make this determination, Sero relied on: 1) witness testimony; 2) brake pedal wear; and 3) driver habit. Sero's specific causation opinion must be excluded because he has not reliably ruled out driver error.") (internal citation omitted); *Jarvis v. Ford Motor Co.,* 283 F.3d 33, 46 (2d Cir. 2002) ("Although Ford argued that the accident was caused instead by driver error, this theory would have been rejected if the jury had believed Jarvis's testimony that she had her feet on the brake and not on the accelerator, as Ford claimed."). Petitioner does not bear the burden of eliminating alternative independent causes of her injury, but "is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case." *See Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). Here, to the extent petitioner herself indicates that she is relying in part on the lack of any alternative explanation, it is not self-evidently true as petitioner suggests that a person who is conscious and of sound mind would not be involved in an accident involving sudden unintended acceleration. As petitioner correctly acknowledged in her reply brief, "[a]nyone might miss the brake pedal and accidentally hit the gas." (ECF No. 79, p. 3.)

Dr. Kinsbourne indicates (without accompanying citation) that "[v]asovagal presyncope/syncope is a well-recognized cause of traffic accidents, as the medical literature attests." (Ex 33, p. 3.) However, this is beside the point. There is no real debate in this case that a person who has fainted or near fainted while driving would be likely to cause an accident. However, the fact that this is an uncontroversial point does

not automatically suggest that it explains what happened in this case given that accidents of sudden unintended acceleration do not happen exclusively as a result of fainting and petitioner clearly testified to misapplying the pedal and losing control of the vehicle as a result. Dr. Kinsbourne also stresses that petitioner's ability to recall losing control of the vehicle is compatible with a presyncopal process. (Ex. 32, p. 2.) Again, however, even if credited, this only speaks to whether petitioner's version of events even remains *potentially* plausible. It is not evidence that it actually occurred, especially in light of petitioner's testimony acknowledging that she pressed the wrong pedal and kept pressing the wrong pedal.

Dr. Kinsbourne offers the specific rationale in his final report that "since her vision was blurry during her presyncope it is probable that she could not verify the correct pedal in her car by sight. A growing feeling of faintness and visual compromise is probably why she pressed the wrong pedal while driving." (Ex. 33, p. 3.) This raises several issues. First, the explanation is speculative at best. Petitioner did not provide any testimony to this effect. In fact, it is inconsistent with petitioner's account as she provided testimony indicating she could see trees pass by at the point she initially lost control of the vehicle, suggesting her vision was intact at that moment. (Tr. 10-11.) Second, Dr. Kinsbourne is a neurologist. While he is qualified to discuss the effects of syncope and presyncope, he has no particular qualification to speak to specific contentions of what type of human errors are likely to lead to an auto accident. Third, even to any lay person with experience driving, Dr. Kinsbourne's explanation remains unsatisfying as a matter of common sense. People generally keep their eyes on the road while driving and do not typically rely on visual confirmation to place their foot on the appropriate pedal. Moreover, the typical driving position is not conducive to visually inspecting the pedals. Fourth, after initially misapplying the accelerator, petitioner described the subsequent events as occurring very fast. (Tr. 54.) Thus, it is not apparent that Dr. Kinsbourne's explanation is even necessary to explain how petitioner's initial pedal misapplication caused the accident. Dr. Kinsbourne himself indicated that the accident became unavoidable as soon as petitioner lost control by misapplying the gas pedal. (Ex. 32, p. 2.) He specifically opined that "once Ms. Kidwell lost control of the car, it was going to crash regardless of her level of consciousness." (*Id*.)

Accordingly, petitioner's auto accident is more likely than not explained by her admitted pedal misapplication and she has therefore not established by preponderant evidence that her post-accident symptoms were causally related to her vaccination.[19] Thus, her alleged injury also does not meet the Vaccine Act's severity requirement.

[19] Because I have concluded that there is not preponderant evidence that petitioner's accident was caused by her alleged syncope/presyncope, I do not reach the further questions of whether her post-accident condition did represent a post-concussion syndrome, whether her symptoms could otherwise be linked accident trauma, or whether her symptoms persisted for at least six months. As noted above, petitioner does not actually recall hitting her head.

VII. Conclusion

Petitioner has my sympathy for the pain and suffering she endured due to her traumatic accident, and I do not doubt her sincerity in bringing this claim. However, for all the reasons discussed above, after weighing the evidence of record within the context of this program, I cannot find by preponderant evidence that petitioner suffered any injury caused by her October 13, 2015 flu vaccination. Therefore, this case is dismissed.[20]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[20] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.