In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 12, 2025

TYLER HERVEY,	*	
Petitioner,	*	No. 17-1305V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Lisa Roquemore, Law Office of Lisa A. Roquemore, Rancho Santa Margarita, CA, for petitioner.
Dorian Hurley, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION[1]

On September 21, 2017, Tyler Hervey[2] ("petitioner") filed a claim in the National Vaccine Injury Compensation Program[3] for his development of cerebellitis following a seasonal influenza vaccine ("flu" or "Flumist") which he received on October 30, 2014. ECF No. 1. After a full review of the evidence presented in this case, in accordance with the applicable legal standards, I conclude that petitioner has not established by preponderant evidence that the flu vaccine caused his injury. Accordingly, the petition is hereby dismissed.[4]

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (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), Petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The case was recaptioned on October 15, 2025, as petitioner has reached the age of majority.

[3] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[4] Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record, including all of the medical records, expert testimony, and literature submitted by the parties. This opinion discusses the elements of the record I found most relevant to the outcome.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

I. Procedural History

Petitioner's parents acting on behalf of the then-minor vaccinee filed the Petition on September 21, 2017. Petition, ECF No. 1; *see also* Exs. 1 – 9 (supporting medical records) (ECF Nos. 7, 9, 10, 13). On February 13, 2018, Respondent formally opposed compensation of the claim. Rule 4(c) Report ("Rept.") (ECF No. 17). Thereafter, petitioners retained two medical experts: neurologist-immunologist Lawrence Steinman, M.D. and infectious disease specialist W. Lawrence Drew, M.D., Ph.D. Petitioner's Exhibits ("Pet. Ex.") 11, 50, 58,65. Respondent retained his own two medical experts: neurologist Michael Kruer, M.D. and infectious disease specialist Hayley Gans, M.D. Respondent's ("Resp't") Exs. A, B, D, E. The parties filed several rounds of expert reports (with the experts' respective curriculum vitae and supporting medical literature), and I offered several preliminary assessments of the case as it developed, encouraging that the parties pursue an informal resolution that would recognize their respective litigative risk and T.H.'s relatively limited injury. *See* Orders entered Nov. 5, 2018 (ECF No. 33); Jan. 24, 2020 (ECF No. 57); Apr. 5, 2021 (ECF No. 73); Dec. 21, 2021 (ECF No. 82).

Respondent remained opposed to any informal resolution, and the parties briefed the disputed issues bearing on entitlement. Pre-Hearing Brief (ECF No. 88); Resp't Response (ECF No. 90). During a July 2022 status conference, the parties agreed to file final supplemental expert reports and then submit the case for adjudication on the written record. Scheduling Order entered July 11, 2022 (ECF No. 101). The parties jointly confirmed they did not intend to file additional expert reports or briefing. Joint Status Rept. (ECF No. 112). Thus, the record is complete, and the matter is ripe for adjudication.

II. Legal Standards for Adjudication

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

A petitioner bears the burden of establishing his or her entitlement to compensation from the Vaccine Program. The burden of proof is by a preponderance of the evidence. § 13(a)(1).

A. Finding of Fact

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, 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). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *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).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Causation

To receive compensation through the Program, petitioner must prove either (1) that [he] suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* --Fed.Appx.— (Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

A petitioner cannot establish entitlement to compensation based solely on his or her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g*., *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly,* 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

III. Summary of Medical Evidence

A. Pre-Vaccination

Petitioner was born in 2006 and generally healthy, performing well academically, and engaged in extracurricular activities, such as flag football. Petition at ¶ 1-2. He was diagnosed with attention deficit hyperactivity disorder ("ADHD') when he was in kindergarten and was taking Focalin extended release. Pet. Ex. 8 at 1. Prior to the vaccination at issue, petitioner had been treated for various illnesses, such as nausea and strep throat. *See* Pet. Ex. 4 at 2-6.

Twenty-two days prior to petitioner receiving the flu vaccine, on October 8, 2014, he had a sick visit with his primary care physician. Pet. Ex. 4 at 15. At this appointment, petitioner was experiencing diarrhea, along with abdominal pain and nausea. *Id.* His sibling was experiencing similar symptoms. *Id.* He was diagnosed with acute gastroenteritis and petitioner's parents were instructed to give him small foods and to rehydrate. *Id.* at 16.

On October 16, 2014, petitioner returned to his pediatrician with a high-grade temperature for two days, followed by a low-grade temperature, a sore throat, wet cough, and congestion. Pet. Ex. 4 at 18. He was diagnosed with a viral upper respiratory infection and instructed to call back if the fever or symptoms worsen over four days. *Id.* at 19. Petitioner's rapid flu A and B tests and step test were negative. *Id.*

The next day, on October 17, 2014, petitioner had a chest X-ray which revealed "focal consolidating infiltrates involving the posterior segment right upper lobe consistent with pneumonia." Pet. Ex. 4 at 24. The impression was "right upper lobe pneumonia," and petitioner

was administered Rocephin by intramuscular injection into his thighs and an oral course of Augmentin. *Id.* at 21, 24; *see also* Pet. Ex. 4 at 21; Pet. Ex. 1 at 330.

B. Vaccination Encounter

On October 30, 2014, petitioner had a follow-up appointment with his pediatrician for his pneumonia. Pet. Ex. 4 at 27. Petitioner's mother provided a history, which explained that petitioner was still coughing and occasionally feeling dizzy. *Id.* He also had a slight headache. *Id.* The physical examination was positive for "very scant effusion but no erythema or pus behind ear drums,' and he had mild congestion. *Id.* at 28. The impression was that petitioner's pneumonia was clinically resolved and therefore, he would receive the flu vaccine. *Id.*

Petitioner received the flu mist vaccine at this encounter.

C. Post-Vaccination Medical Appointments

The next day, on October 31, 2014, petitioner's mother called the pediatrician's office to saying that petitioner was dizzy, weak, and vomited twice, but he did not have any fevers. Pet. Ex. 4 at 29. Petitioner was not experiencing any abdominal pain, but again had a headache. *Id.* The pediatrician prescribed Zofran for nausea and a course of Cefdinir (antibiotic) for 10 days. *Id.*

Later the same day, petitioner was taken to the emergency room of Legacy Children's Health, with the chief complaint of vomiting that started 6-12 hours ago. Pet. Ex. 1 at 4. The pulmonary/chest examination was positive for wheezing in the "right middle field and right lower field," of his lungs. *Id.* at 6. A chest X-ray found "minimal central peri-bronchial thickening without focal airspace opacity." *Id.* at 102. Petitioner vomited during the x-ray; received IV fluids, Zofran, and albuterol; and was admitted to the hospital. *Id.* at 7 – 8.

The "History of Present Illness" taken on October 31, 2014 at admission provides that petitioner had "dizziness," vomiting, and headache for a few days, and that he had been sick for the past two and half weeks and that he had been diagnosed with pneumonia and given a course of antibiotics. Pet. Ex. 1 at 12. However, after four to five days, petitioner was switched to a different antibiotic due to worsening symptoms. *Id.* After finishing the course of the second antibiotic, petitioner still had a cough, dizziness, and fluid in his middle ear. *Id.* Petitioner began Afrin, but his dizziness got worse, and then following morning he began vomiting. *Id.* Petitioner described the headache as "constant" for a few days and being in the front of his head that got worse with movement. *Id.*

On November 1, 2014, petitioner vomited again after eating ice chips and reported still being "very dizzy." Pet. Ex. 1 at 22. The physician, Dr. King, called petitioner's primary care physician and confirmed that petitioner had begun a course of Augmentin, but then Azithromycin was added after no improvement for right upper lobe pneumonia. *Id.* Petitioner's primary care physician also reported that petitioner had received the FluMist on October 30, 2014, but the same day the vaccine was administered, petitioner was experiencing mild dizziness and a headache. *Id.* Petitioner failed the Romberg test during the physical examination, with Dr. King noting that

petitioner was swaying with arms out and began to fall onto his father. *Id.* at 24. Petitioner had a nose swab and a respiratory viral panel by PCR was positive for influenza B and parainfluenza A. *Id.* at 98.

While in the hospital, petitioner continued to endorse a headache, despite being treated with Tylenol. Pet. Ex. 1 at 27, 34 ("significant headache and dizziness"). By November 4, 2014, it was noted that petitioner was unable to move his eyes down, but could move his eyes laterally. Pet. Ex. 1 at 39. He still had a headache and dizziness. *Id.* at 40. On November 5, 2014, petitioner was recorded as having slow speech and "slow wide based ataxic gait." *Id.* at 46. He also had "difficulty with finger to nose missing target by 1 cm." *Id.* At this point, the records note a "concern for cerebellitis after viral infection," and a brain MRI was ordered, and possible transfer to Children's Hospital in Dallas. *Id.*

That day, November 5, 2014, petitioner was transferred to Children's Hospital in Dallas for a concern of cerebellitis. Pet. Ex. 1 at 324. The Review of Symptoms upon admission to CMC Dallas noted petitioner as positive for slower speech, headache, and vomiting. *Id.* at 322. The assessment was, "likely emesis secondary to dizziness, which given the recent changes in his neuro exam is concerning for cerebellitis or acute disseminated encephalomyelitis….Given his most recent infection, this is most likely cerebellitis secondary to his viral infection." *Id.* at 324.

Petitioner had a neurology consult on November 5, 2014 with Dr. Diana Castro. Pet. Ex. 1 at 337. The physical exam was positive for dysmetria on bilateral finger to nose test and slurry speech. *Id.* at 342. The MRI was found to be "unremarkable," and the assessment was "presentation consistent with post-infectious cerebellitis." *Id.* Petitioner was given Zofran for nausea and dizziness and Dr. Castro did not recommend any immunosuppressant or immunomodulatory therapy at the time of evaluation. *Id.* at 337.

Petitioner continued to report headaches until about November 10, 2014. Ex. 1 at 351, 418, 423, 440, 449. The more significant problem was his ongoing dizziness, resulting in nausea and vomiting. *Id.* at 324 ("he likely has the emesis secondary to his dizziness"). He required scheduled Zofran and Pediasure supplements. *Id.* But after T.H. started the additional medication Meclizine on November 11, 2014, his dizziness, nausea, and vomiting "resolved"; "his appetite markedly improved" and he took 100% of his daily caloric needs. *Id.* at 314, 449.

When petitioner was discharged on November 14, 2014, he was able to walk independently, but still had mild dysmetria with finger to nose movement and could not walk heel to toe. Pet. Ex. 1 at 314. His discharge diagnosis was "post-viral acute cerebellitis," and was told to follow-up with neurology. *Id.*

On December 9, 2014, petitioner had an Occupational Therapy Evaluation post-hospitalization. Pet. Ex. 2 at 1239. Petitioner's mother noted that petitioner had increased aggressive outbursts since his hospitalization, and he was still taking medicine to address vertigo as needed. *Id.* Petitioner's fine motor movements were recorded as "slow and methodical." *Id.* According to the examination, petitioner was performing "below average in the areas of fine motor precision, manual dexterity, and upper limb coordination," with his skill level being equal to a "6-7-year-olds." *Id.* at 1241. Additionally, petitioner had "definite deficits with immediate memory"

and petitioner was unable to recall 6 numbers, unable to recall 5 objects, and unable to follow 3 step commands. *Id.* It was recommended that petitioner engage in skilled occupational therapy to address memory, fine motor skills, and upper extremity coordination. *Id.* He attended three sessions and was discharged in April 2015, meeting the goals of therapy. *Id.* at 1238—42, 1331—33, 1343—45, 1355—57.

On January 27, 2015, petitioner had an initial appointment with neurologist, Dr. Robert Chudnow at Child Neurologist Clinics of Texas. Pet. Ex. 8 at 1. Dr. Chudnow wrote that petitioner was treated for acute encephalopathy between October 31-November 17, 2014. *Id.* The "History of Present Illness" provides:

> [Petitioner] developed a walking pneumonia and was treated for 10 days. He developed dizziness at the end of treatment. He had acute balance problems and nausea and vomit on October 31st….He was taken to CMC-L and admitted for suspected gastroenteritis. He was cultured and determined to be positive for parainfluenza type 2 and influenza B. The condition worsened with dystonic reaction to Compazine and worsened encephalopathy and headaches. He had more seizures. He was transferred to CMC-D. There, he had MRI brain (normal?) and a lumbar puncture. Mother was told lumbar puncture was normal except for increased opening pressure. He was not put an on anticonvulsant but was supported for the next two weeks as he convalesced. He remained ataxic with word finding difficulties on discharge. No further seizures noted (no EEG performed?). He was discharged with meclizine. He returned to school with accommodations and wheel chair. He has steadily improved. Now ambulatory and balance is normal. He has subtle difficulties with coordination. He denies further headaches. There has been some goofy sporadic behavior. He is back on Focalin 5 mg.

Id. Dr. Chudnow assessed petitioner with mild static encephalopathy post-acute encephalitis and stated that petitioner's examination "is fundamentally normal but there are subtleties that might be related to chronic recovery." *Id.* at 3. He also noted that petitioner's mother was "interested in primarily in refills for Focalin XR which is about to run out," and that petitioner had an upcoming appointment at CMC-Dallas for his cerebellitis. *Id.* at 3.

On February 11, 2015, petitioner had a follow-up appointment at CMC-Dallas for his cerebellitis. Pet. Ex. 2 at 1292. At this appointment, petitioner was recorded as "doing well," since discharge, and that he was "doing much better with motor skills." *Id.* At this time, petitioner was still having difficulty with short term memory or word finding, demonstrating a "short fuse" and was getting frustrated easily. *Id.* Petitioner's mother expressed concern about petitioner overheating while playing games in the home, as he was not "overdoing activities outside." *Id.* Petitioner was also having some balance issues, and his writing appeared to be "more sloppy." *Id.* The note also indicates that Dr. Chudnow was recommending an EEG for further evaluation, however, petitioner has not had any seizures. *Id.* An EEG was ordered to evaluate recent learning difficulties, along with a possible seizure due to an adverse reaction to a drug and neuropsychology testing recommended to evaluate learning difficulties that have occurred after the acute cerebellar ataxia. *Id.* at 1297.

On March 17, 2015, petitioner had an EEG, which was recorded as normal. Pet. Ex. 2 at 1317.

Petitioner had a follow-up appointment at the Neurology Clinic at CMC-Dallas on August 4, 2015. Pet. Ex. 2 at 1368. Physician-Assistant Huerta noted that petitioner had the EEG, but has yet to make a neuropsychology appointment. *Id.* Further, petitioner had improvement in word finding and memory loss, which also resulted in less anger. *Id.* Petitioner went to two soccer camps over the summer and camps to help him improve his agility and coordination. *Id.* Petitioner also petitioner endorsed symptoms of vertigo, dizziness, and nausea occasionally, and treatment with Zofran and meclizine resolved the symptoms. *Id.* at 1369. Petitioner also described feeling overheated, but was not doing activities such as sports during these episodes. *Id.* At this appointment, petitioner's mother "mentioned that [petitioner] had the flu mist the day prior to the [onset of cerebellitis]," and PA-Huerta stated, "[petitioner] may wish to nevr take the live flu virus again." *Id.* Petitioner was given a referral to an ENT and psychology for a neuropsychology testing. *Id.*

Petitioner returned to Dr. Chudnow on September 4, 2015 for a follow-up for his ADHD. Pet. Ex. 8 at 5. Petitioner reported receiving all A's in school, but he did not want to continue to take Focalin XR, contrary to his mother's opinion. *Id.* Dr. Chudnow noted that petitioner's ADHD pre-dated his encephalitis in October 2014. *Id.* Referring to the episode in October 2014, Dr. Chudnow wrote, "[petitioner] seems to be 100% recovered. The only symptoms might be a tendency to overheat and feel nauseated and dizzy." *Id.* Petitioner's prescription of Focalin was refilled. *Id.* at 7.

The next appointment petitioner had with Dr. Chudnow was almost a year later, on October 5, 2016. Pet. Ex. 8 at 8. Petitioner had just begun 4th grade, continuing his use of Focalin, and was doing well. *Id.* At this appointment, petitioner denied headaches, but expressed being "very sensitive to noise and intense visions," making it so he could not go to movies or watch videos with surround sound. *Id.* His prescription of Focoalin was refilled, with a diagnosis of "unspecified encephalopathy." *Id.* at 10.

Petitioner had another appointment with Dr. Chudnow on July 6, 2017 for his ADHD symptoms. Pet. Ex. 8 at 11. Petitioner completed 4th grade and was going to attend a soccer camp in Mexico for ten days. *Id.* Petitioner did not report any new headaches and his physical exam was normal. *Id.* at 11—12. Petitioner's prescription of Focalin was refilled. *Id.*

Petitioner also had follow-up neurology appointments for his cerebellititis at CMC-Dallas from 2016 through 2019. *See* Pet. Ex. 42; Pet. Ex. 2 at 1292, 1332. He had an appointment on November 13, 2017 with neurologist, Dr. Lauren Dengle, for an "evaluation of school and behavior changes." Pet. Ex. 42 at 2. Petitioner's mother reported petitioner having trouble in all of his classes and being depressed with anger outbursts at home, but not at school. *Id.* Petitioner's mother once again reported that petitioner was "over heating" at times at home, which occurred about once a week. *Id.* A repeat MRI and EEG were ordered and a referral to neuropsychology to assess behavioral issues. *Id.* at 7.

Petitioner underwent neuropsychological testing in March and April of 2018. Pet. Ex. 42 at 35—45. Of note, petitioner's teachers filled out questionnaires and reported that petitioner was functioning at grade level and no behavior issues were reported, although, he needed to be redirected at times and struggled to begin writing assignments. *Id.* at 36. The test revealed some concerns related to petitioner's memory. *Id.* The evaluator noted that petitioner's mother indicated that the memory issues began during his hospitalization for his post-infectious cerebellitis. *Id.* at 37. The evaluator also indicated that the described symptoms of aggression or depression by his mother were not appreciated by his teachers, although these symptoms may be more apparent at home where he feels most comfortable. *Id.* at 38. The evaluator also noted that petitioner's symptoms were "relatively mild and he is functioning quite well in many respects." *Id.* Interestingly, the evaluator described petitioner's performance as "average, despite not having taken his stimulant medication on the day of testing…This evaluation, therefore, did not indicate significant evidence of ADHD at this time." *Id.*

The next neurology appointment at CMC-Dallas, on March 8, 2018, discussed his repeat MRI and EEG, which were normal. Pet. Ex. 42 at 17. Additionally, it was reported that petitioner's behavior was improving and that he was "back to working at grade level, he is just requiring accommodations." *Id.* Neurologist, Dr. Dengle, wrote that there were "no concerning findings on his work up," and that petitioner was "overall gradually improving." *Id.* at 22.

A neurology appointment from February 21, 2019, Dr. Dengle noted that since the last appointment a year ago, petitioner did not need to undergo any additional testing. Pet. Ex. 48 at 2. Petitioner's behavior had improved. *Id.* Petitioner's mother noted that petitioner was going to travel out of the country for soccer and was wondering if petitioner should get vaccinated. *Id.* Petitioner's mother also questioned whether his cerebellilitis was actually Guillain-Barre, and that vaccines "could be contraindicated." *Id.* Dr. Dengle wrote that petitioner "does not have a neurological contraindication to vaccines," and that he could return to the neurology clinic as needed. *Id.* at 7.

IV. Expert Opinions

A. Petitioner's Experts

i. Lawrence Steinman, M.D.

Dr. Steinman is recognized as an expert in neurology, immunology, and neuroimmunology.[5] He submitted five reports in this case. Pet. Ex. 11 (ECF No. 19); Pet. Ex. 50 (ECF No. 47); Pet. Ex. 58 (ECF No. 64); Pet. Ex. 73 (ECF No. 76); Pet. Ex. 89 (ECF No. 104).

[5] Dr. Steinman obtained an undergraduate degree from Dartmouth College in 1968 and graduated from Harvard University Medical School in 1973. Ex. 83 at 1. He completed a residency in pediatrics in 1974 and a residency in pediatric and adult neurology in 1980, both at Stanford University. *Id.* He is board-certified in neurology. *Id.* He is currently a Professor in the Departments of Neurology, Neurological Sciences, and Pediatrics at Stanford. *Id.* at 1. He has cared for adult and pediatric patients with various forms of neuroinflammatory disease. Pet. Ex. 11 at 1. He has diagnosed acute cerebellitis perhaps 20 times in his career (and comments that "it was much more common before the varicella vaccine was approved"). *Id.* Additionally, Dr. Steinman has served on multiple National Institute of Health ("NIH") expert panels pertaining to vaccination, including the Advisory Committee on Pertussis Immunization and

Dr. Steinman agreed with the medical records that the appropriate diagnosis for petitioner was acute cerebellitis ("AC") or acute cerebellitis ataxia ("ACA") and explained in his fifth report that he views acute cerebellitis as encompassing acute cerebellar ataxia. Pet. Ex. 89 at 8. He explained:

> I prefer not to split acute cerebellitis from acute cerebellar ataxia, and instead look at [them] as part of a continuum….Acute cerebellitis (AC) is an inflammatory syndrome characterized by acute onset of cerebellar signs/symptoms (such as ataxia, nystagmus or dysmetria) often accompanied by fever, nausea, headache, altered mental status and brain magnetic resonance imaging (MRI) abnormalities is the element that differs AC and acute cerebellar ataxia (ACA), which is also known in current literature as post infectious cerebellar ataxia.

Id. The Lancella et al. article explains that there are similarities in the clinical presentation with ACA and AC, and often are considered on a continuum. Pet. Ex. 96 at 1.[6] The article also states that average time between onset of signs and symptoms of a fever, rash, or infection and cerebellar symptoms is approximately six days. *Id.* at 6. Additionally, ataxia was the most frequent sign upon hospital admission, and vomiting, fever and headaches were frequent non-cerebellar symptoms that were frequently identified. *Id.* Neurological presentation was often characterized by dysmetry and difficult speech. *Id.* Dr. Steinman also noted that petitioner's treating physicians used acute cerebellitis ataxia and acute cerebellitis interchangeably without making a distinction. Pet. Ex. 96 at 8. Dr. Steinman also stated that regardless of calling petitioner's diagnosis acute cerebellitis or acute cerebellitis ataxia, his theory for how the flu vaccine could cause such injury would not change. *Id.*

In his first report, Dr. Steinman summarized petitioner's history, which briefly mentioned petitioner's pre-vaccination history of a sinus infection, which later was diagnosed as pneumonia. Pet. Ex. 11 at 4—6. at Dr. Steinman opined that on October 30, 2014, the day of vaccination, petitioner "was ill, perhaps from a parainfluenza infection at the time (although he was asymptomatic for it, and it is unlikely a physician would give a live virus vaccine to someone who was showing signs of infection." *Id.* at 23. Dr. Steinman opined that petitioner's onset of dizziness occurred the "evening" of October 30, 2014, and "was most likely due to the combination of a post-vaccination reaction *and* a respiratory infection with parainfluenza 2." Pet. Ex. 11 at 5 (emphasis added).

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the Immunological Sciences Study Section. *Id*. at 2. Dr. Steinman was awarded the Charcot Prize for Lifetime Achievement in 2011 from the International Federation of MS Societies for his work in multiple sclerosis research, and he was elected to the National Academy of Sciences in 2015. *Id.* at 2. Dr. Steinman listed nearly 600 publications on his *curriculum vitae*. Ex. 83 at 5 – 49. This opinion will not detail Dr. Steinman's expertise with molecular mimicry and autoimmune diseases (particularly diseases known to involve MBP and MOG), and his utilization of BLAST and IEDB searches – or Respondent's general opposition to Dr. Steinman's approach - because those issues do not particularly guide *this claim's* outcome, and they have already been explained in many past Vaccine Program opinions.

[6] Lancella L. et al., *Acute Cerebellitis in Children: An Eleven-Year Retrospective Multicentric Study in Italy*, 12 Ital. J. Ped. 43 (2017) [Pet. Ex. 96].

Dr. Steinman opined that ACA/AC can be caused by molecular mimicry between the 2014 – 2015 Flumist vaccine's B/Brisbane strain and myelin oligodendrocyte glycoprotein ("MOG"). Ex. 50 at 4 – 7.[7] Responding to my initial Rule 5 Order, Dr. Steinman noted that there were six of 10 molecular mimics between the influenza B (B/Brisbane) strain used in the FluMist and MOG, which he opine was the "trigger for the cerebellitis." *Id.* at 7. Additionally, in his second report, Dr. Steinman, clarified how an immune response to MOG would result in cerebellitis, stating, "In [Jarius et al.] we read that MOG antibody positive cases have a predilection for cerebellar involvement," and that Jarius et al. found three cases where lesions were present on the cerebellum which was accompanied by limb ataxia and marked gait ataxia. *Id.* at 3; *see also* Pet. Ex. 52 at 11.[8]

Most relevant to this case, Dr. Steinman opined that the onset of petitioner's neuroinflammation or the ACA, was on the morning of October 31, 2014, less than one day after petitioner received the FluMist vaccine. Pet. Ex. 11 at 23. Dr. Steinman opined that a 24-hour onset of this type of injury could occur based on a recall response to a strain of flu vaccine petitioner had receive prior to the vaccination at issue in this matter. *Id.; see also* Pet. Ex. 50 at 8—9; Pet. Ex. 58 at 2—8 (maintaining this opinion and adding that cross-reactive immune cells could more rapidly access the cerebellum due to a specialized fenestration (window) in the blood-brain barrier in the area postrema); Ex. 73 at 3 – 9; Pet. Ex. 89 at 1 – 2. Dr. Steinman opined that there was "insufficient evidence to comment one way or another" whether the Flumist vaccine containing live virus strains "would accelerate the triggering of a recall response compared to" non-live virus vaccines. Ex. 50 at 8.

Partway through the case proceedings, during a Rule 5 conference, I observed that Dr. Steinman had "not address[ed] the mild headache and dizziness reported on the day of vaccination." Dr. Steinman's *assumed* onset of one day post-vaccination was the "best-case analysis" from Petitioner's perspective. Scheduling Order at 3 (ECF No. 57).

However, Dr. Steinman never addressed Petitioner's pre-vaccination headaches and dizziness, and he continued to assume a one-day post-vaccination onset of ACA in his three subsequent reports. *See generally* Pet. Exs. 58, 73 & 89. And Dr. Steinman opted to "leave the response to Respondent's infectious disease expert [Dr. Gans]" to his co-expert Dr. Drew. Ex. 58 at 1.

But Dr. Steinman acknowledged that at Petitioner's hospital admission, a respiratory virus panel was positive for parainfluenza 2 infection. Dr. Steinman opined that parainfluenza can trigger ACA/AC based on the medical literature – and moreover, from Dr. Steinman's own research, parainfluenza shared homology with MOG that was "sufficient to potentially trigger clinical

[7] In his first report, Dr. Steinman endorsed that the 2014 – 2015 Flumist vaccine's A/California strain and MOG; the A/Victoria strain and MOG; the A/Victoria strain and MBP; and the B/Massachusetts strain and MBP – *all* displayed homology "sufficient to trigger experimental neuroinflammation" that could cause ACA/AC. Pet. Ex. 11 at 12 – 13, 15 – 17. In his second report, Dr. Steinman disclaimed the proposed molecular mimicry with the A strains because those were not found on Petitioner's respiratory virus panel, and Dr. Steinman acknowledged that his first report had had not referenced the vaccine's additional B/Brisbane strain. Pet. Ex. 50 at 1.

[8] Jarius, S. et al., *MOG-IgG in NMO and Related Disorders: A Multicenter Study of 50 Patients. Part 3: Brainstem Involvement-Frequency, Presentation, and Outcome,* 13:281 J. of Neuroinflammation, 1-23 (2016). [Pet. Ex. 52].

neuroinflammatory disease." Ex. 11 at 21 – 23; *see also* Ex. 89 at 6 – 8. In his last report, Dr. Steinman concluded: "[P]arainfluenza 2 virus is also a substantial factor in triggering [T.H.'s ACA]. I cannot provide a relative 'weight' for the parainfluenza 2 versus the FluMist in triggering" [T.H.'s ACA]." Ex. 89 at 8. Dr. Steinman did not explain how molecular mimicry would occur between MOG and two different external factors (an infection and a vaccine strain). He did not address whether it mattered which external factor was introduced first – or most crucially here, whether his vaccine causation theory would fit into a factual scenario in which the ACA/AC onset *predated* the vaccine's receipt. Dr. Steinman did not address a scenario of a *pre-vaccination* ACA/AC onset and whether the vaccine could have played a role in its progression.

ii. W. Lawrence Drew, M.D., Ph.D.

Dr. Drew is recognized as an expert in infectious disease.[9] He submitted two reports in the case. Ex. 65 filed Oct. 6, 2020 (ECF No. 65); Ex. 97 filed Aug. 16, 2022 (ECF No. 106).

Dr. Drew opined that the documented parainfluenza 2 infection most likely explained petitioner's upper respiratory symptoms that were documented on October 16, 2014, and the resulting pneumonia diagnosed radiologically one day later. Pet. Ex. 65 at 2. Dr. Drew stated that "parainfluenza 2 "can definitely cause pneumonia, especially a relatively mild case with a minimal pulmonary infiltrate," as seen in this case. *Id.* Dr. Drew stated that petitioner's pneumonia had resolved by the October 30, 2014 appointment, but noted that petitioner's mother reported petitioner still had an occasional cough and "complained of feeling dizzy," but returned to school and football. *Id.* at 1.

Dr. Drew agreed with the diagnosis of cerebellitis, when petitioner presented the following day, October 31, 2014, with impaired gait, vomiting, and headache. *Id.* at 2. Dr. Drew also observed that petitioner tested positive for parainfluenza 2, influenza B and negative for influenza A and also noted that petitioner's PCR test was negative for mycoplasma pneumonia, among other infectious agents. *Id.*

Respondent's infectious disease expert, Dr. Gans, suggested that petitioner's respiratory illness, pneumonia, and subsequent ACA were explained by a mycoplasma pneumoniae infection, Dr. Drew disagreed, specifically opining that the PCP's treatment of T.H. with antibiotics "in no way proves" the fact of a bacterial infection; the CSF sample did not contain the high polymorphonuclear white blood count, very low glucose, and high protein expected for a bacterial

[9] Dr. Drew received his undergraduate degree from Holy Cross College in 1958, his medical degree from Jefferson Medical College in 1962, and his Ph.D. in Experimental Virology from Jefferson in 1966. Ex. 82 at 1. He is board-certified in internal medicine, infectious disease, and medical microbiology. *Id.* He is currently a consultant of infectious diseases as well as director of clinical virology research at the University of California San Francisco ("UCSF") Mount Zion Medical Center, and a co-director of the clinical virology laboratory at UCSF. *Id.* at 1 – 2. After teaching for several decades, he is currently a Professor Emeritus in UCSF's Department of Laboratory Medicine and Medicine. *Id.* Dr. Drew explained that he has extensive experience with parainfluenza 2 virus in both the laboratory and clinic. Ex. 65 at 1. Dr. Drew states that he has testified in over 100 depositions and 15 court appearances on issues involving clinical microbiology and infectious disease. *Id.*; *see also, e.g.*, *Omron Electronics v. Ill. Workers' Comp. Comm.*, No. 1-13-0766WC, 21 N.E. 2d 1245, 1249 – 50 (Nov. 14, 2014); *Kilpatrick v. Superior Court (Holiday Inns, Inc.)*, 233 Cal. App.3d 233, 236 (Jan. 7, 1991). This appears to be Dr. Drew's first experience serving as an expert in the Vaccine Program.

infection; and a PCR sample was negative for mycoplasma. Pet. Ex. 65 at 2; Pet. Ex. 97 at 3. Dr. Drew did not find "any support" for Dr. Gans's opinion that the negative PCR result was to be expected for a mycoplasma infection contracted at least 22 days prior. Pet. Ex. 97 at 3.

Dr. Drew acknowledged the October 30, 2014 documentation of dizziness, but did not address its potential relevance. Pet. Ex. 65. Dr. Drew stressed that the PCP had performed a "thorough neurological examination" which was normal and "did not reveal vertigo." *Id.* at 1, 3. After Dr. Gans opined that the pre-vaccination dizziness and headaches represented the onset of ACA, Dr. Drew disagreed particularly based on the mother's opinion, adopted by the PCP, that Petitioner was just dehydrated. Ex. 97 at 1 – 2.

Dr. Drew would find it "inexplicable" for a child to display a "substantial recovery" from an infection followed by the onset of ACA/AC. He would instead expect to see a "progression and evolution" of the infection as well as ACA/AC. Ex. 65 at 2 – 3.

Finally, Dr. Drew endorsed that the Flumist vaccine can, and did cause the new onset of ACA in this case – but he largely left the causation issues to Dr. Steinman. *See, e.g.*, Ex. 97 at 2 ("Dr. Steinman has addressed the rapidity of the response in his reports.").

B. Respondent's Experts

i. Michael Kruer, M.D.

Dr. Kruer is recognized as an expert in neurology, immunology, and neuroimmunology.[10] He submitted four reports in the case. Resp. Exs. A, D, H & K.

Dr. Kruer did not address the medical record evidence of pre-vaccination headaches and dizziness. *See, e.g.*, Resp. Ex. A at 2 (stating that petitioner "developed vomiting, dizziness, and weakness" the morning of October 31, 2014). Nor did he address the potential onset/ prodromal symptoms for ACA/AC – which he described rather vaguely as an "autoimmune attack on the cerebellum with a stereotypic course." Resp. Ex. D at 1. Like Dr. Steinman, Dr. Kruer omitted

[10] Dr. Kruer obtained an undergraduate degree from Arizona State University in 2001, and a medical degree with distinction in research from the University of Arizona in 2004. Ex. B at 2. He had a residency in pediatrics at Phoenix Children's Hospital/ Maricopa Medical Center from 2005 – 2007. *Id.* at 1. Afterwards, he had an overlapping clinical fellowship in neurodevelopmental disabilities and a post-doctoral fellowship in molecular neurogenetics at Oregon Health & Science University from 2007 – 2011. *Id.* Dr. Kruer previously taught and practiced medicine in South Dakota. *Id.* He is currently an Associate Professor (tenure-track) teaching child health, cellular and molecular medicine, neurology, and genetics at the University of Arizona College of Medicine. *Id.* He is also the Director of the Cerebral Palsy and Pediatric Movement Disorders Program at Barrow Neurological Institute. *Id.* He is an attending neurologist at Phoenix Children's Hospital, where he also serves as the hospital's specialist consultant in pediatric neuroimmunology. Ex. A at 1. Clinically, he has treated many adult and pediatric patients with central nervous system and peripheral nervous system autoimmunity. *Id.* Dr. Kruer is board-certified in pediatrics, neurology (with a subspecialty in child neurology), and neurodevelopmental disabilities. Ex. B at 1. He has also researched topics including the role of autoimmunity in neurological disease, specifically focusing on how autoantibodies directed against brain proteins may lead to disease. Ex. A at 1; Ex. B at 2. He is on the editorial board of the Journal of Child Neurology, and he conducts peer review for other journals in that field. Ex. B at 2.

these issues even after they were raised by Dr. Gans and my preliminary order. *See also* Resp. Exs. H, K (Dr. Kruer's subsequent reports not addressing the onset issue).

Instead, Dr. Kruer focused his efforts on critiquing Dr. Steinman's general approach to identifying potential molecular mimicry, denying that the homology identified in this specific case was sufficient to cause molecular mimicry, and denying that myelin proteins were even relevant to the etiology of ACA/AC. *See generally* Resp. Exs. A, D, H, K.

Additionally, Dr. Kruer emphasized Dr. Steinman's opinion that parainfluenza 2 infection potentially caused or contributed to petitioner's ACA. Ex. A at 2, citing Ex. 11 at 6 (Dr. Steinman writing: "parainfluenza can trigger acute cerebellitis"). Dr. Kruer opined: "Thus, there is no need to invoke influenza B, nor to hypothesize that a 'perfect storm' must have occurred, since Occam's razor and published evidence clearly indicates that sequelae of parainfluenza infection alone could readily account for T.H.'s symptoms." Resp. Ex. A at 2. In his final report, Dr. Kruer reiterated: "From [Dr. Steinman's arguments,] it is not clear to me why the FluMist vaccine would need to be invoked to explain T.H.'s ACA – the parainfluenza virus infection alone appears capable of causing ACA if this Court accept[s] Dr. Steinman's argument that homology alone is to cause disease via molecular mimicry." Resp. Ex. K at 3. But Dr. Kruer did not address whether *mycoplasma or other infections* can cause ACA/AC, as suggested by his co-expert Dr. Gans.

Dr. Kruer disputed that a one-day post-vaccination onset of neurological symptoms would be medically acceptable, even for a recall response. *See generally* Resp. Ex. A at 5 – 8; Resp. Ex. D at 3 – 4; Resp. Ex. H at 2; Resp. Ex. K at 1 – 2.

ii. Hayley Gans, M.D.

Dr. Gans is recognized as an expert in infectious disease, particularly relating to pediatric patients.[11] She submitted three reports. Resp. Exs. E, I, & J.

Dr. Gans opined that there was "no causal connection" between petitioner's October 30, 2014 Flumist vaccine and the ACA event, because petitioner was already showing symptoms of ACA—headaches and dizziness---prior to receiving the vaccine, which continued afterwards in a manner consistent with ACA/AC. Resp. Ex. E at 3—4; Resp. Ex. I at 1—2; Resp. Ex. J at 2.

Dr. Gans explained that ACA/AC is characterized by "acute onset of cerebellar signs/symptoms (such as ataxia, nystagmus, or dysmetria) often accompanied by fever, nausea, headache and altered mental status. Resp. Ex. E at 5. Referencing articles by Nussinovitch et al. and Thakkar et al., she stated that "[t]he time from prodromal illness to symptom onset was 8.8 days, with the earliest reported at 2 days, but none on the day or day after exposure." *Id.*; *see also*

[11] Dr. Gans obtained a bachelor's degree in biochemistry from Connecticut College in 1987, followed by a M.D. from the SUNY Health Science Center at Syracuse in 1991. Ex. F at 1. In 1991, Dr. Gans joined the Stanford University School of Medicine, where she completed an internship and residency in pediatrics, then a fellowship in pediatric infectious disease. *Id.* In addition to continued clinical practice at Stanford, she began teaching medicine there in 1998, and she is currently a clinical professor in the department of pediatrics. *Id.* Dr. Gans is board-certified in pediatrics, pediatric infectious disease, and medical examination. *Id.* at 2. She spends all of her clinical time caring for children with infections, including immunocompetent as well as immunocompromised children. Ex. E at 1.

Resp. Ex. G, Tab 14[12]; Resp. Ex. J, Tab 2 [13]. In her second report, she explained that the symptoms of headache and vomiting preceding the "other more classic symptoms such as ataxia and slurred speech," are present in 20% of children presenting with ACA/AC. Resp. Ex. J at 4. The article by Yildirim et al., which examined cases of 15 cases of pediatric ACA/AC patients, stated that "[t]he most common first symptoms were ataxia, vomiting, and headache." Resp. Ex. J, Tab 2 at 1.[14] Yildirim found that headache and vomiting were first symptoms in 60% of the cases they reviewed. *Id.* at 2.

In her first report, Dr. Gans explained that most cases of ACA/AC are preceded by infections, with varicella infection causing up to 75% of cases, and mycoplasma causing 15%. Resp. Ex. E at 5. She does acknowledge that case reports document a temporal association between vaccination and ACA, including varicella, meningococcal, HPV, and influenza, but that outside of a temporal association, no causal relationship has been established between vaccines and ACA/AC. Resp. Ex. E at 5. One case report, authored by Saito and Yanagisawa, describes a 5-year old female developing acute cerebella ataxia eight days after receiving the flu vaccine. Resp. Ex. G, Tab 17.[15] Sunaga et al. describes a case of a two-year old patient developing nausea and vomiting ten days after receiving the varicella vaccination, and symptoms developed to dysarthria and gait disturbance. Resp. Ex. G, Tab 15 at 2.[16]

Dr. Gans stated, "[petitioner's] entire illness beginning on 10/14 progressing to include neurologic symptoms starting a couple of days prior to the 10/31 admission is inconsistent with the influenza vaccine as the cause," and that the cause of petitioner's ACA/AC "can be explained entirely by an infection, most consistently with mycoplasma." Resp. Ex. G at 6. She explained that on October 14th, petitioner's illness was clinically consistent with a mycoplasma infection and that petitioner's treating physician also suspected mycoplasma by eventually treating petitioner with azithromycin, as mycoplasma is not susceptible to standard antibiotics. Resp. Ex. G at 5. In her third report, Dr. Gans, referencing the medical records, noted that petitioner's illness, which began on October 14th, was unresponsive to the first class of antibiotics (Augmentin and Rocephin) and that his symptoms worsened, which is why petitioner's PCP appropriately treated him with Azithromycin. Resp. Ex. J at 2. Dr. Gans explained that the negative mycoplasma PCR test from November 6 was expected, as "clinical manifestations at this stage of the disease are immune mediated, and would require serology for diagnosis, which was not performed." Resp. Ex. E at 5. Additionally, she agreed with petitioner's expert, Dr. Drew, that by October 30th, petitioner's mycoplasma infection had likely resolved. Resp. Ex. J at 4.

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[12] Nussinovitch, M. et al., *Post-Infectious Acute Cerebellar Ataxia in Children,* 42(7) Clin. Pediatr. 581-584 (2003). [Resp. Ex. G, Tab 13].

[13] Thakkar, K., et al., *Acute Ataxia in Childhood: 11-Year Experience at a Major Pediatric Neurology Referral Center,* 31(9) J. Child. Neurol. 1156-60 (2016). [Resp. Ex. G, Tab 14].

[14] Yildirim, M. et al., *Acute Cerebellitis or Post-infectious Cerebellar Ataxia? Clinical and Imaging Features in Acute Cerebellitis,* 35(6) J. of Child Neurol. 380-388. [Resp. Ex. J, Tab 2].

[15] Saito, H., *Acute Cerebella Ataxia after Influenza Vaccination with Recurrence and Marked Cerebella Atrophy,* 158 Tohoku J. Exp. Med. 95-103 (1998). [Resp. Ex. G, Tab 17].

[16] Sunaga, Y. et al., *Acute Cerebella Ataxia with Abnormal MIR Lesions after Varicella Vaccination,* 13 Peds. Neurol. 340-42 (1995). [Resp. Ex. G, Tab, 15].

Dr. Gans opined that the November 1, 2014 respiratory virus panel finding of parainfluenza 2 infection was not particularly relevant to understanding this case. "The detection of viruses by PCR does not differentiate between the presence of viable or non-viable virus, i.e., if this is causing infection or just present, as [PCR] detects genomic material that is present from viruses even if the virus is not replicating (nonviable)." Resp. Ex. E at 4. "While co-infection with viruses is a common finding in children with mycoplasma, and the presence does not impact the disease manifestations, rather may be a portal of entry, the significance of PIV in the current illness is likely minimal as even the treating physicians did not associate its presence with the current illness. While PIV2 is associated with respiratory infections, the most common manifestation is croup and specifically with serotype 2, there is little lower tract disease. When lower tract disease or pneumonia is documented the findings are typically bilateral. [PIV] [p]eak illness is 5 – 7 days, with resolution in 2 – 3 weeks. Additionally [with PIV], neurologic disease which is extremely rare, especially with serotype 2, which includes encephalitis, febrile seizures, and ventriculitis, but not cerebellitis. Thus, for these reasons PIV2 is inconsistent with [the] current case as the diagnosis of the illness starting 10/14 and resulting in the hospitalization and neurologic disease." *Id.* at 4.[17]

With respect to the onset of petitioner's symptoms, Dr. Gans stated that petitioner was showing neurological symptom on October 30th, which was entirely consistent with onset of ACA/AC post-infection. Resp. Ex. E at 7; Resp. Ex. J at 5. After reviewing petitioner's medical records, she stated that petitioner was symptomatic with dizziness and headaches prior to and on the day he received the influenza vaccination, and those symptoms were not likely caused by dehydration as suggested by petitioner's expert, Dr. Drew. Resp. Ex. E at 6; Resp. Ex. J at 3. She conceded that petitioner may have been mildly dehydrated, but that when petitioner was hydrated during his hospitalization, his headaches and dizziness did not resolve. Resp. Ex. J at 3. Instead, she explained that the onset of the headaches and dizziness, which the medical records endorse occurring a few days *prior* to his 10/31 hospital admission, is more consistent with ACA/AC following a preceding illness. Resp. Ex. I at 2.

Dr. Gans stated that the case reports that demonstrate a temporal relationship between vaccination and the onset of ACA/AC, none show a temporal relationship of 1-day, as was seen in petitioner's case. Resp. Ex. J at 6. Instead, the onset between his illness and symptoms, is most consistent with the medical literature showing a symptom onset of 8.8 days after an illness. Resp. Ex. E at 5.

Dr. Gans' opinion was that petitioner's neurological symptoms of ACA/AC started prior to the vaccination and that the onset of neurological symptoms one-day post-vaccination is inconsistent as the cause or contributor to his ACA/AC. Resp. Ex. E at 6.

V. Analysis

a. Finding of Fact-Onset

[17] Dr. Gans noted that T.H.'s respiratory virus PCR panel was also positive for influenza B, which she opined was from his recent intranasal flu vaccine. Ex. E at 4.

After reviewing the expert reports and parties' briefs, it is necessary first resolve the onset of petitioner's neurological injury. Petitioner and petitioner's experts, argue that the onset of petitioner's neurological symptoms began approximately one day post-vaccination. *See* Pet. Br. at 32; Pet. Ex. 50 at 8. Respondent's expert, Dr. Gans, argues that petitioner's neurological symptoms began *prior* to receipt of the FluMist vaccine. Resp. Ex. E at 7; Resp. Ex. J at 2--3; *see also* Resp. Br. at 23, 28—29.

The Vaccine Act defines an injury's onset by "the occurrence of the first symptom or manifestation of onset." *See* Section 11(c)(1)(C)(i); Section 13(b)(2); Section 16(a)(2). In *Whitecotton*, the Supreme Court explained that in a new-onset claim: "If a symptom or manifestation of a[n]… injury has occurred before a claimant's vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury's onset. There cannot be two first symptoms or onsets of the same injury. Thus, a demonstration that the claimant experienced symptoms of an injury [after vaccination], while necessary, is insufficient to make out a prima facie case. The claimant must also show that no evidence of the injury appeared before the vaccination." *Shalala v. Whitecotton*, 514 U.S. 268, 274 (1995). In *Whitecotton*, the parents of a minor child had alleged a Table injury of a new-onset encephalopathy after receipt of a diphtheria-tetanus-pertussis vaccine. *Id.* at 271. That claim did not prevail because the child was found to have microcephaly – a precursor of encephalopathy – prior to her vaccination. *Id.*

This reasoning has been extended to causation-in-fact claims. For instance in *Lampe*, the Federal Circuit explained that a "parallel analysis applies" to a causation-in-fact claim, because "the statutory basis for recovery by presumption of causation under the Vaccine Injury Table essentially mirrors the statutory basis for recovery by proof of actual causation." The Circuit then affirmed the special master's determination that a young child's seizure condition began with "bicycle-pedaling movements" that predated her January 1976 DPT vaccination, which foreclosed a new-onset causation claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1365 (Fed. Cir. 2000).

And in *Markovich*, the Federal Circuit stressed: "There is a difference between 'a symptom' or 'manifestation of onset.' A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury. For example, in [the *Markovich* case,] the eye-blinking episode was a symptom of a seizure disorder without any diagnosis, while the grand-mal seizure of August 30, 2000 was a manifestation of onset of a seizure disorder." *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007). Onset is marked "objective[ly]" and "focus[ing] on the recognized standards of the medical profession at large." *Id.* at 1360. Moreover, onset does not depend on the "date of official diagnosis." For example in *Carson*, the Circuit did not accept the petitioner-appellants' argument that speech delay was too broad and common a symptom to mark the onset of autism. The Circuit saw "no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal" – but that the special master was not arbitrary and capricious in finding, based on the case-specific context, that speech delay marked the onset of the *Carson* child's autism. *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 – 70 (Fed. Cir. 2013).

In this case, I find the preponderant evidence, which includes petitioner's medical records and the medical literature describing initial symptoms of ACA/AC, demonstrates that petitioner's neurological symptoms began prior to his October 30, 2014 vaccination.

The medical records establish that on October 30, 2014, the date of vaccination, petitioner's mother explained to his primary care physician that he was "complaining of feeling dizzy today," and petitioner had a "slight headache." Pet. Ex. 4 at 27. Additionally, on October 31, 2014, the hospital admission noted that petitioner was experiencing a "headache for a few days." Pet. Ex. 1 at 12, 14 (associated with headache and lightheadedness which pre-existed for 2-3 days). Additionally, it was noted by numerous records that petitioner's headaches and dizziness existed prior to his hospital admission and the date of vaccination. *See e.g.* Pet. Ex. 1 at 14 ("8 y.o. male with persistent vomiting which started today, associated with headache and lightheadedness which pre-existed for 2-3 days, and following a recent diagnosis/treatment course for pneumonia."); Pet. Ex. 1 at 313 ("He continued to have dizziness, however, this *worsened* 10/30 with a decrease in appetite during the night time….He also has had a constant frontal headache for the few days prior to the 31st that is worse with movements.").

While petitioner's experts, mainly Dr. Drew, does not dispute the existence of petitioner's headache and dizziness pre-dating the vaccination, he attributes them to the possibility of dehydration, consistent with what petitioner's mother suggestion at the October 30, 2014 appointment. *See* Pet. Ex. 97 at 2. Dr. Drew relies on the neurological exam performed by petitioner's PCP on October 30, 2014, which states, "No focal deficit. CN II-XII grossly intact with normal reflexes, coordination, muscle strength, and tone," to suggest that petitioner was not experiencing dizziness, and therefore "no evidence of cerebellitis," despite the same record noting petitioner was "feeling dizzy today." *See* Pet. Ex. 4 at 12. However, Dr. Gans credibly explains that petitioner's headaches and dizziness is the cause of his later developed vomiting—rather his lack of fluids caused the headache and dizziness. *See* Pet. Ex. 1 at 12 ("his dizziness got worse, and his appetite decreased"); *Id.* at 314 ("he had significant vertigo resulting in nausea and decreased appetite leading to weight loss"); *Id.* at 330 ("he likely has the emesis secondary to his dizziness which given the recent changes in his neuro exam is suspicious for cerebellitis"). Dr. Steinman did not substantially address the presence of petitioner's headache and dizziness being noted in petitioner's medical records on the day of vaccination.

Dr. Gans' opinion regarding the onset of symptoms is more persuasive than petitioner's experts' opinions. Importantly, she recognized that the sequence of symptoms petitioner was experiencing was consistent with medical literature that described ACA/AC. The Lancella and Yildirim articles both endorse headache and dizziness as common first symptoms of ACA/AC. *See* Pet. Ex 96 at 4; Resp. Ex. J, Tab 2 at 7. Additionally, petitioner's medical treaters attribute petitioner's dizziness and headaches to his ACA/AC. The "HPI" taken on November 5, 2014 at Dallas Children's explains that petitioner "has had a constant frontal headache for the few days prior to the 31st that is worse with movements," and that petitioner was "admitted for dizziness, vomiting, headaches who was unable to tolerate [intake] challenge due to his persistent emesis….he likely has the emesis secondary to his dizziness which given the recent changes in his neuro exam is suspicious for cerebellitis." Pet. Ex. 1 at 330. After the onset of headaches and dizziness, petitioner began to experience other common ACA/AC symptoms, such as

dysarthria, lethargy, and ataxia consistent with the medical literature on ACA/AC. Yildirim et al. explains that the average number of days patients with ACA/AC experience neurological symptoms is 9 days, and that slow speech, lethargy, irritability, ataxia, and head tilt, are also symptoms identified in ACA/AC. Resp. Ex. J, Tab 2 at 2.

Given that petitioner's medical providers viewed petitioner's headaches and dizziness as part of his ACA/AC, the medical records are clear that petitioner was experiencing a headache (and dizziness?) prior to his vaccination, and headaches and dizziness are identified early symptoms of ACA/AC, the preponderant evidence supports a finding that his ACA/AC began prior to the October 30, 2014 influenza vaccination. As explained below, this finding prevents petitioner from establishing *Althen* prongs two and three.

b. Causation

In *Althen,* the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *Althen,* 418 F.3d 1274, 1278-79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of evidence. *Id.*

In this case, petitioner's theory of molecular mimicry between the flu vaccine and MOG and/or myelin basic protein, as proposed by Dr. Steinman, is not necessarily relevant, given that the onset of petitioner's injury began prior to the relevant vaccination. Molecular mimicry has been an accepted theory for how vaccines can cause injuries to the central and peripheral nervous systems by myself and other special masters. *See Conte v. Sec'y of Health & Hum Servs.,* No. 17-403V, 2020 WL 5743696, at *23 (Fed. Cl. Spec. Mstr. July 27, 2020) (noting the theory of molecular mimicry in a GBS case is "well established and well-settled in the Vaccine Program"); *Barone v. Sec'y of Health & Hum. Servs.,* No. 11-707V, 2014 WL 6834577, at *8-9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (explaining molecular mimicry "has been accepted in other Program cases as a reliable medical explanation for how various autoimmune conditions could develop after the receipt of different kinds of vaccinations."). However, Dr. Steinman proposed the theory of molecular mimicry with the assumption that petitioner's symptoms began one day after the administration of the flu vaccine. Pet. Ex. 50 at 9. Dr. Steinman's explained that a one-day onset post-vaccination is a temporally appropriate because petitioner had previously been exposed to the FluMist vaccine components in 2013. *Id.* Even if I accepted Dr. Steinman's theory of molecular mimicry between components of the FluMist vaccine and MOG/myelin basic protein, petitioner's case fails because he is unable to satisfy *Althens* prong two and three by preponderant evidence.

As the onset finding above explains, petitioner's neurological symptoms of his cerebellitis began prior to the administration of the FluMist vaccine on October 30, 2014, therefore petitioner is unable to establish *Althen* prong two by preponderant evidence. Even though petitioner was hospitalized and diagnosed with cerebellitis after he received the FluMist

vaccine on October 30, 2014, the medical records preponderantly establish that the headache and dizziness were petitioner's initial symptoms of his condition, and those began prior to vaccine administration. As petitioner's cerebellitis symptoms began prior to vaccination and were present on the day of vaccination, he cannot logically establish that the flu vaccine was the cause of his injury. *See Locane v. Sec'y of Health & Hum. Servs.,* 685 F.3d 1375, 1381 (Fed. Cir. 2012).

Finally, petitioner cannot preponderantly establish an appropriate temporal association between the Flu vaccine he received on October 30, 2014 and his ACA/AC if the onset predated the vaccine. Additionally, the onset of petitioner's headache and dizziness, which are early symptoms of ACA/AC, is consistent with the onset of symptoms after an infection described in the medical literature.

Nussinovitch et al. explained that the latency between onset of a prodromal illness and ataxia was approximately 8.8 days, with a range of 2-21 days. Resp. Ex. G, Tab 13 at 3. Connolly et al., which described the clinical course and outcome of children with acute cerebella ataxia, found a latency from prodromal illness to onset of ataxia averaged 9.9 days. Resp. Ex. G, Tab 12 at 3. As the medical records demonstrate, petitioner had a well-documented infection that began around October 16, 2014 and then his symptoms of cerebellitis began approximately 13 days later, on October 29, 2014, consistency with the latency period described in Nussinovitch. Pet'r Ex. 4 at 18-20; 28-30.

Additionally, the case reports cited by petitioner's experts where cerebellitis was temporally associated to vaccination, the onset of symptoms was found between eight to twelve days post-vaccination, not one day, as Drs. Steinman and Drew opine as temporally appropriate. *See* Pet. Ex. 99; Resp. Ex. G, Tab 15; Resp. Ex. G, Tab 16. The Saito case report found the onset of ACA/AC associated symptoms of dysarthria and staggering gait eight days after administration of the flu vaccine. Pet. Ex. 99 at 2. Sunaga et al. describes the onset of ACA/AC symptoms of nausea, vomiting and staggering gait approximately 10-days after a two-year old boy received a varicella vaccine. Resp. Ex. G, Tab 15 at 2. Finally, the Yonee et al. article described the onset of ACA/AC symptoms approximately 12-days after administration of an HPV vaccine in a 12-year-old female patient. Resp. Ex. G, Tab 16 at 3. These case reports suggest a longer period between vaccination and onset of ACA/AC symptoms than proposed by petitioner's experts, making even a one-day onset difficult to establish an appropriate temporal relationship.

Ultimately, the medical records establish that petitioner was diagnosed and treated with a respiratory infection approximately thirteen days before he began to experience early symptoms of cerebellitis, which began prior to petitioner's receipt of the FluMist vaccine on October 30, 2014. Accordingly, petitioner cannot establish preponderant evidence of an appropriate temporal relationship between the flu vaccine and cerebellitis and has failed to satisfy *Althen* prong three.

VI. Conclusion

After a careful review of the record, petitioner has failed to provide preponderant evidence that his cerebellitis was caused by the flu vaccine he received on October 30, 2014. Accordingly, petitioner's claim is hereby **DISMISSED.**

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master