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

TRENTON GOODWIN,	*	
	*	No. 19-503V
Petitioner,	*	
	*	Special Master Christian J. Moran
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Filed: October 7, 2025
	*	
Respondent.	*	

Kirk "Trip" Otto, Rawls Law Group, Richmond, VA, and Isaiah Kalinowksi, Bosson Legal Group, Fairfax, VA, for Petitioner;
Lauren Kells and Sara DeStefano, United States Dep't of Justice, Washington, DC, for Respondent.

PUBLISHED DECISION ON REMAND
DENYING ENTITLEMENT TO COMPENSATION[1]

Trenton Goodwin alleges a human papillomavirus ("HPV") vaccine was the cause-in-fact of an incidence of transverse myelitis that he developed.[2] The

[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), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

[2] Sheri McCluskey originally brought this claim on behalf of her son. After Mr. Goodwin reached the age of majority, he became petitioner. Order, issued March 24, 2024. This decision refers to petitioner as "Mr. Goodwin," although most steps in the litigation were carried out by Ms. McCluskey on Mr. Goodwin's behalf.

Secretary contested Mr. Goodwin's allegation. Both Mr. Goodwin and the Secretary retained experts. After the Court's Opinion and Order remanding the case, a hearing was held.

Mr. Goodwin is not entitled to compensation. A preponderance of the evidence shows that he developed transverse myelitis 68 days after the vaccination. This latency is outside the period for which an inference of causation is appropriate. In addition, Mr. Goodwin has not demonstrated that the HPV vaccine can cause transverse myelitis by presenting a reliable theory. Finally, there is an absence of evidence that Mr. Goodwin developed an antibody that is essential to his expert's theory of causation. For these reasons, compensation is denied.

I. Summary of Evidence about Mr. Goodwin

A. Before Vaccination and Vaccination

Mr. Goodwin was born in 2004. Exhibit 3. He received various vaccinations throughout his life, starting with a diphtheria-tetanus-acellular pertussis vaccine in 2004 when he was an infant. Id. A report from 2018 states that he had a seizure (staring spells) when he was 7 years old. Exhibit 7 at 650. He also had autism. Id. at 649; Tr. 45-46.

When Mr. Goodwin was nearly 13 years old, he was seen for a variety of problems, including mental health issues. A checkbox form for review of systems shows that Mr. Goodwin was positive for constipation and negative for bladder leakage. Exhibit 80 at 143 (Sep. 28, 2017).[3] Most of the history of present illness reflects mental health problems. However, in this context, Ms. McCluskey "reports enuresis." Id. at 144. "Enuresis" is a medical term for "urinary incontinence." Dorland's Illus. Med. Dictionary 621 (33rd ed.).

Roughly two months later, Ms. McCluskey provided information to school officials to assist with Mr. Goodwin receiving educational programming that was appropriate for him. Ms. McCluskey stated that Mr. Goodwin was "toilet-trained by age three and one half years. He currently toilets independently, but occasionally has an accident at night. He waits until the last minute and reports he

[3] This medical record, which contains information about Mr. Goodwin's health before the vaccination, was filed after the hearing. The Secretary cited it in his August 11, 2025 brief. In contrast, Mr. Goodwin did not cite any medical records obtained after the hearing and, instead, maintained that the "facts are substantially the same as previously described in both Petitioner's Brief on Entitlement, and Respondent's Brief on Entitlement." Pet'r's Post-Hearing Br. at 1.

does not feel the need to go." Exhibit 79 at 82 (Dec. 1, 2017). There was also a note, from either Ms. McCluskey or a teacher that he "had an accident (bowel movement) in pants recently at school." Id.

At the age of 13 years, when he was in sixth grade, on March 22, 2018, Mr. Goodwin attended a well-child visit at Texas Health Family Care with Ms. McCluskey. Exhibit 6 at 2-24. The primary provider was a nurse practitioner, Justin Eric Decoux. Academically, Mr. Goodwin was doing well. He also had signs of a learning disability, delayed speech. Id. Mr. Goodwin's past medical history included attention deficit hyperactivity disorder, asthma, autism, eczema, obsessive compulsive disorder, and oppositional defiant disorder. Exhibit 6 at 4.

Ms. McCluskey reported that there was "no bed wetting." Id. at 2. Upon the review of systems, Mr. Goodwin was negative "for dysuria, frequency and urgency." Id. at 5. Ms. McCluskey also stated that she was concerned about her son possibly having a seizure recently. However, she did not take him to an emergency room. Id. at 3. Mr. Decoux referred the family to a neurologist. Id. at 7, 48.

Mr. Decoux planned to update the vaccinations. Exhibit 6 at 7-8. Accordingly, Mr. Goodwin received the allegedly causal HPV vaccine on March 22, 2018. Exhibit 3 at 1; Exhibit 6 at 7. Although he received other vaccines on that date, Mr. Goodwin's claim rests upon the HPV vaccine.

B. Interlude between Vaccination and Hospitalization

Ms. McCluskey and Mr. Goodwin returned to Texas Health Family Care the following day, March 23, 2018. Exhibit 6 at 25-45. He was complaining about dizzy spells. Id. at 25. He was diagnosed with otitis media and given a prescription for amoxicillin-clavulanate. Id. at 29. Another prescription was for meclizine, a medication for nausea. Id. Ms. McCluskey was informed that if Mr. Goodwin did not improve in the next 2-3 days or if he worsens with a high fever, they should return to the medical office or go to an emergency room. Id. at 29.

Via an affidavit submitted after remand, Ms. McCluskey averred that employees of Jean McClung Middle School called her at the end of March and early April 2018 because Mr. Goodwin had lost control of his bladder. Exhibit 43 (signed Nov. 13, 2024). A record created approximately a year and a half later recounts that Ms. McCluskey informed neurologists Lauren Tardo and Benjamin Greenberg that approximately "1.5 – 2 weeks" after receiving vaccines on March 22, 2018, Mr. Goodwin "started having episodes of bowel and bladder

incontinence at school." Exhibit 42 at 2394 (Dec. 13, 2019).[4] Ms. McCluskey also told Dr. Tardo that "episodes of incontinence continued a few times per week during April and this continued into May." Id.

Ms. McCluskey and Mr. Goodwin returned to Texas Health Family Care on April 11, 2018. Exhibit 6 at 56-72. Nurse Practitioner Decoux saw him again. The complaint was a "fever blister on right side of mouth, X2 weeks now." Id. at 51. Although the medical record documents Ms. McCluskey's description of the blister, she testified "it was a pimple." Tr. 59. The April 11, 2018 record does not memorialize any concerns about loss of bladder control. See Exhibit 6. The review of systems states "Negative for tingling and sensory changes." Id. at 53. Mr. Decoux diagnosed "herpes labialis without complication" and prescribed acyclovir. Id. at 54.

The next appointment at Texas Health Family Care occurred on May 10, 2018.[5] Exhibit 6 at 73-94. Ms. McCluskey told Mr. Decoux that Mr. Goodwin was "having hearing issues" at school and home. Id. at 73. This note does not memorialize a complaint about loss of bladder control. See id. The review of systems was positive for hearing loss and negative for dizziness and tingling. Id. at 75. After a hearing test, Mr. Decoux diagnosed Mr. Goodwin as having "Bilateral hearing loss, unspecified hearing loss type." Id. at 76. Mr. Decoux referred Mr. Goodwin to an audiologist with an expectation that a referral to an ENT might be appropriate. Id. at 77, 93.

C. Hospitalization

At nearly 10:00 PM on May 30, 2018, Ms. McCluskey brought Mr. Goodwin to an emergency department at Texas Health Hurst-Euless-Bedford. Exhibit 78 at 46. The chief complaint was heat exposure that occurred while he was doing yard work. During their evaluations, medical personnel determined that Mr. Goodwin was ataxic. Id. at 50. Thus, Mr. Goodwin was transferred to a hospital that had additional resources. Id. at 50, 69.

Early in the morning on May 31, 2018, Ms. McCluskey brought Mr. Goodwin to the emergency department at Cook Children's. Exhibit 7 at 64 (nurse's triage note from 2:33 A.M.). Ms. McCluskey reported that Mr. Goodwin

[4] This history appears to be carried into the record for a June 12, 2020 telehealth appointment. Exhibit 41 at 912.

[5] Mr. Goodwin does not recount this episode in his November 18, 2024 brief.

"was outdoors throughout the day today, helping his Mother clean out her car. [Mr. Goodwin] became overheated around 1800 and started vomiting." Id.[6] This note states that Mr. Goodwin was being transferred to Cook Children's from THR HEB. In addition to continued vomiting, Mr. Goodwin had difficulty with walking, balance, and coordination. Id. Mr. Goodwin was hospitalized.

While in the hospital, Mr. Goodwin underwent various tests, including MRIs. The MRI of the thoracic spine was consistent with transverse myelitis. Exhibit 7 at 1349; see also id. at 99. The neurologists whom the parties retained agreed that transverse myelitis is an appropriate diagnosis. See Exhibit 11 (Dr. Steinman's report) at 15, Exhibit A (Dr. Ghosh's report) at 7. The interval between March 22, 2018 (the date of vaccination) and May 30, 2018 (the potential onset of symptoms) is 68 days.[7]

While Mr. Goodwin was in the hospital, a neurologist (Warren Marks) and nurse practitioner (Marcie Mara Baldwin) saw Mr. Goodwin on June 26, 2018 at approximately 10:00 A.M. Exhibit 7 at 112-16. This note comments upon a possible link between the vaccine and the transverse myelitis:

> Have previously discussed vaccines 8 weeks+ prior to onset of TM, doubtful cause of TM, TM has multiple causes, comes in clusters in the community. Further vaccines per PCP [presumably primary care physician] or ID [presumably infectious diseases] and Red Book but would not give him anything for about a year to let the immune system calm down.

Id. at 113.[8]

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[6] Given the context of the outdoor activities and the early hour, the reference to "today" appears to mean May 30, 2018. See Pet'r's Post-Remand Br. at 3.

[7] Although the Secretary's Rule 4(c) Report states that the onset of Mr. Goodwin's illness was 69 days post-vaccination, the parties have since referenced an onset of 68 days. This Decision adopts the parties' presentation.

[8] Similar passages about vaccines "8 weeks+ prior" are found in the hospital records. See Exhibit 7 at 313 (June 26, 2018 case management note by Nurse Lisa Wafer); Id. at 108 (June 27, 2018 progress note written by Nurse Practitioner Baldwin and signed by Dr. Marks); Id. at 311 (June 27, 2018 case management note written by Nurse Joan Ford); Id. at 102 (June 28, 2018 progress note written by Nurse Practitioner Baldwin and signed by Dr. Marks); Id. at 310 (June

Mr. Goodwin remained hospitalized for transverse myelitis until June 29, 2018. Exhibit 7 at 73 (discharge summary). In the hospital, a pediatric urologist stated that Mr. Goodwin was suffering from "urine retention secondary to transverse myelitis." Exhibit 7 at 90. Other medical professionals noted that Mr. Goodwin had difficulty with balance and walking. See, e.g., id. at 88-89 (report from occupational therapist, dated June 5, 2018); id. at 133 (report from neurologist describing ataxic gait).

At discharge, Dr. Marks endorsed a report written by a nurse practitioner. This report states that Mr. Goodwin "has progressed to walking stand by assist using a wheelchair for distances re: fatigue. He requires minimal assistance with ADLs [activities of daily living]. He initially required I/O [intraosseous] catheterizations but has since begun to void spontaneously." Exhibit 7 at 76. In an examination, Mr. Goodwin had a "sensory deficit, decreased light touch, pressure and temperature is present below the hip, able to feel the touch but not differentiate." Id. The discharge instructions included that Mr. Goodwin "Needs 24 hour adult supervision." Id. at 79. He was also expected to follow up with therapists and his primary care physician in the next weeks. Id. at 80.

D. Remainder of 2018

After Mr. Goodwin's discharge, many medical records discuss residual problems stemming from his transverse myelitis. Although these medical records would be relevant to determining the amount of compensation for the transverse myelitis, they tend not to be relevant to determining whether the vaccine *caused* the transverse myelitis. For details about these records, see Pet'r's Post-Remand Br. at 6-7; Resp't's Post-Remand Br. at 3-9.[9]

However, some records do touch upon the issue of causation. On July 13, 2018, Ms. McCluskey brought her son to see a pediatric neurologist, Adrian Lacy. Exhibit 7 at 2746-54. Dr. Lacy's history begins with a lengthy summary of events during Mr. Goodwin's recent hospitalization. As part of this recitation of history,

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28, 2018 case management note written by Nurse Ford). It appears that all derive from the June 26, 2018 progress note from Nurse Practitioner Baldwin and Dr. Marks.

[9] The parties filed several briefs after the case was remanded. The briefs filed on November 18, December 9, and December 23, 2024 are referred to as the parties' Post-Remand briefs and reply. Although cited as "Post-Remand," these briefs functioned as pre-hearing briefs. The briefs filed on August 11, September 5, and September 8, 2025 are referred to as the parties' Post-Hearing briefs and replies.

Dr. Lacy noted: "No CSF studies are seen in EPIC.[10] Serum NMO/MOG antibodies are also not seen. He did have vaccination in March, menactra and DTAP and HPV." Id. at 2749. Since the discharge from the hospital, Mr. Goodwin "is walking only short distances, uses wheelchair for longer distances. He does not have control of bladder." Id. Dr. Lacy, Ms. McCluskey, and Mr. Goodwin "discussed idiopathic transverse myelitis, and other potential syndromes, including NMO and MOG antibody syndromes, which may relapse." Id. at 2753. Dr. Lacy, accordingly, ordered testing to detect antibodies associated with NMO and MOG. Id. at 2754; see also id. at 2769 (telephone or email exchange between Dr. Lacy and a nurse).

The testing for the antibody associated with NMO was negative. Exhibit 7 at 2983 (date of result: Aug. 6, 2018). On August 7, 2018, Dr. Lacy informed Ms. McCluskey that the results for NMO were negative. Exhibit 7 at 3022. This led to an exchange of telephone messages memorialized in the chart.

Ms. McCluskey asked if the vaccines could have been the cause. Id. Dr. Lacy's response was to "defer this [question] to ID [infectious diseases] to follow up results of their testing. Epidemiology does not show an increased rate of children receiving vaccines having transverse myelitis." Id.

While there is a result for the NMO test, the result of any test for MOG antibodies does not appear in the medical records. See Exhibit 29 (Dr. Steinman's second report) at 6 ("the evaluation never succeeded in measuring anti-MOG antibodies and never reported either positive or negative results in the chart").

E. More Recent Medical Records

Mr. Goodwin spent most of 2019 living in Pittsburgh, Pennsylvania. There, he was treated for a musculoskeletal curve, which the doctors associated with his transverse myelitis. See Exhibit 40 at 179.

This problem remained when he returned to Texas. See Exhibit 42 at 2539, 2542-43 (discussing Mr. Goodwin's spinal curvature at a November 12, 2019 appointment). He also had follow-up appointments with a urologist. Id. at 2562.

Mr. Goodwin saw neurologists, Dr. Tardo and Dr. Greenberg, on December 13, 2019. It was at this appointment that Ms. McCluskey first reported that Mr. Goodwin "started having episodes of bowel and bladder incontinence at school"

[10] Epic is the name of a system for creating and storing medical records electronically.

within two weeks of his vaccination. Exhibit 42 at 2394. After an examination and review of the May 31, 2018 MRI images, Dr. Tardo assessed Mr. Goodwin as having acute flaccid myelitis. She wrote: "Exam today demonstrated LMN findings in his back which likely lead to his rapid scoliosis and UMN findings in [] his lower extremities (brisk reflexes, up-going toes). Presentation at this time is most consistent with acute flaccid myelitis affecting the thoracic spine." She ordered another MRI and lab testing and directed Mr. Goodwin to physical therapy.

The source of material for the lab studies was collected on the date of the appointment with Doctors Tardo and Greenberg, December 13, 2019. Exhibit 42 at 2442. A Mayo Clinic Laboratory reported that the test for NMO was negative and the test for MOG was also negative. Id. As discussed below, the parties dispute the significance of the negative result for MOG antibodies.

The follow up MRIs took place on January 6, 2020. The brain MRI showed "No significant intracranial abnormality." Exhibit 42 at 2260. The interpreting radiologist noted: "No evidence of optic neuritis." Id.

For Mr. Goodwin's spine, the radiologist obtained imaging for his cervical, thoracic, and lumbar spines. Exhibit 42 at 2263-71. The radiologist compared the results from the earlier MRIs from May 31, 2018. Across these three images, the radiologist found that "The previously noted abnormal signal intensity within the ventral thoracic spinal cord has essentially resolved. There appears to be some subtle cystic change in the ventral cord at the T3 level." Id. at 2263. The radiologist also noted the "Interval development of prominent S-shaped spinal scoliosis." Id.

Mr. Goodwin's experience in physical therapy for transverse myelitis does not help determine the cause of the transverse myelitis. Similarly, Mr. Goodwin's follow up appointments with orthopedists, urologists, and neurologists appear not to affect the expert's opinions regarding causation. For details, see Resp't's Post-Remand Br. at 8-9; Resp't's Post-Hearing Br. at 10-13.

II. Procedural History

A. Events in Litigation before and until Remand

1. Events before Expert Reports

Mr. Goodwin's mother, Sheri McCluskey, initiated the litigation by filing a petition on April 4, 2019 when Mr. Goodwin was still a minor. Mr. Goodwin filed his medical records on various dates.

The Secretary disputed Mr. Goodwin's entitlement to compensation. Resp't's Rep. The Secretary questioned whether an onset of 69 days was appropriate. Id. at 8.

The parties retained experts. Mr. Goodwin retained Lawrence Steinman. Before remand, Dr. Steinman wrote four reports. Exhibits 11, 27, 29, and 37.

The Secretary retained two experts: Partha Ghosh, a pediatric neurologist, and S. Mark Tompkins, who has earned a Ph.D. in immunology but is not a medical doctor. Each wrote three reports before remand. Dr. Ghosh's reports are Exhibits A, AA, and JJ. Dr. Tompkins's reports are Exhibits K, CC, and LL. A recitation of the key points from the expert reports, beginning with the earliest report follows:

2. Dr. Steinman and His First Report

Dr. Steinman has often been retained by petitioners in the Vaccine Program, and special masters have become accustomed to reviewing his opinions. Dr. Steinman graduated from Harvard Medical School in 1973. He completed his residency at Stanford University Hospital in pediatrics in 1974, held fellowships between 1975-1977, and returned to Stanford as a resident in pediatric and adult neurology from 1977-1980. Dr. Steinman thereafter served in various academic roles, primarily at Stanford University, which he continues to the present. He served as chairman of Stanford's Program in Immunology from 2002-2011 and since 2008 he has been the incumbent of the George A. Zimmerman Chair as professor of neurological sciences, neurology, and pediatrics. He has been board certified in neurology since 1984. Exhibit 12 at 1-2.

Dr. Steinman is an attending neurologist at Stanford. Exhibit 11. He has published hundreds of articles related to neuroinflammation, including transverse myelitis, acute disseminated encephalomyelitis, neuromyelitis optica and multiple sclerosis, and had cared for over 50 individuals with transverse myelitis or

neuromyelitis optica in the five years prior to writing his first expert report for this case in 2020. Id.

In his first report, Dr. Steinman reviewed his qualifications and disclosed the material he reviewed. Exhibit 11 at 1-4. Dr. Steinman also summarized the pertinent medical records, by, in part, quoting from the Secretary's report. Id. at 4-5. Dr. Steinman described transverse myelitis and asserted that Mr. Goodwin suffered from transverse myelitis. Id. at 5-6. These foregoing aspects of Dr. Steinman's first report are not meaningfully disputed.

Dr. Steinman disclosed a theory how the HPV-9 vaccine can cause transverse myelitis. Exhibit 11 at 6-15. As discussed in more detail below, Dr. Steinman relies upon the theory of molecular mimicry. By searching a computer database, Dr. Steinman identified portions of the HPV vaccine and portions of myelin oligodendrocyte glycoprotein that share sequences of amino acids. Id. Citing a paper by Jarius et al., Dr. Steinman asserted that "MOG is known to be targeted in transverse myelitis." Id. at 11. Dr. Steinman maintained that his three-step process, which is further assessed below, "make a compelling theory that molecular mimics in the HPV9 vaccine received by petitioner could trigger immunity to MOG culminating in transverse myelitis." Id. at 15 (emphasis in original).

Dr. Steinman next discussed the timing. Dr. Steinman stated: "The onset following the immunization on March 22, 2018 was May 30, 2018. . . . The interval would be approximately 9 weeks and 5 days." Exhibit 11 at 15. As to why this interval is one for which an inference of causation is appropriate, Dr. Steinman wrote two sentences: "An interval of several months was reported in a series by Menge et al on neuromyelitis optica following HPV vaccination. The intervals in the four cases were 5 months case 1, 5 months in case 2, unknown interval case 3, and 5 months in case 4." Id. at 16.

For the second Althen prong, Dr. Steinman wrote one sentence: "The theory is logical in that it is based on the concept of molecular mimicry which is widely recognized and where there is considerable support in the peer reviewed literature including the papers cited here." Exhibit 11 at 16. Dr. Steinman dismissed any non-vaccine potential causes. Id.

3. Dr. Ghosh and His First Report

Dr. Ghosh received his degree in medicine from the University of Calcutta in India in 1999. He completed a residency in pediatrics in 2003 and a fellowship

in neurology in 2006, both at the Postgraduate Institute of Medical Education and Research in India. Dr. Ghosh then completed a residency in pediatrics and a fellowship in child neurology at the Cleveland Clinic in Ohio between 2007 and 2012, and fellowships in neuromuscular disorders and clinical neuropsychology at the Mayo Clinic in Rochester, Minnesota between 2012 and 2014. Since 2014, Dr. Ghosh has taught classes in neurology at Harvard Medical School and has worked as an attending neurologist at Boston Children's Hospital. He has been the director of the EMG laboratory at Boston Children's Hospital since 2014, and the co-director of the hospital's Muscular Dystrophy Association Care Center since 2017. Dr. Ghosh is board-certified by the American Board of Psychiatry and Neurology with a special qualification in Child Neurology and is a diplomate of the American Board of Electrodiagnostic Medicine. Exhibit B.

Dr. Ghosh has published more than 60 peer-reviewed articles on "various topics of pediatric neurology," including transverse myelitis. Exhibit A at 1-2. At the time of writing his report, he had seen more than five cases of transverse myelitis in the previous five years. Id. at 2.

Like Dr. Steinman, Dr. Ghosh began his first report by presenting his qualifications and listing the material he reviewed. Exhibit A at 1-2. Dr. Ghosh recited events from Mr. Goodwin's medical records and summarized information about transverse myelitis. Id. at 2-7. Dr. Ghosh mentioned---twice---that he did not see any results of tests for MOG antibodies. Id. at 3, 6. Dr. Ghosh agreed that Mr. Goodwin suffered from acute transverse myelitis, which Dr. Ghosh abbreviated as "ATM." Id. at 5. Thus, much of this background material is not meaningfully disputed.

As to the means by which the HPV vaccine could cause transverse myelitis, Dr. Ghosh deferred to the Secretary's second expert, Dr. Tompkins. Exhibit A at 7. However, Dr. Ghosh introduced several articles, including articles by Agmon-Levin, Baxter, the Institute of Medicine, and Pidcock. Id. at 7-10. These articles are discussed in more detail below.

As to timing, Dr. Ghosh disagreed with Dr. Steinman's reliance on Menge. Dr. Ghosh maintained: "NMO [neuromyelitis optica] and ATM are not the same disease and the cases cited by petitioner's expert do not support a proximate temporal relationship between the HPV vaccine and ATM." Exhibit A at 10. In his conclusion, Dr. Ghosh emphasized the long latency between the vaccination and the onset of the transverse myelitis:

> Even when we find a possible association between these two entities [vaccinations and transverse myelitis], it is clear that the strongest case for a causal relationship is when vaccines were administered within a month of development of ATM. Hence, I conclude that in this case, onset of ATM after 68 days following vaccinations lacks significant causal relationship.

Id. at 11.

4. Dr. Tompkins and His First Report

Dr. Tompkins received a Ph.D. in Immunology and Molecular Pathogenesis from Emory University in 1997. Exhibit K; Exhibit L. He did postdoctoral work in Immunology at Northwestern University and in Virology/Immunology at the Center for Biologics Evaluation and Research in the FDA. Exhibit L. Since 2005, he has taught courses in the Department of Infectious Diseases within the College of Veterinary Medicines at the University of Georgia, progressing from an assistant professor to a full professor to the assistant department head and curriculum coordinator. Id. His research "focuses on understanding the interactions of influenza virus and influenza vaccines with the host." Exhibit K at 1. Dr. Tompkins has co-authored over 90 peer-reviewed articles and book chapters on immunology and virology, serves as an ad hoc reviewer for NIH study sections and scholarly journals, and serves on the editorial board for several journals. He has not published in peer-reviewed journals about "the vaccine or adverse events related to this case." Id. at 1-2. Dr. Tompkins is not licensed to practice medicine and holds no board certifications.

As with Dr. Steinman and Dr. Ghosh, Dr. Tompkins starts his report by presenting his qualifications, listing the materials he reviewed, and summarizing events from Mr. Goodwin's medical records. Exhibit K at 1-4. Again, this background material is not meaningfully disputed.

The controverted aspects of Dr. Tompkins's report concern molecular mimicry. He asserts: "while molecular mimicry is extensively studied and is an accepted hypothesis for how various insults (e.g. infection) may turn an individual's immune system against itself, there is a paucity of experimental evidence demonstrating a wild type infection (meaning no manipulation of the system) triggering autoimmune disease through molecular mimicry." Exhibit K at 4. Dr. Tompkins offers more specific challenges to aspects of Dr. Steinman's

three-step process, but a description of these details is deferred until section VI.A. below.

As to timing, Dr. Tompkins disputed Dr. Steinman's reliance on Menge. Dr. Tompkins offered at least three arguments, including the discrepancy in latency as reported by Menge and as reported in other articles by Pidcock and De Goede. Id. at 5-6. Dr. Tompkins maintains that "it is unlikely that the HPV9 vaccine resulted in TM almost 10 weeks later." Id. at 6. Dr. Tompkins supported this assertion by referencing studies about the duration of antibodies following human papillomavirus vaccines. Id. at 6-7.

Dr. Tompkins also asserted that: "there is considerable data demonstrating the safety of HPV vaccines." Exhibit K at 7. He cited a study by the World Health Organization.

Finally, for Mr. Goodwin's case, Dr. Tompkins suggested that the evidence surrounding herpes virus "is at least as strong, if not stronger" than the evidence regarding the HPV vaccine. Exhibit K at 7. Dr. Tompkins maintained that an opinion based upon the herpes virus "fulfills the three criteria of Althen." Id. at 8.

5. Dr. Steinman's Second Report

As both Dr. Ghosh and Dr. Tompkins had challenged aspects of Dr. Steinman's opinion, Dr. Steinman addressed both in his next report. With respect to Dr. Ghosh, Dr. Steinman asserts that two of the four patients in the Menge article "could well have been MOG driven transverse myelitis cases." Exhibit 27 at 2. As to whether Mr. Goodwin had MOG antibodies, Dr. Steinman agreed with Dr. Ghosh that results of testing for MOG antibodies were not found. Id.

Dr. Steinman's response to Dr. Tompkins repeats Dr. Steinman's assertion that two of the Menge patients could have MOG. Exhibit 27 at 4. Thus, Dr. Steinman implies that the presence of a case report of a neurologic disease developing about five months after a vaccination means that the latency in Mr. Goodwin's case (about two and a half months) is an interval for which an inference of causation is appropriate. Id. In further support of timing, Dr. Steinman cites the duration of antibody responses. Id. at 4-5.

Dr. Steinman also defended his proposal of molecular mimicry in response to Dr. Tompkins's criticisms of it. Dr. Steinman contended that Dr. Tompkins seems to be asking for studies done specifically on Mr. Goodwin. Exhibit 27 at 3-4.

Finally, Dr. Steinman responded to Dr. Tompkin's identification of herpes virus as a potential alternative cause. Dr. Steinman opined that herpes virus was not likely because a Blast search failed to detect much homology between herpes simplex virus-1 and MOG. Exhibit 27 at 6.

6. Dr. Ghosh's Second Report

Dr. Ghosh made two points in his second report. First, he argued that the patients in Menge suffered from NMO, not transverse myelitis. Exhibit AA at 1-2. Second, he argued that Mr. Goodwin's transverse myelitis was idiopathic, not associated with MOG antibodies. Id. at 2-4.

7. Dr. Tompkins's Second Report

Dr. Tompkins identified a few issues from Dr. Steinman's previous report to which he wanted to respond. First, Dr. Tompkins challenged molecular mimicry in the context of Mr. Goodwin's case. Dr. Tompkins asserted that "there is no experimental evidence from an animal model of neuropathy or similar system demonstrating that the HSV L1 capsid is presented by antigen-presenting cells to elicit cross-reactive T cells that also recognize MOG epitopes (e.g. CWKITLFVIV), that then attack neuronal tissues and trigger autoimmune disease." Exhibit LL at 2. In this context, Dr. Tompkins also cited studies about the safety of the HPV vaccine.

Dr. Tompkins's second and third points argue against the latency between the HPV vaccination and the onset of Mr. Goodwin's transverse myelitis. The second point discussed the Menge article. The third point discussed the duration of T cells. Exhibit LL at 3.

Dr. Tompkins's fourth point maintained that herpes virus can trigger a neuropathy like transverse myelitis. Dr. Tompkins proposed that the herpes virus can directly infect neurons. Exhibit LL at 4. Thus, to Dr. Tompkins, he was not proposing molecular mimicry, making Dr. Steinman's use of Blast searches irrelevant. He also cited a series of case reports in which an infection with herpes virus preceded the development of myelitis. Id.

8. Dr. Steinman's Third Report

Much of Dr. Steinman's third opinion was focused on defending his reliance on Menge. Dr. Steinman stated that he cited Menge because "it is the only article [Dr. Steinman] can find in the literature that links HPV vaccine to cases where longitudinally extensive transverse myelitis is seen." Exhibit 29 at 1. Dr.

Steinman maintained that the disease affecting Mr. Goodwin, transverse myelitis, is a "prominent feature of NMO," the disease studied in Menge. Id. at 4.

Dr. Steinman also explained why his Blast search involving MOG fit Mr. Goodwin's case. Noting that Dr. Lacy had ordered a test for MOG antibodies but no result appears, Dr. Steinman distinguished between the "absence of evidence" and "evidence of absence." Exhibit 29 at 6-8. Thus, Dr. Steinman appears to suggest that Mr. Goodwin could have developed antibodies to MOG.

Dr. Steinman further asserted that his opinion regarding molecular mimicry should be credited, despite Dr. Tompkins's criticisms. Exhibit 29 at 8-9.[11] Dr. Steinman added another case report in which an HPV vaccination preceded the onset of NMO. Id. at 9, citing Chang. Dr. Steinman also asserted that the antibodies generated through a process starting with an HPV vaccination persist for at least two years. Id. at 10.

Finally, Dr. Steinman responded to Dr. Tompkin's raising a herpes infection as a possible alternative cause. Among other points, Dr. Steinman asserted that PCR testing was not done to show herpes. Id. at 10.

9. Dr. Ghosh's Third Report

Dr. Ghosh's third report tends to repeat what he previously asserted. Dr. Ghosh stated that the patients in the Menge article suffered from NMO, not acute transverse myelitis. In response to Dr. Steinman's statement that the Menge article was the only article linking HPV vaccine to longitudinally extensive transverse myelitis, Dr. Ghosh answered: "The Menge paper was published in 2012. If there was any association with the HPV vaccine and longitudinally extensive TM, one would expect many more reported cases of HPV and longitudinally extensive

[11] Dr. Steinman also extensively quoted from a decision of a special master in White v. Sec'y of Health & Hum. Servs., No. 15-1521V, 2019 WL 7563239 (Fed. Cl. Spec. Mstr. Dec. 19, 2019). Exhibit 29 at 1-3. Dr. Steinman's discussion of legal precedents exceeds his role. See, e.g., D.G. v. Sec'y of Health & Hum. Servs., No. 11-577V, 2019 WL 2511769, at *189 (Fed. Cl. Spec. Mstr. May 24, 2019). As a doctor, Dr. Steinman should focus upon medicine. See Exhibit 29 at 4 (Dr. Steinman defining his job as "educat[ing] the Court."). Mr. Goodwin is represented by attorneys, who are capable of bringing forward analogous legal precedents. Although White is an example in which a special master credited Dr. Steinman's molecular mimicry theory, 2019 WL 7563239, at *23-24, this ruling does not constitute binding precedent. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019).

transverse myelitis to have been published in the last nine years, especially given the millions of HPV vaccines that have been administered." Exhibit JJJ at 2.

Dr. Ghosh also commented about MOG antibodies. Dr. Ghosh stated: "MOG antibodies were not tested in the case of TDG. However, one cannot conclude- as Dr. Steinman does- that if TDG's physicians had tested for MOG antibody, the test could have been positive, and that this hypothetical positive result proves the association of MOG associated transverse myelitis with HPV vaccine." Id. at 3.

10. Dr. Tompkins's Third Report

Although in Dr. Tompkins's second report he had identified four issues with Dr. Steinman's opinion, Dr. Tompkins identified six short disputes in his third report. First, there was a continued discussion over whether Mr. Goodwin could have suffered from MOG-associated transverse myelitis. Exhibit CCC at 2. Second, Dr. Tompkins returned to the Menge article. He asserted: "Case reports do not provide evidence of causation and Menge et al. (2012) does not offer evidence associating the [HPV] vaccination with disease." Id. at 3. Dr. Tompkins addressed Dr. Steinman's recently cited case report, Chang. Dr. Tompkins also maintained that the "absence of VAERS data or other similar studies suggesting a possible safety signal involving HPV vaccination and TM argues strongly that there is no evidence of association." Id. at 3.

Dr. Tompkins's third and fourth point concerned the timing. Dr. Tompkins stated that Menge's "single case with information on timing of vaccination had a five-month interval between vaccination and onset of symptoms. This is sparse support for Dr. Steinman's hypothesis." Exhibit CCC at 3. Dr. Tompkins also disputed whether the duration of antibodies "can explain onset of TM or NMO." Id. at 4. Dr. Tompkins continued: "A 42-day risk period is widely used to determine temporal association between vaccination and an adverse event. This risk window is based upon many epidemiologic studies with infections and/or vaccinations. Dr. Steinman fails to provide an argument as to why this time interval should be different for HPV vaccination and onset of TM."

Fifth, Dr. Tompkins stated, "we are left with no experimental evidence that HPV infection or vaccination with HPV L1 proteins can cause any autoimmune disease, including TM." Exhibit CCC at 4.

Sixth, Dr. Tompkins maintained that an infection with herpes virus is a plausible trigger for neuropathy. Exhibit CCC at 5.

11. Dr. Steinman's Fourth Report

Dr. Steinman's response to Dr. Ghosh essentially repeated what Dr. Steinman had said previously. This repetition is not terribly surprising as Dr. Ghosh's most recent report generally reiterated what Dr. Ghosh had said before.

In response to Dr. Tompkins, Dr. Steinman added references about molecular mimicry in the contest of Epstein-Barr virus potentially causing multiple sclerosis. Exhibit 37 at 3-5. Dr. Steinman has frequently relied upon these articles.

12. Events after Submission of Expert Reports

After the parties filed this series of reports, a status conference was held. A primary question was whether 68 days is an appropriate interval. The parties agreed to submit briefs. Order, issued May 24, 2022.

Both parties advocated. Mr. Goodwin filed his primary brief on July 25, 2022, and his reply on December 21, 2022. In between, the Secretary submitted his brief on September 23, 2022.

Mr. Goodwin was found not entitled to compensation. First Entitlement Decision, issued April 16, 2024, 2024 WL 2033563. The reason was that Mr. Goodwin had not established that 68 days was an interval for which an inference of causation was appropriate.

Mr. Goodwin challenged this determination. Pet'r's Mot. for Rev., filed May 16, 2024. The Court granted the motion for review and vacated the April 16, 2024 decision on October 10, 2024. 2024 WL 4758470.

B. Events in Litigation after Remand

Following remand, the parties worked commendably quickly and cooperatively to expedite proceedings. For example, within about two weeks of the Opinion and Order remanding the case, Mr. Goodwin asked for and received authorization to subpoena medical records.

Due, in part, to the end-of-the-year holidays and commitments in other cases, Mr. Goodwin and the Secretary jointly requested that the Court extend the deadline for completing the remand for an additional 60 days (or until March 10, 2025). The Court ruled that the Vaccine Act does not allow the Court to extend the time for remand beyond 90 days. Order, issued Oct. 28, 2024, citing 42 U.S.C.

§ 300aa–12(e)(2). However, the Court added that "there does not appear to be a consequence for exceeding the 90-day remand period." Id., citing Greene v. Sec'y of Health & Hum. Servs., No. 11-631V, slip. op. at 3 (Fed. Cl. May 30, 2018) and Paluck v. Sec'y of Health & Hum. Servs., 111 Fed. Cl. 160, 165 (2013). The Court, therefore, interpreted the parties' joint request "as a waiver of their ability to request any action on enforcing the Court's 90-day remand order until after the period of their requested extension---March 10, 2025---has passed." Id. With cooperation from the parties, a hearing was scheduled for January 9-10, 2025. Order, issued Nov. 5, 2024.[12]

Mr. Goodwin submitted updated medical records on November 15, 2024. Exhibits 40-41. In a comprehensive memorandum, he argued that he met all Althen prongs. Pet'r's Post-Remand Br.[13] He also submitted additional medical articles.[14] Finally, Mr. Goodwin introduced an affidavit from his mother, the original petitioner. Ms. McCluskey avers that around March 30, 2018, someone from her son's middle school called her to say he had lost control of his bladder, and he needed clean clothes. Exhibit 43. In response to this assertion, Mr. Goodwin was directed to obtain records from the school system. Order, issued Nov. 25, 2024.

The Secretary maintained that Mr. Goodwin was not entitled to compensation. Resp't's Post-Remand Br. Although the Secretary agreed that Mr. Goodwin suffered from transverse myelitis (Resp't's Post-Remand Br. at 13-14), the Secretary basically contested four points. First, the Secretary contended that a preponderance of the evidence did not support a finding that Mr. Goodwin experienced episodes of losing his bladder. Resp't's Post-Remand Br. at 14-16. Second, largely based upon the opinions from Dr. Tompkins, the Secretary challenged the reliability of molecular mimicry as a theory to explain how the human papillomavirus vaccine can cause transverse myelitis. Id. at 16-21; see also id. at 28-30 (discussing non-binding decisions from special masters rejecting Dr. Steinman's opinions). Third, the Secretary argued that the timing presented an

[12] Scheduling a hearing in the Vaccine Program to take place approximately two months later is remarkably quick. The parties' flexibility and willingness to prioritize the hearing in this post-remand case is greatly appreciated.

[13] The July 25, 2022 brief and the December 21, 2022 reply addressed only Althen prong three.

[14] Normally, the submission of medical articles without an accompanying report from an expert explaining the relevance of the medical articles is frowned upon, if not forbidden. However, the expedited nature of a remand supported the use of shortcuts.

interval for which an inference of causation was not appropriate. Id. at 14-16. To some degree, the Secretary's arguments overlapped with the arguments whether Mr. Goodwin lost control of his bladder. The Secretary added that Dr. Steinman disclosed an opinion that the onset of transverse myelitis was 68 days after vaccination. Resp't's Post-Remand Br. at 16, citing Exhibit 11 (Dr. Steinman's report). Finally, the Secretary maintained that Mr. Goodwin had not established a logical sequence of cause and effect. Resp't's Post-Remand Br. at 21-24. The Secretary raised several points, including the lack of persuasive evidence regarding Althen prongs one and two, the lack of statements from treating doctors supporting causation, the lack of proof regarding MOG antibodies, and the presence of a potential alternative cause (an infection with herpes virus).

Two aspects of the Secretary's arguments required prompt attention. Thus, a status conference was held on December 17, 2024. Mr. Goodwin stated that his mother and he would testify at the upcoming fact hearing regarding the episodes of bladder loss. In addition, Mr. Goodwin planned to obtain a supplemental report from Dr. Steinman discussing whether episodes of loss of bladder were early manifestations of transverse myelitis.

Mr. Goodwin submitted an affidavit on December 20, 2024, averring that there were times "before [he] was in the hospital" that he lost his balance and lost control of his bladder in school. Exhibit 57.[15] He noted that the school nurse had to call his mother to bring him a change of clothes. Id. Although Mr. Goodwin attempted to corroborate the phone calls by subpoenaing records from T-Mobile and AT&T, Mr. Goodwin eventually determined that these records did not establish that the school system had telephoned his mother. See Pet'r's Status Rep., filed Jan. 22, 2025 (addressing AT&T records) and Pet'r's Status Rep., filed Feb. 26, 2025 (addressing T-Mobile records).[16]

Dr. Steinman's supplemental report was filed on December 23, 2024. Exhibit 58.[17] Dr. Steinman opined that the onset of Mr. Goodwin's TM was within two weeks of his March 22, 2018 vaccination and that the loss of bladder control and loss of leg mobility in March and April 2018 were the initial manifestations of

[15] Mr. Goodwin's affidavit was originally mislabeled as exhibit 49.

[16] The problem was that Ms. McCluskey did not remember her cell phone number accurately.

[17] When this report was first filed, it was erroneously labeled as Exhibit 50.

TM. His opinions on the first and second Althen prongs "remain[ed] unchanged." Id. at 3.

Dr. Ghosh's supplemental report, which was prepared quickly, brought forward essentially two points. Exhibit SSS (dated Dec. 30, 2024). First, Dr. Ghosh discussed the December 13, 2019 appointment with Dr. Tardo. Dr. Ghosh noted the results of the physical examination, the lab tests, and the MRIs. In Dr. Ghosh's view, Mr. Goodwin "did not have recurrence of myelitis or optic neuritis, which is commonly seen in neuromyelitis optica (NMO), MOG-associated conditions or multiple sclerosis (MS)." Id. at 3. Thus, Dr. Ghosh "strongly disagree[d] with Dr. Steinman's assertion of bringing NMO and MOG in this case (Ex. 50) when it is clear that the petitioner neither has NMO or MOG." Id. Next, Dr. Ghosh discussed the significance of the assertion that Mr. Goodwin had intermittent episodes of urinary incontinence in April and May 2018. Dr. Ghosh opined that these symptoms could not be attributable to the spinal cord "without any objective clinical or radiological evidence." Id. at 4. Dr. Ghosh added: "Moreover, in ATM, progression to nadir is between 4 hours and 21 days following onset of symptoms, which does not fit with petitioner's temporal course of urinary incontinence." Id.

Although the parties had strived to schedule a hearing relatively promptly, events interfered. The federal Government was unexpectedly closed for the first day of the scheduled two-day hearing due to the funeral for former President Carter. See Order, issued Jan. 2, 2025. In a status conference, the parties expressed their preference that the hearing be completed on consecutive days. Thus, the second day of the hearing was also canceled. Order, issued Jan. 3, 2025. The parties agreed to hold the hearing on March 19-20, 2025. Order, issued Jan. 17, 2025.

During this extension, Mr. Goodwin filed additional evidence. For example, Mr. Goodwin filed attendance records from his school from March through April 2018. Exhibit 67-68. Unfortunately, some information was no longer available as the school system retains complete information for only five years. The submitted material shows that on three occasions, Mr. Goodwin was "present." "Present," in turn, means that "the student was present at school but missed part of his instructional day. The entry might occur if a student has a Doctor's Appt." Exhibit 68 at 1 (email from a paralegal of the school district).

The hearing was held, as scheduled for a second time, on March 19-20, 2025. Again, the attorneys and witnesses cooperated to make sure that the hearing was held as soon as possible. Part of this cooperation involved starting the hearing

at 10:30 A.M. Eastern Time to reflect that Dr. Steinman was testifying from the Pacific Time Zone.

During the hearing, Ms. McCluskey, Mr. Goodwin, Dr. Steinman, Dr. Ghosh, and Dr. Tompkins testified. Ms. McCluskey provided information about medical professionals who treated her son and whose records had not been produced previously. For example, when the family lived in McKeesport, Pennsylvania before moving to Texas, Ms. McCluskey brought Mr. Goodwin to a pediatrician. Tr. 37. Similarly, on May 30, 2018, when Mr. Goodwin was not feeling well, the family brought him to an emergency room in Bedford before he was transferred to Cook Children's Hospital. Tr. 61-62.

Ms. McCluskey and Mr. Goodwin otherwise generally narrated events that, in their view, happened between the vaccination and May 30, 2018. More specifically, Ms. McCluskey and Mr. Goodwin each discussed the two episodes in which Mr. Goodwin lost control of his bladder and wet his pants. Tr. 23-24, 84.

Dr. Steinman's direct testimony was generally in accord with the opinions he had disclosed in his reports. For example, just as he wrote in his second report, Dr. Steinman testified that the results of MOG testing were absent. Tr. 102. (Other details of Dr. Steinman's oral testimony are presented in the context of various topics below.)

On cross-examination, Dr. Steinman was again asked about testing for MOG antibodies. Dr. Steinman was surprised to learn that testing from December 13, 2019 showed that Mr. Goodwin did *not* have MOG antibodies. Tr. 154-56.[18] Dr. Steinman's spontaneous answer was that the testing occurred too late (approximately 18 months later) to detect MOG antibodies. Thus, Dr. Steinman opined that the negative test for MOG in December 2019 did not mean that Mr. Goodwin also did not have MOG antibodies in May 2018.

[18] Dr. Steinman suggested that he was being unfairly surprised with this information. Tr. 158. However, there was nothing unfair. Dr. Tardo and Dr. Greenberg ordered the MOG testing as part of the visit in which they memorialized Ms. McCluskey's history about two episodes of loss of bladder control. Exhibit 42 at 2394. Due to the importance of this medical record as a primary piece of evidence supporting a theory that Mr. Goodwin's transverse myelitis started less than 68 days after vaccination, Dr. Steinman should have been aware of it. Moreover, Dr. Ghosh identified the results of the December 13, 2019 MOG testing in his December 30, 2024 report. Exhibit SSS at 2-3. Thus, Dr. Steinman should have known about the results of the 2019 MOG testing before his testimony.

At approximately 9:00 A.M. on the day after Dr. Steinman testified, Mr. Goodwin submitted two articles about the duration of MOG antibodies. Exhibits 74-75. Off the record, the Secretary objected to the introduction of articles during the hearing. See Tr. 444-45. The Secretary's objection was well-founded. However, despite the Secretary's valid point about the need for an orderly presentation of material, the Secretary's objection was overruled and neither Exhibit 74 nor Exhibit 75 were struck from the record. The basic reason was that since the Court's remand, the parties have been attempting to proceed quickly. In the attempt to move expeditiously, some steps were taken out of normal order. For example, the Secretary filed his post-remand brief before Dr. Ghosh completed the disclosure of his opinions. In this sequence, both Mr. Goodwin's counsel and Dr. Steinman missed Mr. Goodwin's negative MOG results. Thus, to avoid penalizing Mr. Goodwin for the mistakes of professionals he has retained, Dr. Steinman's two new articles about MOG antibodies remained in the record.[19]

During the hearing, Dr. Ghosh and Dr. Tompkins testified in accord with the opinions expressed in their reports, which are summarized above. Additional details about their oral testimony are discussed below.[20]

Following the hearing, the Secretary was permitted to file a supplemental report from Dr. Ghosh regarding the two articles about MOG antibodies that Dr. Steinman located during the hearing. Exhibit WWW. With that report, Dr. Ghosh cited another article. Exhibit XXX. The presentation of that material closed the evidence regarding the duration of MOG antibodies. See Order, issued April 15, 2025.

Mr. Goodwin also filed additional factual information, including his school records and some pre-vaccination medical records. Exhibits 79-80.

The parties jointly proposed that they both submit briefs 45 days after the last medical record was filed, which they did on August 11, 2025. They also

[19] On the other hand, Mr. Goodwin also filed an article about narcolepsy (Exhibit 76) on the morning of the second day of the hearing. After a discussion about the appropriateness of submitting articles during the hearing, Mr. Goodwin agreed to withdraw the narcolepsy article. Arguably, the narcolepsy article could support an argument that the latency between vaccination and an onset of a disease can encompass 68 days. However, the 68-day latency has been the primary issue throughout this litigation. Mr. Goodwin could not claim surprise. Thus, the article about narcolepsy is not part of the record.

[20] Counsel's cross-examination of Dr. Tompkins was particularly effective.

defended their positions through replies. With the submission of these briefs, the case is ready for adjudication.[21]

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a); see also Townsend v. Sec'y of Health & Hum. Servs., 170 Fed Cl. 130, 141 (2024), appeal docketed, No. 24-1740 (Fed. Cir. April 25, 2024). The preponderance of the evidence standard requires a "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 & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

This decision resolves three issues. First, whether preponderant evidence supports a finding that Mr. Goodwin experienced urinary incontinence shortly after receiving the vaccine. Second, assuming that there is preponderant evidence showing Mr. Goodwin sometimes lost control of his bladder, whether these episodes of urinary incontinence are manifestations of transverse myelitis. Third, whether Mr. Goodwin has met his burden to show that the HPV vaccine caused his transverse myelitis.

[21] As mentioned in the procedural history, the resolution of Mr. Goodwin's case exceeded the time anticipated in the Court's October 10, 2024 Opinion and Order. Nevertheless, the parties complied with the spirit, if not exactly the letter of the Opinion and Order. In the same vein, the issuance of this Decision within about one month of the final submission attempts to demonstrate a good faith effort to prioritize Mr. Goodwin's case.

IV. First Issue: Whether Mr. Goodwin Suffered Urinary Incontinence in March and April 2018

A. Introduction

Before the First Entitlement Decision, issued April 16, 2024, the parties agreed that the onset of Mr. Goodwin's transverse myelitis was on May 30, 2018. See Pet'r's Br. regarding Timing, filed July 25, 2022, at 6, 8; Resp't's Resp., filed Sep. 23, 2022, at 5. However, upon remand, the recent discovery of evidence led Mr. Goodwin to propose a different onset date, which was within one to two weeks of the vaccination. See Pet'r's Post-Remand Br. at 36; Pet'r's Post-Hearing Br. at 19. The Secretary disputes the assertion in two respects. First, the Secretary disputes the persuasiveness of the evidence underlying the assertion that Mr. Goodwin experienced episodes of urinary incontinence. Resp't's Post-Remand Br. at 14-16; Resp't's Post-Hearing Br. at 18-19. Second, Dr. Ghosh opined that episodes of urinary incontinence were not manifestations of transverse myelitis. Exhibit SSS at 4.[22] The Secretary's first point raises a pure question of fact: whether preponderant evidence establishes that Mr. Goodwin had episodes of urinary incontinence in March and April 2018. (The Secretary's second point regarding the diagnostic significance is discussed next in section V below).

B. Additional Standards for Adjudicating Questions of Fact

From time to time, the parties in the Vaccine Program disagree over whether (or when) a vaccinee developed problems and special masters resolve these disputes routinely. See, e.g., Britt v. Sec'y of Health & Hum. Servs., No. 17-1352V, 2021 WL 4282596 (Fed. Cl. Spec. Mstr. Aug. 27, 2021). In determining how the evidence preponderates, a basic starting point is that medical records are presumptively accurate in describing events that occurred contemporaneously with the creation of the medical records. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993); Martinez v. Sec'y of Health & Hum. Servs., 165 Fed. Cl. 76, 90 (2023). From this starting point, special masters have sometimes reasoned that the lack of documentation in a medical record created close in time to when the event allegedly happened can be a basis for finding that the alleged event did not happen. See Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1574 (Fed. Cir. 1993) (rejecting an argument that the special

[22] Due to the rapid schedule of events after the Court's remand, neither Dr. Steinman nor Dr. Ghosh had issued supplemental reports addressing the potential of urinary incontinence before the parties filed their briefs.

master was arbitrary in relying upon "the absence of medical records"); see also Britt, 2021 WL 4282596, at *2 (collecting appellate cases).

However, the Federal Circuit has cautioned that medical records are not always complete. Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Thus, a special master may credit later accounts about what allegedly happened despite the lack of documentation in a medical record created around the time of the event. See La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 203 n.33 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). Even after the Federal Circuit's opinion in Kirby, a special master may reject testimonial assertions about when events allegedly happened provided that the special master considers the entire record. Trinnaman v. Sec'y of Health & Hum. Servs., 171 Fed. Cl. 317, 325-26 (2024) (denying motion for review).

C. Summary of Parties' Evidence and Arguments

Mr. Goodwin relies upon two types of evidence. The first is medical records created during appointments with neurologists, Dr. Tardo and Dr. Greenberg. Exhibit 42 at 2394 (Dec. 13, 2019).[23] Ms. McCluskey reported that after receiving vaccines on March 22, 2018 "~1.5-2 weeks later in April 2018 [Mr. Goodwin] started having episodes of bowel and bladder incontinence at school."[24] The second type of evidence is a series of testimonial assertions. The category of testimonial assertions includes Ms. McCluskey's affidavit (Exhibit 43), Mr. Goodwin's affidavit (Exhibit 57), Ms. McCluskey's oral testimony during the hearing, and Mr. Goodwin's testimony during the hearing. Mr. Goodwin argues that this evidence should be credited. Pet'r's Post-Remand Reply at 1-6; Pet'r's Post-Hearing Br. at 19-20. Mr. Goodwin argues: "These incidents of incontinence are either true, or were dishonestly reported, then intentionally left hidden during the expert reports, initial dismissal, the appeal, and the remand of the case. There is no other logical explanation." Id. at 19.

In contrast, the Secretary tends to rely upon a lack of evidence. The Secretary points out that Ms. McCluskey did not present this chronology to doctors between March 2018 and December 2019. Resp't's Br. at 15. The Secretary

[23] Technically, petitioner's brief identified a June 12, 2020 progress note. Pet'r's Post-Remand Br. at 37, citing Exhibit 41 at 912. In doing so, Mr. Goodwin appears to have overlooked an earlier notation described in the text.

[24] This history appears to be carried into the record for a June 12, 2020 telehealth appointment. Exhibit 41 at 912.

further argues that Mr. Goodwin's supporting evidence merits little weight as the affidavits were "made retrospectively for purposes of litigation." Id. The Secretary further characterizes the accounts presented to Dr. Tardo and Dr. Greenberg as "subjective reports." Resp't's Post-Hearing Br. at 18.

D. Assessment

The evidence preponderates in favor of finding that Mr. Goodwin experienced two episodes of bladder incontinence in March or April 2018. The primary basis is that his pre-vaccination records, which were not filed until after the hearing, document other instances in which Mr. Goodwin had accidents. See Exhibit 80 at 144 (Sep. 28, 2017); Exhibit 79 at 82 (Dec. 1, 2017). This evidence alters the picture.

Before these pre-vaccination records were filed, it appeared that the alleged March and April 2018 episodes were new.[25] If Mr. Goodwin had not previously experienced urinary incontinence as a teenager, then episodes of urinary incontinence could be alarming. An abrupt start to a new problem could prompt loving parents, like Ms. McCluskey, to seek medical attention for their child. In this situation, a memorialization of the episodes in medical records could reasonably be expected.

On the other hand, the September 28, 2017 and December 1, 2017 medical records establish that Mr. Goodwin had at least some episodes of enuresis. Thus, any episodes that arose in March and April 2018 would not necessarily have shocked his mother. In March and April 2018, Ms. McCluskey did not search for answers about the cause for incontinence on the internet and she did not start to buy Mr. Goodwin adult diapers. Tr. 57. Mr. Goodwin's experience with urinary incontinence also helps explain why no medical record from Texas Family Health memorializes the episodes of incontinence. See Exhibit 6 at 56-72 (April 11, 2018); Exhibit 6 at 73-94 (May 10, 2018).[26] It seems likely that the family did not

[25] Ms. McCluskey stated that the episodes of urinary incontinence in April and May were "unusual" and that Mr. Goodwin "never had problems with his bladder before 2018." Tr. 14, 47; accord Tr. 84 (Mr. Goodwin). This testimony, which was provided before Ms. McCluskey's attorney had filed the pre-vaccination records, is not accurate.

[26] Ms. McCluskey testified that she brought Mr. Goodwin to the doctor's office following the second episode of urinary incontinence. Tr. 14, 24, 58; see also Tr. 85 (Mr. Goodwin's testimony). In light of the omission of any complaints about urinary incontinence in the relevant medical records, this testimony is rejected as inaccurate.

view the episodes as something requiring medical attention, perhaps because of Mr. Goodwin's autism.

The school records provide a modicum of support for the assertions that Mr. Goodwin experienced two episodes of urinary incontinence. On March 29, 2018, April 13, 2018, April 18, 2018, and April 23, 2018, he was marked "present." Exhibit 67 at 21-22. "Present," in turn, means "student was present at school but missed part of his instructional day. The entry might occur if a student . . . does not attend some of their classes." Exhibit 68. An absence from class due to a need to receive clean clothes is consistent with a notation of "present." See Pet'r's Post-Hearing Br. at 19.[27]

Finally, in December 2019, Ms. McCluskey told Doctors Greenberg and Tardo about the episodes. Exhibit 42 at 2394. Unlike the school attendance records, the record from December 2019 was not created around the time the episodes of urinary incontinence took place, which was April and May 2018. The lack of contemporaneousness means that the December 2019 record could be less valuable due to the passage of time, which impairs people's memories. On the other hand, the Secretary has not otherwise impeached the accuracy of this account.

In short, sufficient evidence preponderates in favor of finding that Mr. Goodwin experienced two episodes of urinary incontinence within two weeks of his vaccination. Whether these episodes are manifestations of his transverse myelitis is discussed next.

V. Second Issue: When did Mr. Goodwin's Transverse Myelitis Begin

"If there is a dispute as to the nature of the petitioner's injury, the special master may opine on the nature of the petitioner's injury." Contreras v. Sec'y of Health & Human Servs., 844 F. 3d 1363, 1368 (Fed. Cir. 2017).

Any finding that Mr. Goodwin experienced episodes of urinary incontinence would not necessarily determine that these episodes marked the beginning of transverse myelitis. Although urinary incontinence can be a symptom of

[27] To be sure, the school records do not establish that Mr. Goodwin had episodes of urinary incontinence beyond a reasonable doubt. For example, the nurse's notes do not memorialize any trips to the nurse's office around this time. But, the lack of notation in the nurse's notes is not controlling because it is not entirely clear that a nurse would have logged a visit for a non-medical reason, such as a change in clothes, and because the nurse's notes were obtained years later and may not be complete.

transverse myelitis, see Marco v. Sec'y of Health & Hum. Servs., No. 15-1178, 2018 WL 8755888 (Fed. Cl. Spec. Mstr. Aug. 1, 2018), urinary incontinence can be associated with other conditions as well. See Curry v. Sec'y of Health & Hum. Servs., No. 22-729V, 2025 WL 1693655 (Fed. Cl. Spec. Mstr. Apr. 28, 2025) (doctors considered whether urinary retention was a manifestation of prostatitis).

Based primarily upon the medical records from Doctors Tardo and Greenberg, Dr. Steinman opined that the onset of Mr. Goodwin's transverse myelitis was 7-14 days after the HPV vaccination. Exhibit 58 at 3. Dr. Steinman did not explain how transverse myelitis would exist in Mr. Goodwin for such a long time before it was diagnosed.[28]

Dr. Ghosh opined that he "did not think the earlier intermittent symptoms of urinary incontinence or a single brief episode of leg weakness could be attributable to spinal cord involvement without any objective clinical or radiological evidence." Exhibit SSS at 4. In addition, Dr. Ghosh referenced the diagnostic criteria for acute transverse myelitis.

In 2002, a group of experts proposed a set of diagnostic criteria with some inclusion criteria and some exclusion criteria. Exhibit C. Of the six inclusive criteria, the relevant one is: "Progression to nadir between 4 h and 21 d following the onset of symptoms." Id. at 500 (table 1). The authors explained that the "maximal deficit is arbitrary" but "valid based on the authors' clinical experience and review of the literature." Id. at 501. A purpose of this criterion was to distinguish acute transverse myelitis from "a slowly progressive or stuttering hereditary myelopathy, spinal cord tumor, myelopathy due to a dural arteriovenous fistulas, and a chronic progressive form of [multiple sclerosis]." Id.

Special masters have relied upon this set of criteria. See Eloyan v. Sec'y of Health & Hum. Servs., No. 18-1450V, 2023 WL 9053983 at *9 (Fed. Cl. Spec. Mstr. Nov. 17, 2023) (finding petitioner did not suffer transverse myelitis due to progression of symptoms for longer than 21 days and citing cases reaching similar conclusions); White v. Sec'y of Health & Hum. Servs., No. 15-1521V, 2019 WL 7563239 at *19 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (finding vaccinee suffered from transverse myelitis).

[28] Dr. Steinman emphasizes that one of the authors of the report, Dr. Greenberg, is a "an expert on transverse myelitis." Exhibit 58 at 1. However, Dr. Greenberg did not conclude that Mr. Goodwin's transverse myelitis started shortly after the vaccination. Dr. Greenberg and his associate, Dr. Tardo, simply memorialized the history given to them by Ms. McCluskey.

The experts disagreed about the value of the Working Group criteria. Dr. Steinman emphasized that the diagnostic criteria can be "arbitrary." Tr. 96-98. Dr. Ghosh agreed with the Working Group's definition that the nadir for transverse myelitis should occur between 4 hours and 21 days of the onset of symptoms. Tr. 198; see also Tr. 223-24.

The authors of the Working Group had extensive experience in studying and treating patients with transverse myelitis. Dr. Steinman has not persuasively established a reason for revising what the authors proposed as diagnostic criteria for transverse myelitis.[29] Dr. Ghosh sensibly relies upon the published diagnostic criteria in opining that even if Mr. Goodwin experienced two episodes of loss of bladder in early or mid-April, these episodes would not be manifestations of transverse myelitis. See Salah v. Sec'y of Health & Hum. Servs., No. 18-1772V, 20224 WL 1925381, at *17 (Fed. Cl. Spec. Mstr. Apr. 12, 2024) (considering the 21-day maximum time to nadir in determining when a vaccinee's transverse myelitis began).

Another problem with the opinion that Mr. Goodwin's transverse myelitis starting with two episodes of urinary incontinence in early or mid-April is the ways in which this opinion is inconsistent with other information. Both Ms. McCluskey and Mr. Goodwin testified that Mr. Goodwin had two, and only two, episodes of urinary incontinence. Tr. 14, 85. If Mr. Goodwin's episodes of urinary incontinence were due to transverse myelitis (meaning that he had an inflammatory lesion in his spinal cord), then Mr. Goodwin would be expected to experience more episodes of urinary incontinence. Dr. Ghosh testified that "urinary incontinence would not be attributed to transverse myelitis when the symptoms are very transient and did not persist." Tr. 197. He stated that if these were symptoms of transverse myelitis, Mr. Goodwin would have reached nadir within three weeks of the onset of the first symptoms, i.e., by the third or fourth week of April. Tr. 198. Dr. Steinman did not persuasively explain a way that any spinal cord lesion would have healed without any intervention. See Tr. 162-63.

[29] Mr. Goodwin asserts that Dr. Steinman "treats more transverse myelitis patients." Pet'r's Post-Hearing Br. at 20. However, Mr. Goodwin fails to cite evidence for this assertion. Dr. Steinman stated that in the last five years, he has treated about five patients with transverse myelitis. Tr. 93. Dr. Ghosh stated that over the last ten years, he has treated 10-15 patients with transverse myelitis. Tr. 190. Thus, Dr. Steinman's and Dr. Ghosh's recent experience with treating patients with transverse myelitis is roughly comparable, about one patient per year. In this situation, Dr. Steinman does not possess such greater experience with transverse myelitis that his opinion regarding the diagnostic criteria should be credited.

Relatedly, when Mr. Goodwin unquestionably was experiencing transverse myelitis at Cook Children's Hospital, he reported that he was having trouble voiding. Exhibit 7 at 92. In other words, his problem was urinary retention, not urinary incontinence. Although transverse myelitis can be associated with urinary incontinence if the symptom persists and is not transient, transverse myelitis is most commonly associated with urinary retention. Tr. 197. Dr. Steinman did not persuasively explain how one person could experience one problem and then evolve into the other problem without any medical intervention over the course of approximately six weeks. He agreed that it was "a puzzle," and stated that he didn't "have a very strong opinion of moving from day 68," but that he could not ignore the episodes of bladder incontinence in early April. Tr. 162-63.

Finally, Mr. Goodwin contends that "There is no other proposed reason for why this young man, with no history of wetting his pants at school, wet his pants twice roughly two weeks after his HPV vaccination." Pet'r's Post-Hearing Br. at 20. Mr. Goodwin's statement of "no history of wetting his pants at school" is inconsistent with the records filed after the hearing in which Ms. McCluskey stated that he was having enuresis and in which Mr. Goodwin was reported to have had an accident. See Exhibit 80 at 144. While it might be technically correct to assert that Mr. Goodwin had "no history of wetting his pants at school," Mr. Goodwin seems to be overlooking the more general point that he did not always control his bladder.[30]

In short, while Mr. Goodwin did experience two episodes of urinary incontinence, the evidence does not preponderate in favor of finding that these episodes were manifestations of the transverse myelitis that was manifest on May 30, 2018. This finding, in turn, affects the third Althen prong, which is discussed below.

VI. Third Issue: Whether the HPV Vaccination Caused Mr. Goodwin's Transverse Myelitis

With the resolution of those two preliminary issues, the analysis turns to the heart of the case: whether Mr. Goodwin established with preponderant evidence that the HPV vaccine caused his transverse myelitis. Because transverse myelitis is not listed on the Vaccine Table, Mr. Goodwin bears the burden of showing that the vaccine was the cause-in-fact of the injury. The elements are well known.

[30] Mr. Goodwin makes a more refined argument in attempting to distinguish loss of bladder control while sleeping from loss of bladder control while awake. See Pet'r's Post-Hearing Reply at 7. However, even loss of bladder control while sleeping would be unusual.

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

A. *Althen* Prong One: A Medical Theory

"To meet prong one, 'a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be legally probable, not medically or scientifically certain." Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640, 651-52 (2023) (internal quotation marks and citations omitted), appeal dismissed, No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024).[31] A petitioner does not prevail on prong one simply by invoking the "magic words" molecular mimicry. Instead, "a petitioner needs to cite to evidence, circumstantial or otherwise, suggesting reason to find it plausible that the proposed autoimmune cross-reaction triggered by the relevant vaccine does occur." Townsend, 170 Fed. Cl. at 142.

The evidence regarding whether the HPV vaccine can cause transverse myelitis can be categorized into three types. The first is epidemiology and other studies. The second is case reports. The third is the opinion of Dr. Steinman.

1. Epidemiology and Other Studies

For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020).

The Secretary's experts cited various epidemiological articles in an attempt to undermine the contention that the HPV vaccine can cause transverse myelitis. For the reasons discussed below, the Secretary's effectiveness was mixed.

[31] Mr. Goodwin maintains that "the tension between the terms 'plausible theory' and 'preponderance of the evidence' is very real in the Vaccine Injury Compensation Program." Pet'r's Post-Hearing Reply at 2. It appears that the reviewing Court has already resolved this issue in Dennington. Thus, an elaboration on the different precedents is not required.

a) Baxter

Dr. Ghosh cited an article by Baxter et al. Exhibit A at 8. For this study, the researchers consulted the Vaccine Safety Datalink. Exhibit H.[32] They looked for instances of either transverse myelitis or another demyelinating disease (acute disseminated encephalomyelitis, which is often abbreviated "ADEM"). Approximately two million doses of an HPV vaccine were considered as part of this study. The adjusted odds ratio of developing transverse myelitis in 5-28 days after an HPV vaccine was zero. Exhibit H at 2, table 2.

With respect to Baxter, Mr. Goodwin and his team did relatively little to challenge Baxter's value. In the course of his testimony, Dr. Steinman referred to the 2012 IOM report. Tr. 116-27. Under the heading "Epidemiological Evidence," this report stated: "No studies were identified in the literature for the committee to evaluate the risk of transverse myelitis after the administration of HPV vaccine." While this statement about a lack of epidemiology may have been accurate when the report was written, the Baxter study was published in 2016.

Mr. Goodwin argues that "lazy or biased epidemiology cannot be used to disprove a causative link." Pet'r's Post-Hearing Br. at 22. This argument appears to lack any evidentiary foundation, in part, as Mr. Goodwin did not cite any evidence that would justify characterizing the Baxter researchers as either "lazy" or "biased." Mr. Goodwin also argues that "Epidemiologic studies that do not take Lazarus[33] or VAERS reports into account must be viewed with caution. Scientific studies must take actual data and actual limitations into account, or they are of little value." Pet'r's Post-Hearing Br. at 21. Again, this argument seems to be one coming from an attorney, not one based upon evidence. The data for the Baxter study is the information contained in the Vaccine Safety Datalink.[34] Mr. Goodwin has failed to show that the Baxter researchers failed to take "actual data . . . into account." Furthermore, Mr. Goodwin has not explained why researchers who are

[32] The Secretary filed the Baxter article in its manuscript form. Thus, citations to specific pages do not correspond to the pagination in the published journal.

[33] The Lazarus report was also filed by Mr. Goodwin and is discussed in Section VI.A.1.d below.

[34] The Vaccine Safety Datalink is "a collaborative effort of the Centers for Disease Control ("CDC"), a governmental agency, and eight large non-governmental organizations that provide health care, known as 'managed care organizations.'" In re Claim for Vaccine Injuries Resulting in Autism Spectrum Disorder, 2007 WL 1983780, at *4 (Fed. Cl. Spec. Mstr. May 25, 2007).

using the Vaccine Safety Datalink should also use VAERS reports.[35] In short, Mr. Goodwin's attempts to minimize the reliability of the Baxter study largely fell flat.[36]

Thus, the Baxter study tends to undermine the claim that HPV vaccines can cause transverse myelitis. But, as a single epidemiological study, Baxter is not dispositive. Epidemiology cannot be used to prove a negative. Heddens v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. 193, 199 (2019) ("the special master did not abuse his discretion in considering epidemiology and did not elevate petitioner's burden of proof").

b) World Health Organization

Dr. Tompkins cited a report from the World Health Organization. Exhibit K at 7. A committee from the World Health Organization reviewed the safety of vaccines for human papillomavirus. This committee cited various studies that generally did not find that the receipt of a vaccine for human papillomavirus increased the risk of developing different diseases. Thus, the World Health Organization considered the vaccines to be safe. Exhibit X at 6-9; accord Tr. 265-68. However, this report carries less weight because the underlying studies appear not to have investigated a potential link to transverse myelitis.

[35] By way of contrast, researchers who are using the VAERS system may want to consider the Lazarus study. See Section VI.A.1.d below.

[36] The Baxter authors addressed the limitations of their study, acknowledging: "The method depends on selection of an appropriate risk (exposure) interval, so if the interval is misspecified, an increased risk could have been missed." Exhibit H at 6. Dr. Steinman also noted this "pitfall," but explained that Baxter and colleagues selected this interval based on the 1976 swine flu studies, which is also "the basis for a lot of intervals in the vaccine table." Tr. 186. He stated, "you work with the best tools at hand, the best data at hand, but you have to admit to the limitations." Id. Given the general acceptance of this interval, Baxter remains a credible study. See Martinez v. Sec'y of Health & Hum. Servs., No. 16-738V, 2022 WL 4884923, at *30 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) ("It is reasonable to contend, as Petitioners do, that Baxter contains some methodologic weaknesses that limit how much probative weight its findings should receive. But it still undermines Petitioner's theory—especially given the degree to which Petitioners relied on case reports in the alternative") (internal citation omitted), mot. for rev. denied, 165 Fed. Cl. 76 (2023).

c) Donahue

Dr. Tompkins cited an article by James G. Donahue et al. Exhibit LL at 3. The researchers accessed two years of data collected at six cites in the Vaccine Safety Datalink. Exhibit PP at 2.[37] The researchers looked for people developing peripheral neuropathies, Guillain-Barré syndrome, or chronic inflammatory demyelinating polyneuropathy. Although these researchers "did not identify any new safety concerns," Id. at 7, this (lack of) finding has less relevance in the present case, which concerns transverse myelitis.

d) Shimabukuro

Dr. Tompkins also cited an article by Tom T. Shimabukuro et al. Exhibit LL at 3. In this project, the researchers looked at VAERS reports filed from December 2014 to December 2017.[38] During these three years, approximately 28 million doses of the nine-virus version of the HPV vaccine were distributed. Exhibit OO at page 1.[39] The researchers "calculated crude 9vHPV AE [adverse events] reporting rates for all reports and serious reports by dividing the number of reports by the total number of doses of 9vHPV distributed in the United States from 2014 through 2017. We also calculated crude AE reporting rates for the following prespecified conditions of interest." For this three-year period, the researchers did not find any reports of transverse myelitis. Id. at 6. The researchers commented on the value of their findings:

> VAERS data cannot be used to assess risk of AEs and generally cannot be used to determine if a vaccination caused an AE. Crude AE reporting rates using vaccine doses distributed should be interpreted with caution because the actual number of doses administered is not known and the amount of underreporting of AEs is also not known. Limitations notwithstanding, VAERS is a valuable monitoring system to detect potential vaccine

[37] The Secretary filed a manuscript version of the Donahue article. Thus, the cites to pages do not correspond to the pagination in the published journal.

[38] On cross-examination, Dr. Tompkins acknowledged that one of the co-authors worked for the manufacturer of an HPV vaccine, Merck. Tr. 384; see also Pet'r's Post-Hearing Reply at 10.

[39] The Secretary filed a manuscript version of the Shimabukuro article. Thus, the cites to pages do not correspond to the pagination in the published journal.

> safety concerns that might require further assessment in more robust systems.

Exhibit OO at 7.

Unlike Baxter, which Mr. Goodwin did not really challenge in any effective way, the Shimabukuro article was attacked by Mr. Goodwin in two different respects. First, Mr. Goodwin's attorneys located at least some examples of VAERS reports showing that after an HPV vaccination, a person developed transverse myelitis in the relevant time. Exhibit 70.

Second, Mr. Goodwin introduced the Lazarus report. Exhibit 50. It appears that the Agency for Healthcare Research and Quality, a component of the Department of Health and Human Services, awarded a grant to Harvard Pilgrim Health Care, Inc. One purpose of the grant was to "develop systems to monitor ambulatory care electronic medical records for adverse effects following vaccine administration." Exhibit 50 at 3 (Aim 1). The grantees focused on electronic medical records created by Atrius Health, which "employs approximately 700 physicians to serve 500,000 patients . . . . throughout the greater Metropolitan Boston area." Id. at 6. Within Atrius Health, "[e]very patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions [were] evaluated for values suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically." Id. at 3-4. The researchers collected "preliminary data" "from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified." Id. at 6.

Although the report is not perfectly clear on this point, it appears that the researchers looked to see whether the potential adverse vaccine events they identified were reported to VAERS. They wrote: "fewer than 1% of vaccine adverse reports are reported." Id. at 6. Further, the researchers stated that: "Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation." Id.

During the hearing, there was a limited amount of testimony about the Lazarus report. For example, Dr. Steinman did not testify about it. Through cross-examination of Dr. Tompkins, Mr. Goodwin proposed that (a) if there were one

report of transverse myelitis following a vaccine per year included in the VAERS database, and (b) Lazarus's assertion that fewer than one percent of vaccine adverse events that occur within 30 days of a vaccination are reported to VAERS, then (c) the actual number of transverse myelitis events following vaccination would be 100 per year. Further, because transverse myelitis has an incidence of approximately 1400 cases per year, the share of transverse myelitis cases that occur within 30 days after a vaccination would be approximately seven percent (100/1400). Tr. 392-401. Mr. Goodwin argues that this analysis constitutes a "signal" that the Secretary should further investigate. Pet'r's Post-Hearing Br. at 21.

Mr. Goodwin raises some intriguing ideas about the Lazarus report. One question is how the Lazarus group defined "adverse events." If "adverse events" included relatively common, but probably transient, events such as redness or swelling at the injection site, then the conclusion that fewer than one percent of adverse events were reported to VAERS seems more likely. However, if the suggestion is that 99 out of 100 doctors whose patients developed transverse myelitis within a month of a vaccine failed to submit a report to VAERS, then the suggestion appears more questionable.

e) Summary on Epidemiology

Overall, the value of this evidence is mixed. Two articles (the report from the World Health Organization and the Donohue article) did not directly study transverse myelitis. The Shimabukuro article relied upon VAERS data, which is a questionable methodology. See, e.g., Analla v. Sec'y of Health & Hum. Servs., 70 Fed. Cl. 552, 558 (2006) (upholding special master's concerns about the reliability of VAERS data and noting expert testimony that VAERS data "offers very little information regarding causality"); Ryman v. Sec'y of Health & Hum. Servs., 65 Fed. Cl. 35, 43 (2005) (special master did not "act arbitrarily or capriciously in refusing to accord substantial weight to the VAERS reports"). In this regard, Dr. Tompkins appears to lack a background in epidemiology sufficient to mitigate these weaknesses. See Tr. 420. On the other hand, Baxter did look for an association between HPV vaccines and transverse myelitis and did not find an association. Its methodology was not impeached in a meaningful way. Thus, Baxter tends to make Mr. Goodwin's claim that an HPV vaccine can cause transverse myelitis less likely.

2. Case Series and Case Reports

The second category of evidence is the set of case series and case reports.

a) Agmon-Levin and Pidcock

The record includes articles by Agmon-Levin et al. and Pidcock et al. They are roughly similar. In Agmon-Levin, the researchers surveyed medical journals, looking for instances in which a person received a vaccine and then developed transverse myelitis. Exhibit G at 1198. Over the course of approximately 39 years, they identified 37 instances involving a variety of vaccines. Id. at 1200; accord Tr. 435. However, this research was conducted before HPV vaccines were widely available and none of the examples involve the HPV vaccine.

In Pidcock, the researchers collected information about 47 children who were treated at the Johns Hopkins Transverse Myelitis Center from January 2000 to February 2004. Exhibit J at 1475. They found that "Twenty-eight percent of cases (13/47) had a confirmed immunization or allergy shot within 30 days . . . of the first symptom of ATM [acute transverse myelitis]." Id. at 1476. However, this study too was before the HPV vaccine.

Dr. Steinman did not cite either Agmon-Levin or Pidcock in his reports. He also did not discuss these articles during his testimony. Mr. Goodwin cites Agmon-Levin in the context of prong 3. See Pet'r's Post-Hearing Br. at 22. Thus, a more detailed analysis of this article is deferred until then.

b) Package Insert

As a foundation for his computer search, Dr. Steinman relied upon the manufacturer's package insert. Exhibit 11 at 4; see also Tr. 102. The package insert also presents information about safety studies. For a detailed examination of components of a package insert, see Cottingham v. Sec'y of Health & Hum. Servs., No. 15-1291V, 2021 WL 6881248, at *30-33 (Fed. Cl. Spec. Mstr. Sept. 27, 2021), mot. for rev. denied, 159 Fed. Cl. 328 (2022), aff'd without op., 2023 WL 7545047 (Fed. Cir. 2023).

On cross-examination of Dr. Tompkins, Mr. Goodwin probed the usefulness of information reported in the package insert. Tr. 369-79. Mr. Goodwin characterizes Merck's clinical trials as "abysmal." Pet'r's Post-Hearing Br. at 21. Whether Merck's clinical trials were actually substandard is irrelevant to Mr. Goodwin's case. But see In re Gardasil Prods. Liab. Litig., 770 F.Supp.3d 893, 910 (W.D.N.C. Mar. 11, 2025) (MDL) (discussing post-licensing reports of adverse events). For Mr. Goodwin's case, the critical question is whether the information presented in the package insert can be understood to support a finding, on a more probable than not scale, that the HPV vaccine can cause transverse

myelitis. It does not. Exhibit 15 at 9; Werderitsh v. Sec'y of Health & Hum. Servs., No. 99-319V, 2005 WL 3320041, at *7 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) ("federal regulations specifically preclude the contents of drug product labels, as reproduced in the PDR, from serving as admissions regarding causation").[40]

c) Menge and Chang

As part of his report supporting causation, Dr. Steinman initially identified the Menge article. Exhibit 11 at 17. Dr. Tompkins identified Chang. Exhibit CCC at 3.

Both articles present instances in which people received an HPV vaccine and then developed some type of demyelinating disease. Exhibit 25, Exhibit EEE.[41] On the question of whether the antecedent event (vaccination) caused the subsequent event (disease), these case reports carry little weight. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11 (Fed. Cl. Spec Mstr. July 7, 2016) (discussing the limited value of case reports).

Accordingly, the general evidence does not support a finding that it is likely that the HPV vaccine can cause transverse myelitis. Nevertheless, because this general evidence is not required, Dr. Steinman's theory is explored next.

3. Molecular Mimicry

To explain how the HPV vaccine can cause transverse myelitis, Dr. Steinman relied upon molecular mimicry. In the Vaccine Program, petitioners frequently assert this theory. For a list of more than 75 examples, see Hoffman v.

[40] Mr. Goodwin seems to suggest that how the manufacturer of the HPV vaccine acquired information about adverse events was suspicious. Pet'r's Post-Hearing Reply at 10-11; see also Tr. 372-81 (questioning by counsel). This argument is difficult to follow and, therefore, not persuasive. Mr. Goodwin's burden is to show with affirmative evidence that the HPV vaccine "can cause" transverse myelitis. See Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (recognizing "can cause" as the equivalent of Althen prong one). For the reasons explained in the text, information presented in the package insert does not support a finding that the HPV vaccine can cause transverse myelitis. Whether the package insert supports an alternative finding that the HPV cannot cause transverse myelitis is not the same question.

[41] Menge also appears in the record as Exhibits BB and NNN. Chang also appears in the record as Exhibit PPP.

Sec'y of Health & Hum. Servs., No. 19-111V, 2024 WL 4444773, at *8 (Fed. Cl. Spec. Mstr. Sept. 13, 2024) (appendices).

a) Appellate Precedents regarding Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C., 704 F.3d 1352, and Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately five years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.[42] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68, 478 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild Tdap virus as potentially causing the disease. Id. When examining this

[42] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." Dorland's Medical Dictionary 868 (32nd ed. 2012).

analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Faulkenberry on behalf of WCF v. Sec'y of Health & Hum. Servs., 176 Fed. Cl. 700, 709 (2025) (finding special master acted within his discretion to reject the theory of molecular mimicry); Stricker v. Sec'y of Health & Hum. Servs., 170 Fed. Cl. 701, 720-21 (2024) (finding the special master did not require scientific certainty in assessing molecular mimicry); Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 660-61 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Doles v. Sec'y of Health & Hum. Servs., No. 2023-2404, 2025 WL 1177875, at *5 (Fed. Cir. Apr. 23, 2025) (noting the Secretary's expert did not challenge molecular mimicry); Patton, 157 Fed. Cl. at 169 (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting Tdap vaccine to brachial neuritis).

When evaluating a theory of molecular mimicry, one opinion from the Court of Federal Claims is especially illuminating (even if the opinion is not binding). The Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal dismissed, No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop GBS. Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The chief special master denied entitlement. Id. at 656.

The Court of Federal Claims denied a motion for review because the chief special master did not commit any error in evaluating Ms. Dennington's prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." Id. at 653.
- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." Id. at 653-54.
- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.
- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

> In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap, molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

These cases provided a foundation for evaluating Mr. Goodwin's theory and evidence.

b) Evidence

Dr. Steinman's theory is presented as a series of five steps.[43] These are reviewed below.

The first step is to identify the components of the vaccine, which is the HPV vaccine in this case. Dr. Steinman relied upon the package insert. Exhibit 11 at 6-7; Tr. 102. This step is not controverted.

The second step is to identify portions of human tissue potentially attacked in the relevant disease, which is transverse myelitis in this case. Dr. Steinman identified a protein known as myelin oligodendrocyte glycoprotein ("MOG"). Exhibit 11 at 11; Tr. 102. Dr. Ghosh acknowledged that MOG is a potential target of an autoimmune reaction leading to transverse myelitis. Tr. 225.

In the third step, Dr. Steinman enters the relevant protein sequences into a computer program known as the Basic Local Alignment Search Tool (BLAST). Dr. Steinman's use of the BLAST program is potentially disputed in two respects. First, there appears to be some question as to whether the BLAST program should be used to detect the degree of similarity between proteins to look for potential cross-reactions. See Tr. 121-22 (Dr. Steinman's discussion of the Silvanovich article). However, compared to other cases, the Secretary did not meaningfully develop this argument. See, e.g., Gamboa-Avila v. Sec'y of Health & Hum. Servs., No. 18-925V, 2023 WL 6536207, at *14 (Fed. Cl. Spec. Mstr. Sep. 11, 2023), mot. for rev. denied, 170 Fed. Cl. 441 (2024), appeal docketed, No. 24-1765 (Fed. Cir. May 1, 2024). Second, Dr. Tompkins testified that to obtain the results Dr. Steinman used, Dr. Steinman altered the standard settings for BLAST searches. Tr. 287-88; see also Resp't's Post-Hearing Br. at 21-22; Pet'r's Post-Hearing Br. at 13.

Mr. Goodwin defends Dr. Steinman's BLAST search methods, arguing that Dr. Tompkins does not explain whether the default settings are designed for specific molecular mimicry searches, or how the default settings relate to the question of whether there is sufficient alignment between proteins. Pet'r's Post-Hearing Reply at 8. This latter point pertains to the fourth step of Dr. Steinman's method.

[43] This decision's enumeration of steps differs from how Dr. Steinman presents them. Dr. Steinman does not number the first two steps. Thus, Dr. Steinman's "first" step corresponds to this decision's "third" step.

In the fourth step, Dr. Steinman examines the degree of similarity that the BLAST search produced. Dr. Steinman is looking to see whether five amino acids out of a string of 12 amino acids align. Exhibit 11 at 9; Tr. 104, 110, 143. The source of this criterion is a series of papers often referred to as the Gautam articles.

The parties disputed the usefulness of this standard. Dr. Steinman pointed to the Gautam articles on which he served as a co-author as well as a more recent articles connecting the Epstein-Barr virus to multiple sclerosis. Tr. 106-10 (discussing the Lanz article and the Santernarzod article). By way of contrast, Dr. Tompkins discussed articles that stated that similarities between viral and human proteins are not surprising because of the limited number of amino acids. Tr. 280-84 (discussing Silvanovich and Kanduc).

A close review of the evidence shows that homology at a level of five out of 12 amino acids can produce an adverse cross-reaction sometimes, but not always. See Sparrow v. Sec'y of Health & Hum. Servs., No. 18-295V, 2024 WL 1599165, at *24 (Fed. Cl. Mar. 19, 2024) (citing Dr. Steinman's testimony about a Gautam paper), mot. for rev. denied, 173 Fed. Cl. 177 (2024), appeal docketed, No. 25-1161 (Fed. Cir. May 7, 2025). In this regard, Dr. Tompkins is persuasive when he testified "there's so much overlap between, in this case, viral and human peptides," that "having homology is a first step, but it's certainly far from sufficient to define molecular mimicry as a mechanism for autoimmune disease." Tr. 283-84.

Before going on to Dr. Steinman's final step, which he labels as step three and this decision calls step five, a legal argument must be addressed. After describing the Gautam standard and the results of Dr. Steinman's BLAST searches, Mr. Goodwin argues: "This simple fact [of the detection of a homology more frequent than five out of 12] is the end of the inquiry." Pet'r's Post-Hearing Br. at 7. Later, Mr. Goodwin adds: "one could simply remove the [fifth] step and just check for 5 out of 12 homology. This approach worked in the Gautum papers." Id. at 11.

If Mr. Goodwin is simply arguing that a BLAST search's detection of a homology at a level of five out of 12 makes Dr. Steinman's theory of molecular mimicry persuasive, then this argument is rejected. Kanduc shows that homology occurs frequently enough that if homology, by itself, led to an autoimmune reaction, then autoimmune diseases would be much more common. See Exhibit VVV. One set of authors maintained that: "new computational and experimental screening tools make identification of candidate epitopes almost too easy. Indeed, those attracted by the concept of epitope mimicry must now be wondering less

about how autoimmunity is provoked and more about why it does not happen more often." Exhibit MM (Benoist and Mathis) at 800.

Further, when Dr. Steinman was collaborating with his colleagues on the experiments that led to the Gautam papers, Dr. Steinman did not stop with identifying amino acid sequences with various degrees of homology. Dr. Steinman and colleagues varied the composition of a certain peptide for myelin basis protein, known as Ac1-11, by changing the amino acids. See, e.g., Exhibit 21 (Gautam) at 606, figure 1.A. They also assessed how different compositions affected the uptake of thymidine. Id. at figure 1.B. From this information, Dr. Steinman and colleagues were able to determine which sequences of amino acids stimulated T cells. Dr. Steinman and colleagues continued. They wondered whether difference sequences "might trigger the onset of autoimmunity through molecular mimicry. To examine this issue, [the researchers] were particularly interested in determining whether peptides with multiple alanines could initiate responses in vivo." Id. at 607. Thus, the researchers gave different peptides to mice to stimulate an autoimmune disease, experimental autoimmune encephalitis. Id. at 607, especially Table 1. In short, Dr. Steinman's work in the Gautam experiments show that although homology at a level of 5 out of 12 amino acids sometimes shows that an autoimmune reaction can occur, homology at that level does not always lead to an autoimmune reaction.

Regardless of whether Mr. Goodwin is arguing that further support for the theory of molecular mimicry is not needed, Dr. Steinman certainly attempted to present some additional support. In his fifth step, Dr. Steinman consulted the immune epitope database ("IEDB"). Exhibit 11 at 13. The IEDB "catalogs experimental data on antibody and T cell epitopes studied in humans, non-human primates, and other animal species in the context of infectious disease, allergy, autoimmunity, and transplantation." Id. (citation omitted). The IEDB lists peptides that have been used in experiments. But, many peptides listed in the IEDB may not have an immunologic function. Tr. 289-90. Because the IEDB is so general, special masters have found Dr. Steinman's reliance on the IEDB not persuasive. Anderson v. Sec'y of Health & Hum. Servs., No. 20-830V, 2024 WL 4892529, at *15-16 (Fed. Cl. Spec. Mstr. Nov. 1, 2024); Le v. Sec'y of Health & Hum. Servs., No. 16-1078V, 2023 WL 3049203, at *30 (Fed. Cl. Spec. Mstr. Mar. 30, 2023) (noting that the Secretary's expert had "effectively discredited" Dr. Steinman's use of BLAST searches and the IEDB); L.R. / Baxter v. Sec'y of Health & Hum. Servs., No. 16-922, 2024 WL 1912575, at *20-21 (Fed. Cl. Spec. Mstr. Mar. 28, 2024). Thus, an article's appearance in the IEDB is less important than

what the article says. Dr. Tompkins is persuasive when he stated that the reference needs to be reviewed. Tr. 291.[44] This process led to the Mars article.

Dr. Steinman came across the Mars paper after he saw a particular epitope in the IEDB step of his filtration. Tr. 168. Although Dr. Steinman included a screenshot from the IEDB in his first report, Dr. Steinman did not include Mars among the references in his first report. See Exhibit 11 at 15.[45]

In response to Dr. Steinman's first report, Dr. Tompkins located the Mars article and discussed it.[46] Dr. Tompkins asserted that "the epitope described in this paper and found by Dr. Steinman in IEDB may not be cross-reactive with the HPV 18 peptide and may not be biologically relevant in humans." Exhibit K at 5.

When Dr. Steinman responded to Dr. Tompkins, Dr. Steinman maintained that, in Dr. Steinman's opinion, Dr. Tompkins is demanding too much proof of his theory. Exhibit 27 at 3-4. Without specifically citing Mars, Dr. Tompkins answered Dr. Steinman in Dr. Tompkins's next report. Dr. Tompkins wrote: "there is no experimental evidence from an animal model of neuropathy or similar system demonstrating that the HSV L1 capsid is presented by antigen-presenting cells to elicit cross-reactive T cells that also recognize MOG epitopes (e.g. CWKITLFVIV), that then attack neuronal tissues and trigger autoimmune disease." Exhibit LL at 2. Dr. Steinman did not contradict Dr. Tompkins's assertion that "there is no experimental evidence from an animal." Instead, Dr. Steinman stated that although he has created animal models for other diseases, he did not expect that such work would be funded by the Vaccine Program. Exhibit 29 at 9. In turn, Dr. Tompkins acknowledged that Dr. Steinman has not developed an animal model. "So, we are left with no experimental evidence that HPV infection or vaccination with HPV L1 proteins can cause any autoimmune disease, including TM." Exhibit CC at 4.

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[44] To the extent that Dr. Steinman's purpose of consulting the IEDB to ask whether "has anyone seen at least part of [an amino acid] sequence in their experiments that the immune system actually recognizes," Tr. 106; accord Pet'r's Post-Hearing Br. at 10, this purpose adds little, if anything.

[45] With the benefit of hindsight, Mr. Goodwin might have been better served if Dr. Steinman had explained in his first report why Mars was useful.

[46] Because Dr. Tompkins was the first expert to include Mars among his references, the Secretary filed the Mars article, designating it Exhibit N. This history explains why an article that Dr. Steinman maintains supports his opinion is designated with a letter, not a number.

The extent to which Mr. Goodwin is advancing Mars is not clear. Various clues suggest that Dr. Steinman found that this article was not especially supportive. Dr. Steinman did not cite Mars in his first report. See Exhibit 11. He testified that he was not "extolling" Mars. Tr. 125.

Similarly, Mr. Goodwin also seems not to rely on Mars heavily. In his two briefs filed before the hearing, Mr. Goodwin did not cite Mars at all. See Pet'r's Post-Remand Br., Pet'r's Post-Remand Reply. As part of Dr. Steinman's direct examination, Mr. Goodwin elicited relatively little testimony from Dr. Steinman. See Tr. 125. Presumably, if Mars were an important part of Mr. Goodwin's evidence, then Mr. Goodwin would have spent more time on this article. Cf. Tr. 334 (special master suggesting that Mr. Goodwin may want to question Dr. Steinman about Mars in rebuttal testimony).

The brevity of Dr. Steinman's discussion of Mars in either his written reports or oral testimony may have contributed to some confusion. After the hearing, Mr. Goodwin argues that Dr. Tompkins did not understand how Dr. Steinman was using the IEDB. Pet'r's Post-Hearing Br. at 9. Mr. Goodwin contends that Dr. Steinman uses the IEDB "to ask 'has anyone seen at least a part of that sequence in their experiments as something that the immune system actually recognizes?'" Id. at 10. If that is the sole purpose of checking the IEDB, then the step has relatively little value as the special masters have found in Anderson, Le, and L.R. / Baxter.

By way of contrast, Mr. Goodwin recognizes that Dr. Steinman is not using the IEDB to show "the same exact amino acids caus[e] the exact same disease." Pet'r's Post-Hearing Br. at 8. "Dr. Steinman never claims that this third [fifth] step is to refine the homology or claim that molecular mimicry would work the same way in any study discovered in the IEDB search." Id. at 12. Consistent with this view, Mr. Goodwin argues that "one could simply remove [Dr. Steinman's] third step and just check for 5 out of 12 homology." Id. at 11.

With this understanding, a discussion of the details of the Mars article appears unnecessary. To be clear, although the Mars article has been reviewed, see Tr. 168, Mr. Goodwin is not arguing that the experiments in Mars are roughly analogous to what he alleges happened to him.[47]

[47] As to whether the mice in the Mars experiment resemble Mr. Goodwin, Dr. Tompkins raised some differences, such as the presence of a potent adjuvant and a model for multiple sclerosis, not transverse myelitis. Tr. 296, 428.

4. Summary/conclusion on Althen Prong One

In sum, the evidence does not preponderate in a finding that the HPV vaccine can cause TM. Mr. Goodwin did not effectively undermine the Baxter article. Even if other epidemiological studies were weakened by Mr. Goodwin's arguments, a neutralized study does not in turn mean that TM *is* associated with the HPV vaccine. The other proffered evidence, case reports and case studies, carry little weight and do not lend much support to Mr. Goodwin's theory. Finally, Dr. Steinman has not presented persuasive and reliable evidence for finding that his proposed homology can cause a cross-reaction.

B. *Althen* Prong Three: Timing

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

1. Onset

As discussed above, after the Court's remand, Mr. Goodwin obtained and filed medical records that support an opinion that his transverse myelitis was first manifest within approximately two weeks of his HPV vaccination. Exhibit 42 at 2394-97. Notes from Dr. Greenburg on June 12, 2020 (approximately two years after Mr. Goodwin's initial hospitalization) stated that Ms. McCluskey reported that Mr. Goodwin experienced episodes of bowel and bladder incontinence a school about 1.5 to 2 weeks after his March 22, 2018 vaccination. Exhibit 41 at 912. She stated that these episodes "continued a few times per week during April and this continued into May." Id. Ms. McCluskey also filed an affidavit, dated November 13, 2024, recounting that Mr. Goodwin had a seizure during a blood draw around March 29, 2018, and then lost bladder control at school around March 30, 2018. Exhibit 43. She stated that he had another bladder accident a couple days later, and that he lost mobility in his legs briefly sometime in early April 2018. Id.

Based upon an acceptance of the accuracy of this information, Dr. Steinman presented an alternative opinion. Exhibit 58. Dr. Steinman opined that "the events in March and April 2018, beginning 7 to 14 days after [Mr. Goodwin's] HPV vaccination, were the initial manifestations of his transverse myelitis." Id. at 3. He therefore placed the date of onset between seven and fourteen days post-

vaccination. However, Dr. Ghosh disagreed. He noted that these urinary symptoms and leg weakness were not reported in histories prior to December 13, 2019, and that there was no "objective documentation of urinary problems or neurological deficits in the medical record." Exhibit SSS at 3. He stated, "I do not think the earlier intermittent symptoms of urinary incontinence or a single brief episode of leg weakness could be attributable to spinal cord involvement without any objective clinical or radiological evidence." Id. at 4. Furthermore, he noted that the progression to nadir in ATM is between 4 hours and 21 days of onset, which would not fit with Mr. Goodwin's course. Id. He maintained that onset was 68 days post-vaccination.

The evidence does not weigh in favor of accepting that the onset of Mr. Goodwin's injury was 7 to 14 days post-vaccination. As explained in Section V, above, Mr. Goodwin has not carried his burden of showing with preponderant evidence that the two episodes of loss of bladder control were manifestations of his transverse myelitis.

Thus, for these reasons, Dr. Ghosh is persuasive in asserting that the onset of Mr. Goodwin's transverse myelitis was on May 30, 2018. This date is 68 days after the vaccination.

2. Appropriate Interval

The second part of the timing is prong is to determine the "timeframe for which it is medically acceptable to infer causation." Shapiro, 101 Fed. Cl. at 542-43. The Federal Circuit has explained the significance of the medically acceptable time frame.

> Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the "but-for" prong of the causation analysis. . . . If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor.

Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006).

The April 16, 2024 First Entitlement Decision found that Mr. Goodwin had not established that 68 days was an interval for which an inference of causation was appropriate. 2024 WL 2033563. However, the Court vacated this decision. Order and Opinion, issued Oct. 10, 2024, 2024 WL 4758470. The Court did not mandate a particular result.

The evidence regarding the appropriate interval has been considered again. The evidence on remand also includes some evidence, such as the witnesses' oral testimony, that was produced after the remand. The evidence preponderates in favor of finding that 68 days is outside the interval for which an inference of causation in appropriate.

The basis for this finding is that Dr. Ghosh's testimony and opinion about the appropriate interval are persuasive and credited. He stated that a maximum amount of time for molecular mimicry to happen is six weeks, which is 42 days. Tr. 433. The basis for Dr. Ghosh's opinion are studies that evaluated when the swine flu could cause Guillain-Barré syndrome. Tr 433-34; see Benedict v. United States, 785 F. Supp. 97, 99 (N.D. Ohio 1991) (epidemiology does not support 69 days).

As part of Dr. Steinman's direct testimony, he discussed the Langmuir and Schonberger articles that looked at the incidence of Guillain-Barré syndrome after swine flu. Tr. 134-35.[48] However, Dr. Steinman discounted Langmuir and Schonberger because those studies were done more than 50 years ago. Tr. 135.

Dr. Steinman's suggestion that Langmuir and Schonberger are outdated is not credible. A primary reason for rejecting Dr. Steinman's opinion about Langmuir and Schonberger in the present case is that it is inconsistent with Dr. Steinman's opinion in other cases. "When addressing credibility, previously published expert reports and testimony by the same expert, may be reviewed and considered by the Special Master. Repeat experts who have testified or submitted expert reports regularly in a particular field have to live with, or explain away,

[48] Because the Schonberger and Langmuir articles are critical articles on this topic, special masters are generally familiar with them. Limited reliance upon this background is permitted. See Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996). However, this decision's discussion of the Schonberger and Langmuir articles is limited because neither study is in evidence. Unlike some cases cited later in the decision, Dr. Steinman did not include Schonberger or Langmuir among his references. See Exhibit 11 at 17-18.

their previous testimony and their previously filed expert reports." K.A. v. Sec'y of Health & Hum. Servs., 164 Fed. Cl. 98, 116 (2022), aff'd without opinion, No. 2023-1315, 2024 WL 2012526 (Fed. Cir. May 7, 2024).

One example of Dr. Steinman relying upon Schonberger and Langmuir came from an opinion a special master issued while the motion for review was pending:

> Dr. Steinman stated that "two to 42 days seems like friendly turf for just about any vaccine-related case" that he has seen. Tr. 151.
>
> * * *
>
> Further, he offered the Menge paper, which discussed Gardasil vaccine and four cases of NMO with onset within the six-to-seven-week timeframe as support for the timeframe associated with various vaccines and neuroinflammatory conditions. Tr. 69-70; Pet. Ex. 40.65 He added that the six-to-seven-weeks is within the 2-42-day timeframe established by epidemiologists Dr. Shoenberger and Dr. Langmuir as an acceptable interval between a vaccine and a potential injury, specifically Guillain-Barré Syndrome ("GBS"). Tr. 70-71. He stated he was not going to try to fit it into a box other than to say that based on the literature provided, it was within a medically appropriate timeframe for onset. Tr. 155. While imperfect because it is a different vaccine and a different disease, the best he can do is rely on Shoenberger and the Menge paper on NMO. He acknowledged that petitioner did not have NMO. Tr. 155-56; Pet. Ex. 40.

Girardi v. Sec'y of Health & Hum. Servs., No. 17-181V, 2024 WL 4565887, at *12-13 (Fed. Cl. Spec. Mstr. Sept. 27, 2024).

The example of Girardi is just one of many. Dr. Steinman has relied upon Schonberger and Langmuir in multiple cases. See, e.g., Cobb v. Sec'y of Health & Hum. Servs., No. 17-1123V, 2023 WL 6457568, at *23 (Fed. Cl. Spec. Mstr. Aug. 21, 2023) (discussing Schonberger and Langmuir and finding that Dr. Steinman "provided persuasive testimony on the applicability of those studies to" a case involving the HPV vaccine and narcolepsy); Pierson v. Sec'y of Health & Hum.

Servs., No. 17-1136V, 2022 WL 322836, at *32 (Fed. Cl. Jan. 19, 2022) (discussing Schonberger and Langmuir and finding that Dr. Steinman was "persuasive in placing the outermost medically appropriate onset date for vaccine-caused GBS at eight weeks, or 56 days, post-vaccination"); Robinson v. Sec'y of Health & Hum. Servs., No. 14-952V, 2021 WL 2371721, at *8, 22-23 (Fed. Cl. Spec. Mstr. Apr. 12, 2021) (noting that Dr. Steinman cited Schonberger and Langmuir, and finding that "Dr. Steinman provided persuasive testimony on the applicability" to a case of the flu vaccine causing multiple sclerosis); Rolshoven v. Sec'y of Health & Hum. Servs., No. 14-439V, 2018 WL 1124737, at *9 (Fed. Cl. Spec. Mstr. Jan. 11, 2018) (noting Dr. Steinman's reliance on Schonberger and Langmuir to support the timing aspect of his theory); Giannetta v. Sec'y of Health & Hum. Servs., No. 13-215V, 2017 WL 4249946, at *21, 24-25 (Fed. Cl. Sept. 1, 2017) (discussion of Schonberger and Langmuir and finding that Dr. Steinman persuasively testified that 42 days was an appropriate onset for multiple sclerosis after a meningococcal vaccine); Quackenbush-Baker v. Sec'y of Health & Hum. Servs., No. 14-1000V, 2018 WL 1704523, at *19, 23 (Fed. Cl. Spec. Mstr. Mar. 14, 2018) (noting that Dr. Steinman cited Schonberger and Langmuir and finding that "Dr. Steinman's explanation of the timing and his supporting literature are also persuasive").

The work of Langmuir, in turn, is generally accepted in the medical community. Its general acceptance is one factor, although not a dispositive factor, for finding that Dr. Ghosh's opinion that the maximum duration for molecular mimicry is six weeks is reliable and persuasive. See Terran v. Sec'y of Health & Hum. Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (authorizing a special master to use the Daubert factors, including whether a theory "enjoys general acceptance within a relevant scientific community," as a "tool or framework for conducting the inquiry into the reliability of the evidence").

A basis that Langmuir's time is generally accepted includes Dr. Ghosh's testimony and Dr. Steinman's opinion in other cases.[49] Evidence also includes the Baxter study in which the authors looked for various conditions, including transverse myelitis, that developed within 2-42 days of a vaccination. Exhibit H at 4; Tr. 175, 186, 217-18. The researchers explicitly explained why they selected this period:

[49] Dr. Tompkins accepted a narrower window, one limited to a maximum of four weeks. Tr. 302, 304; But see Exhibit CCC (Dr. Tompkins's third report) at 4 (accepting a "42-day risk period").

> On the basis of prior studies and expert opinion, we used 2 exposure intervals: (1) 5-28 days as the most likely interval following immunization to result in a demyelination illness and (2) 2-42 days as reassurance that we are not missing an increased risk with the same type of vaccine, beyond the shorter 5- to 28- day exposure interval.

Exhibit H at 4.

The researchers in Pidcock limited their analysis to cases of acute transverse myelitis within 30 days of vaccination. Exhibit J at 2. The decision by the Pidcock researchers not to extend their analysis to a longer period of time (say 75 days or 90 days after vaccination) leads to an inference that these researchers did not consider a longer period relevant to the analysis. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1381 (Fed. Cir. 2021) (recognizing that a special master may draw "plausible inferences"). After all, if the Pidcock researchers had thought that a period of 75 days or 90 days would capture cases of transverse myelitis potentially caused by an infection or vaccination, then the Pidcock researchers would have extended their analysis to this much time.

The same reasoning can be found when looking at the Lazarus / Pilgrim report. Exhibit 50. As reviewed above (see Section VI.A.1), researchers used computerized records to search to see whether vaccinees experienced any "adverse vaccine event." Notably, the period these researchers selected was "30 days." Id. at 3. Again, if a longer period were relevant, the researchers would have searched computers with a different parameter.[50]

To be sure, other researchers have presented instances in which a person developed a neurologic problem more than 42 days after a vaccination. Prominent examples in the Mr. Goodwin's case include Menge and Agmon-Levin.

[50] Mr. Goodwin observes, accurately, that Baxter and Pidcock did not study potential effects of vaccines extending to 68 days. Pet'r's Post-Remand Br. at 41-43; Pet'r's Post-Hearing Br. at 22-23. Although this observation is correct, there are two problems with attempting to use a lack of study to extend the appropriate temporal relationship to 68 days. First, as noted in the text, the choice to use either 42 days (Baxter) or 30 days (Pidcock) tends to show that longer intervals are not informative. Second, to the extent that Mr. Goodwin is implying that if a study did look at a longer interval, then the study would have discovered something, this argument would not be based upon evidence.

The Menge paper is a case series examining four instances of patients with NMO symptoms after receipt of an HPV vaccine. Exhibit BB at 1. Across the four cases, the onset occurred 4 months, 5 months, an unknown time, and 5 months after the vaccinees' most recent vaccination. Id. The authors stated that "NMO may have been triggered by a recent HPV vaccination," but acknowledged that "the data currently available cannot establish a pathogenic link." Id. at 2.

Of the four examples, Dr. Steinman opined that the latter two of these four cases might have been TM cases due to their negative MOG antibodies. Tr. 137. Thus, because one of the latter two cases has an unknown onset, there is effectively one report, which has an onset of a neurologic problem five months after an HPV vaccine. Even if none of the cases in Menge were instances of TM, Dr. Steinman maintained that the paper has comparative value to Mr. Goodwin's case, but he did not elaborate as to why. Tr. 139. Dr. Steinman admitted that the case reports do not speak to causation, but maintained that one should not "draw hard lines in the sand unless we're talking about the 1976 swine flu." Tr. 179. For a disease that is sufficiently rare and has a limited information base, Dr. Steinman opined that "six months may be okay." Tr. 181.

Another potential useful article is Agmon-Levin. See Pet'r's Post-Remand Br. at 43 (citing Exhibit G). In this paper, the researchers, including Yehuda Shoenfeld, consulted various databases and located 37 cases in which a person developed transverse myelitis after various vaccines over a 39-year period. Exhibit G.[51] "In most of these reported cases the temporal association was between several days and 3 months, although a longer time frame up to several years was also suggested." Id. at 1202.[52] Agmon-Levin and colleagues reported cases of transverse myelitis "4 years," "6 years," and "9 years" after an oral polio vaccine. Id. at 1200 (Table 1).

Just as it was fair to reason that the Pidcock researchers did not analyze cases that occurred more than 30 days after vaccination because the researchers

[51] Agmon-Levin conducted their research before the HPV vaccine was widely available.

[52] Of the group of 37 cases, 28 instances occurred in four weeks or less from the vaccination. Exhibit G at 1200 (table 1). Four weeks is within the period that Dr. Ghosh proposed as generally accepted. Agmon-Levin also reports that cases occurred "3 months," "2 months," "3 months," and "12 weeks" after the vaccination. Exhibit G at 1200 (table 1). Thus, although Agmon-Levin and colleagues are accurate when they state that "most" cases had an onset of less than three months, it is also accurate to state that a majority of cases (28 out of 37) had an onset of four weeks or less.

presumably thought those cases were not relevant, it seems fair to infer that when Menge (and colleagues) and Agmon-Levin (and colleagues) included cases with longer latencies that the Menge authors and Agmon-Levin authors thought a causal connection was possible.[53] In his work as an expert in the Vaccine Program, Dr. Shoenfeld has testified "any vaccine can cause any autoimmune disease at any time." Harris v. Sec'y of Health & Hum. Servs., No. 10-322V, 2014 WL 3159377 at *14 (Fed. Cl. Spec. Mstr. June 10, 2014); accord Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760, at *12 (Fed. Cl. Spec. Mstr. Mar. 23, 2018).

Thus, some evidence shows that some learned people suggest that a vaccine can cause transverse myelitis that develops within five months of the vaccination. Examples of these people include Dr. Menge, Dr. Agmon-Levin, Dr. Shoenfeld, and Dr. Steinman. However, the presence of this evidence, which favors petitioner's position, does not mean that petitioner wins automatically. See Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (noting the presence of some evidence that does not support a special master's finding does not make the finding arbitrary); Kindle v. Sec'y of Health & Hum. Servs., No. 20-1423, 2025 WL 2251738, at *19 (Fed. Cl. Aug. 7, 2025) (ruling that a special master was not arbitrary in finding that 9 weeks was an inappropriate amount of time). The question is not whether one individual or a handful of individuals would accept the temporal relationship is correct.[54] The question is whether the temporal relationship is "medically acceptable." Althen, 418 F.3d at 1281.

[53] Mr. Goodwin seems to argue that Dr. Ghosh accepted a causal latency could extend to 90 days based upon Agmon-Levin. Pet'r's Post-Hearing Br. at 22, citing Tr. 437. This appears to be a misinterpretation of Dr. Ghosh's opinion. At page 437, Dr. Ghosh accepted that the "temporal association" was as long as "three months" in "most cases" reported by Agmon-Levin.

[54] To prevail under Althen, a theory must be supported by sound and reliable evidence. If just the opinion of one person automatically showed that a vaccination preceded the onset of a disease within a period for which an inference of causation is appropriate, then Althen prong three would be effectively meaningless. Experts retained from petitioners always assert that the timing is appropriate. See Hennessey v. Sec'y of Health & Hum. Servs., 91 Fed. Cl. 126, 142 (2010) (stating that Dr. Shoenfeld's opinion that a vaccine can cause any autoimmune injury at any time would make Althen prong three a "nullity"). Here, although Dr. Steinman supported Mr. Goodwin's claim, the Secretary is "is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case[-]in-chief." Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008). The Secretary effectively and persuasively countered Dr. Steinman's opinion with Dr. Ghosh's opinion.

As stated earlier, Dr. Ghosh's opinion, which rests upon epidemiologic studies, is more persuasive than Dr. Steinman's opinion, which rests upon the Menge case report. See Exhibit 11 at 16 (citing Menge); Exhibit 29 at 1 (stating that Menge is "the only article [Dr. Steinman could] find in the literature that links HPV vaccine to cases where longitudinally extensive transverse myelitis is seen"); Exhibit 37 at 2 (discussing Menge); Tr. 178-79 (Dr. Steinman stating that "in this context, case reports are important," but acknowledging that "it has to be a bigger picture than just case reports"). This conclusion appears consistent with the Federal Circuit's reasoning:

> Moreover, the Special Master's requirement for strong temporal evidence is consistent with the third prong of the Althen test: demonstrating a proximate temporal relationship between the vaccination and the injury. See Althen, 418 F.3d at 1278. Again, without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.

Pafford, 451 F.3d at 1358.

3. Summary for prong 3

The evidence preponderates in a finding that Mr. Goodwin's condition began 68 days post-vaccination. Mr. Goodwin has not established that any episodes of incontinence were symptoms of his transverse myelitis. Furthermore, it is widely accepted in the scientific community that 42 days is an acceptable timeframe to infer causation. Mr. Goodwin has not shown that 68 days would also be within an acceptable limit.

C. *Althen* Prong Two: Logical Sequence

The final element of petitioner's causation-in-fact claim is the "logical sequence of cause and effect." Given that Mr. Goodwin has established neither a theory nor appropriate timing, it follows as a matter of logic that he cannot establish a logical sequence of cause and effect, linking the HPV vaccination to his transverse myelitis. See Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012). Nevertheless, if simply for the sake of completeness, this aspect is also evaluated. Within this element, three items merit extensive discussion: the views of treating

doctors, the (lack of) evidence for the MOG antibody, and the potential presence of an alternative cause.[55]

1. Treating Doctors

With respect to the second Althen prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, two doctors wrote that the vaccine was not likely to be the cause of the transverse myelitis. First, Dr. Marks stated that: "Have previously discussed vaccines 8 weeks+ prior to onset of TM, doubtful cause of TM, TM has multiple causes, comes in clusters in the community." Exhibit 7 at 113 (June 26, 2018). Second, Dr. Lacy deferred a question about the vaccine as a cause to infectious diseases. He added: "Epidemiology does not show an increased rate of children receiving vaccines having transverse myelitis." Exhibit 7 at 3022 (Aug. 7, 2018). These statements do not assist Mr. Goodwin in meeting his burden regarding prong 2.[56]

2. MOG Antibodies

A logical presentation can entail showing that Mr. Goodwin's response to the HPV vaccine was consistent with the theory articulated by petitioner's expert. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 52-57 (2013); La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 205 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). Here, Dr. Steinman's theory is that the HPV vaccine caused an attack on MOG. Exhibit 11 at 11, Tr. 102, 130. Thus, it is

[55] Dr. Steinman's opinion regarding the second Althen prong was one sentence. Exhibit 11 at 17. Thus, it does not add much, if anything.

[56] Ms. McCluskey testified that the doctors who treated her son during his hospitalization were "dismissive" of the idea that a vaccine caused his transverse myelitis. Tr. 19. This testimony was not expected as she had not previously disclosed this opinion. See Exhibit 1 (affidavit, dated Mar. 28, 2019) and Exhibit 43 (affidavit dated Nov. 13, 2024). Whereas Ms. McCluskey's testimony suggests she took a negative view of the doctor's dismissal of the causal relationship (Tr. 19), she otherwise felt they were "conscientious" and "interested in Trenton's well-being" (Tr. 63-64).

Regardless, even if Ms. McCluskey's testimony is credited and these doctors' views are given less weight, the evidence becomes neutral at best. That the doctors may have been quick to dismiss vaccine causation does not mean that they ignored a clear case of vaccine injury—that is, failure to thoroughly consider a possibility does not mean that the possibility was the answer.

"logical" for there to be some evidence that Mr. Goodwin developed anti-MOG antibodies.

Evidence about how a vaccinee did (and did not) respond can be considered. See Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1362-63 (Fed. Cir. 2019) (when petitioners' theory was predicated upon an assertion that the child-vaccinee had a brain stem defect, special master erred in assuming this defect); Howard v. United States, No. 16-1592, 2023 WL 4117370, at *7 (Fed. Cl. 2023) (when petitioner's theory involved the pathogenic role of antibodies, the special master did not err in noting the absence of those antibodies), aff'd without op., No. 2023-1816, 2024 WL 2873301 (Fed. Cir. 2024); Baldwin v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. 431, 447 (2020) (petitioner "was required to prove by a preponderance of the evidence that one of her expert's theories actually occurred"); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 93-94 (2019) (when petitioner claimed to have suffered an autoimmune problem, special master did not err in looking for evidence of autoimmunity); Copenhaver v. Sec'y of Health & Hum. Servs., 129 Fed. Cl, 176, 182-83 (2016) ("Petitioners' theory relies on the presence of cytokines. It would be completely unjustified to leap to the conclusion that cytokines caused [the child / vaccinee's] death when there is a complete lack of evidence that cytokines were even present at the time of his death"); Cedillo v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 158, 181 (2009) (ruling that special master reasonably found that petitioners did not establish prong two when they failed to show that the measles virus persisted in the child-vaccinee), aff'd in relevant part, 617 F.3d 1328, 1343-44 (Fed. Cir. 2010); L.R. / Baxter v. Sec'y of Health & Hum. Servs., No. 16-922V, 2024 WL 1912575, at *21-22 (Fed. Cl. Spec. Mstr. Mar. 28, 2024) (although Dr. Steinman assumed that the child-vaccinee had dormant antibodies, petitioner did not prove the existence of these antibodies); Quintana v. Sec'y of Health & Hum. Servs., No. 15-1273V, 2022 WL 621698, at *36 (Fed. Cl. Spec. Mstr. Feb. 15, 2022), mot. for rev. denied, 2022 WL 1873849 (Fed. Cl. 2022).

Here, there is not preponderant evidence that Mr. Goodwin developed anti-MOG antibodies. Information on this topic comes, in a way, from two sources. First, when Mr. Goodwin was first hospitalized, the results of any tests for anti-MOG antibodies were never returned. Tr. 102, 112, 154. In this context, Dr. Steinman maintains that the "absence of evidence is not evidence of absence." Tr. 113. True enough. But, the absence of evidence is also not affirmative evidence of presence.

Second, at the end of 2019, Doctors Tardo and Greenberg ordered MOG testing. The result was negative. Exhibit 42 at 2442.

Despite the Secretary's objection, Mr. Goodwin was permitted to introduce two articles about the persistence of MOG antibodies during the hearing. These are the articles by Forcadela (Exhibit 74) and Huda (Exhibit 75). To compensate for Mr. Goodwin's presentation of literature during the hearing, the Secretary addressed those articles via a supplemental report from Dr. Ghosh in which he discussed a different article on the persistence of MOG antibodies, the Ren article. Exhibit VVV. Thereafter, the parties sparred over which articles are most probative. See Pet'r's Post-Hearing-Br. at 3-5; Resp't's Post-Hearing Br. at 26-27.

Although these articles have been reviewed, a detailed discussion is not needed to resolve Mr. Goodwin's case. Collectively and generally, the articles stand for the proposition that MOG antibodies sometimes remain for as long as approximately 18 months after the onset of the disease and sometimes MOG antibodies do not persist that long. An interpretation that is favorable to Mr. Goodwin's case is that the articles do not make the scenario in which (a) Mr. Goodwin was positive for MOG antibodies in June 2018 yet (b) Mr. Goodwin was negative for MOG antibodies in December 2019 absolutely impossible.

If Dr. Steinman's opinion plus the Forcadela and Huda articles neutralized the negative MOG results from 2019, there remains a lack of evidence showing that Mr. Goodwin had MOG antibodies in June 2018. At best for Mr. Goodwin, there is no reliable evidence about his status in June 2018. But, Mr. Goodwin bears the burden of proving his case. A finding that the evidence is in equipoise or a finding that there is no relevant evidence means that the party with the burden of proof loses. In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, 2004 WL 1660351, at *8 (Fed. Cl. Spec. Mstr. July 16, 2004) ("in legal factfinding, if there is no evidence, the factual issue is simply resolved against the party having the 'burden of proof'"); see also Cox v. Merit Syst. Prot. Bd., 817 F.3d 100, 101 (Fed. Cir. 1987) ("Because [petitioner] . . . offered no evidence in support of his assertion, . . . he failed to carry his burden of proof").

With respect to the absence of evidence, Mr. Goodwin's case resembles Howard. Mark Howard alleged that a tetanus-diphtheria-acellular pertussis vaccine caused him to suffer chronic inflammatory demyelinating polyneuropathy. Howard v. Sec'y of Health & Hum. Servs., No. 16-1592V, 2022 WL 4869354, at *1 (Fed. Cl. Spec. Mstr. Aug. 31, 2022). To support his claim, Mr. Howard presented reports from an expert, Kazim Sheikh, who opined that the vaccine could lead to antibodies that would attack portions of the nervous system. Id. at *9. The chief special master found that Mr. Howard was not entitled to compensation because, in part, "No testing results established the existence of any of the

autoantibodies proposed by Dr. Sheikh to be associated with CIDP." Id. at *26. After Mr. Howard challenged the denial of compensation through a motion for review, the Court of Federal Claims found the result was not arbitrary. Howard v. United States, No. 16-1592V, 2023 WL 4117370 (May 18, 2023). With respect to the detection of antibodies, the Court reasoned: "Because Petitioner's theory relied on the pathogenetic role of certain antibodies, Petitioner cannot then fault the Decision for noting the absence of evidence preponderantly indicating their presence." Id. at *7. Upon an appeal, the Federal Circuit affirmed the judgment without an opinion.[57] Howard v. Sec'y of Health & Hum. Servs., No. 2023-1816, 2024 WL 2873301 (Fed. Cir. 2024).

Although neither the chief special master's decision in Howard, nor the opinion from the Court of Federal Claim, nor the Federal Circuit's determination constitute binding precedent, the reasoning is persuasive. When a petitioner proposes the vaccine leads to the production of certain antibodies, whether those antibodies were detected in the petitioner is a relevant consideration. When this rationale is used in Mr. Goodwin's case, his evidence is lacking. He has not persuasively shown that he developed anti-MOG antibodies as the theory from Dr. Steinman predicts.

These two reasons are sufficient grounds to find that Mr. Goodwin did not carry his proof regarding Althen prong two. Nevertheless, one more factor is also analyzed.

3. Alternative Causes

Whether an argument regarding an alternative cause for the vaccinee's injury should be considered within Althen prong two is not entirely clear. Compare Winkler v. Sec'y of Health & Hum. Servs., 88 F.4th 958, 962 (Fed. Cir. 2023) (ruling special master did not err in considering a potential alternative cause in prong two); Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1357 (Fed. Cir. 2006) (ruling that the special master could consider alternative causes); id. at 1360 (Dyk, J., dissenting) (the "majority holds that petitioner seeking

[57] Petitioner-Appellant raised the antibody issue, arguing, in part, that the special master "used an incorrect legal standard and elevated the burden of proof required for petitioner's evidence of medical theory" when he ruled that "a connection between the toxoid and any *specific antibody* arguably relevant to CIDP" would be necessary to "flesh out Petitioner's theory." Brief for Petitioner-Appellant, Howard v. Sec'y of Health & Hum. Servs., No. 2023-1816, 2023 WL 4583434, at *17-23; see also Reply for Petitioner-Appellant, 2023 WL 6214990 at *13-14.

compensation . . . must establish . . . an absence of 'alternative causes' of the injury") with Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1149 (ruling that requiring a "petitioner to establish a lack of alternative causation was erroneous").

Here, Dr. Tompkins, but not Dr. Ghosh, proposed that Mr. Goodwin's infection with a herpes virus caused Mr. Goodwin's transverse myelitis. Exhibit K at 7-8. There are several problems with this opinion.

Preliminarily, Dr. Tompkins is not a medical doctor. Although his qualifications as a Ph.D. immunologist allow Dr. Tompkins to critique some aspects of Dr. Steinman's opinion, it is not readily apparent that he can assign an etiology to a disease a person is suffering. Tr. 300; But see Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014) (stating that a special master erred in giving less weight to the testimony of Ph.D. immunologist).

More significantly, Dr. Tompkins struggled to explain how a herpes virus can cause transverse myelitis. In his reports before the hearing, he disclosed that he was not relying upon molecular mimicry. Exhibit LL at 4. He seemed to propose direct replication or bystander activation. Id. At the hearing, Dr. Tompkins stated, "I'm not really even suggesting a mechanism of bystander activation." Tr. 302. Later, Dr. Tompkins said the theory was bystander activation. Tr. 421. In any event, the discussion of bystander activation was not robust.

Regardless, the proposal that the herpes virus caused Mr. Goodwin's transverse myelitis runs into the same problem as the theory that the HPV vaccine---timing. On April 11, 2018, Ms. McCluskey reported that Mr. Goodwin had a cold sore for about two weeks. Exhibit 6 at 51. Thus, the apparent manifestation of the herpes infection was about March 28, 2018. See Tr. 407-11; Pet'r's Post-Hearing Br. at 26. Thus, the latency between the manifestation of the infection and the onset of transverse myelitis is 63 days.

Although the latency for herpes infection to onset of transverse myelitis (63 days) is shorter than the latency for HPV vaccination to onset of transverse myelitis (68 days), the latency for the infection is still long. The latency exceeds the 42-day limit, which is generally accepted. See Tr. 207 (Dr. Ghosh: the anticipated interval for a herpes infection to cause transverse myelitis is within three or four weeks).

For these reasons, the Secretary did not present a persuasive argument that a herpes infection caused Mr. Goodwin's transverse myelitis. This lack of persuasiveness regarding a potential alternative cause does not affect the outcome of Mr. Goodwin's claim because the burden did not shift to the Secretary to rebut Mr. Goodwin's evidence. See LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014). Mr. Goodwin's claim fails because he has not met the burden of proof. The fact that neither the HPV vaccine nor the herpes infection has been persuasively shown to have caused Mr. Goodwin's transverse myelitis simply means that something else caused it. Special masters may reach this conclusion. See Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353-54 (Fed. Cir. 2008).

VII. Conclusion

Mr. Goodwin's transverse myelitis was a traumatic experience, which continues to have consequences for his health approximately seven years later. Both Ms. McCluskey and he deserve sympathy for what they have endured.

However, special masters are required to resolve cases based upon evidence. Here, the evidence does not persuasively show that the HPV vaccination caused Mr. Goodwin's transverse myelitis. Thus, he cannot be awarded compensation.

Pursuant to Vaccine Rule 28.1(a), the Clerk's Office is directed to provide this decision to the assigned judge. The Clerk's Office is also instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

Appendix: List of Articles Cited[1]

1. N. Agmon-Levin et al., Transverse myelitis and vaccines: a multi-analysis, 18 LUPUS 1198 (2009). Filed as Exhibit G.

2. R. Baxter et al., Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis, 63 CLIN. INFECT. DIS. 1456 (2016). Filed as Exhibit H.

3. Christophe Benoist & Diane Mathis, Autoimmunity provoked by infection: how good is the case for T cell epitope mimicry?, 2 NAT. IMMUNOL. 797 (2001). Filed as Exhibit MM.

4. Hyeyeon Chang et al., Recurrent optic neuritis and neuromyelitis optica-IgG following first and second human papillomavirus vaccinations, 144 CLIN. NEUROLOG. NEUROSURG 126 (2016). Filed as Exhibits EEE and PPP.

5. Christian G.E.L. De Goede et al., Acquired transverse myelopathy in children in the United Kingdom--a 2 year prospective study, 14 EUR. J. PAEDIATR. NEUROL. 479 (2010). Filed as Exhibits R and SS.

6. James G. Donahue et al., Near Real-Time Surveillance to Assess the Safety of the 9-Valent Human Papillomavirus Vaccine, 144 PEDIATRICS 1 (2019). Filed as Exhibit PP.

7. Mirasol Forcadela et al., Timing of MOG-IgG Testing Is Key to 2023 MOGAD Diagnostic Criteria, 11 NEUROL. NEUROIMMUNOL. NEUROINFLAMM. 1 (2023). Filed as Exhibit 74.

8. Anand M. Gautam et al., A Polyalanine Peptide with only Five Native Myelin Basic Protein Residues Induces Autoimmune Encephalomyelitis, 176 J. EXP. MED. 605 (1992). Filed as Exhibit 21.

9. Anand M. Gautam et al., Minimum structural requirements for peptide presentation by major histocompatibility complex class II molecules: implications in induction of autoimmunity, 91 PROC. NATL. ACAD. SCI. USA 767 (1994). Filed as Exhibit 22.

[1] All articles have been considered.

10. Anand M. Gautam et al., A viral peptide with limited homology to a self peptide can induce clinical signs of experimental autoimmune encephalomyelitis, 161 J. IMMUNOL. 60 (1998). Filed as Exhibit 23.

11. Saif Huda et al., Predictors of relapse in MOG antibody associated disease: a cohort study, 11 BMJ OPEN 1 (2021). Filed as Exhibit 75.

12. Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality 1 (2012). Filed as Exhibit 52.

13. Institute of Medicine, The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies 1 (2013). Filed as Exhibit 51.

14. Darja Kanduc et al., Massive peptide sharing between viral and human proteomes, 29 PEPTIDES 1755 (2008). filed as Exhibit VVV.

15. Tobias V. Lanz et al., Clonally expanded B cells in multiple sclerosis bind EBV EBNA1 and GlialCAM, 603 NATURE 321 (2022). Filed as Exhibit 49.

16. Ross Lazarus, Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP: VAERS) 1 (2010). Filed as Exhibit 50.

17. Lennart T. Mars et al., CD8 T Cell Responses to Myelin Oligodendrocyte Glycoprotein-Derived Peptides in Humanized HLA-A*0201-Transgenic Mice, 179 J. IMMUNOL. 5090 (2007). Filed as Exhibit N.

18. Til Menge et al., Neuromyelitis optica following human papillomavirus vaccination, 79 NEUROLOGY 285 (2012). Filed as Exhibits 25, BB, and NNN.

19. F.S. Pidcock et al., Acute transverse myelitis in childhood: center-based analysis of 47 cases, 68 NEUROLOGY 1474 (2007). Filed as Exhibits J, Q, and RR.

20. Changhong Ren et al., Clinical and Radiologic Features Among Children With Myelin Oligodendrocyte Glycoprotein Antibody-Associated Myelitis, 143 PEDIATR. NERUOL. 96 (2023). Filed as Exhibit XXX.

21. Neda Sattarnezhad et al., Antibody reactivity against EBNA1 and GlialCAM differentiates multiple sclerosis patients from healthy controls, 122 PROC. NATL. ACAD. SCI. USA 1 (2025). Filed as Exhibits 63 and 73.

22. Tom T. Shimabukuro et al., Safety of the 9-Valent Human Papillomavirus Vaccine, 144 PEDIATRICS 1 (2019). Filed as Exhibits OO and HHH.

23. Tom T. Shimabukuro et al., Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS), 43 VACCINE 4398 (2019). Filed as Exhibits P, QQ, and GGG.

24. Andre Silvanovich et al., The value of short amino acid sequence matches for prediction of protein allergenicity, 90 TOXICOL. SCI. 252 (2006). Filed as Exhibit UUU.

25. World Health Organization, Meeting of the Global Advisory Committee on Vaccine Safety, 7–8 June 2017, 92 WKLY. EPIDEMIOL. REC. 393 (2017). Filed as Exhibit X.