REDACTED OPINION

In the United States Court of Federal Claims

No. 16-989V
Filed: October 17, 2022
Redacted Version Issued for Publication: February 10, 2023[1]

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K.A.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* * * * * * * * * * * * * * *

Robert J. Krakow, Law Office of Robert J. Krakow, P.C., New York, NY, for petitioner.

Nina Ren, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent. With her were **Heather L. Pearlman**, Assistant Director, Torts Branch, **C. Salvatore D'Alessio**, Acting Director, Torts Branch, **Brian M. Boynton**, Principal Deputy Assistant Attorney General, Civil Division.

O P I N I O N

HORN, J.

On August 11, 2016, petitioner K.A. filed a petition for compensation with the National Vaccine Injury Compensation Program (Vaccine Program), under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2018) (Vaccine Act), for an off-Table injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (2018). Petitioner claimed that an August 12, 2013 Tetanus Diphtheria acellular-Pertussis (Tdap) vaccination caused him to experience Guillain-Barré syndrome. On April 18, 2022, Chief Special Master Brian H. Corcoran denied petitioner's claim for an award of

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[1] This Opinion was issued under seal on October 17, 2022. Petitioner proposed redactions to the Opinion, which were incorporated into this version. The court made additional conforming redactions for consistency. Consistent with Chief Special Master Brian H. Corcoran's February 1, 2023 Order, the Opinion refers to petitioner by the initials "K.A."

compensation, finding that petitioner had not shown, by a preponderance of the evidence, that he was entitled to compensation. Subsequently, petitioner filed a Motion for Review of the Chief Special Master's decision denying his claim pursuant to Rule 23 and Rule 24 of the Vaccine Rules of the United States Court of Federal Claims (2021) (Vaccine Rules) in the United States Court of Federal Claims.

FINDINGS OF FACT

On August 12, 2013, petitioner, a medical researcher, received the Tdap vaccine, when he was fifty-one years old. Prior to receiving the vaccine, petitioner had a medical history of high cholesterol, hypertension, and a chronic leg condition. Following his vaccination, on September 1, 2013, petitioner was admitted to the North Shore University Hospital Emergency Department in Manhasset, New York and petitioner reported that he had experienced three days of flu-like symptoms, including dry cough, chills, and swelling of his throat. The medical professionals treating petitioner noted that he appeared neurologically sound and was not in distress, although they observed petitioner displaying many common symptoms of an upper respiratory infection or influenza like illness (URI/ILI), including fever, chills, weakness, nasal discharge, congestion, dyspnea, and cough. Petitioner was discharged the following day on September 2, 2013, and petitioner maintains that he continued to experience a fever through September 3, 2013.

On September 4, 2013, petitioner was discovered in his driveway complaining of numbness on his left side, and was transported via ambulance to the emergency department at St. Francis Hospital in Roslyn, New York. Emergency responders noted that petitioner walked with an "unsteady gait" and that he had been treated for flu-like symptoms recently. The same day, September 4, 2013, petitioner was admitted to St. Francis Hospital for further evaluation. Medical records from petitioner's September 4, 2013 visit to St. Francis Hospital indicate that petitioner stated

> [t]he current episode started in the past 7 days. The problem occurs intermittently. The problem has been unchanged. Associated symptoms include weakness. Pertinent negatives include no numbness. Nothing aggravates the symptoms. He has tried nothing for the symptoms. [P]atient presents to the emergency department for evaluation of weakness of the left arm leg and face. Patient states symptoms are [sic] originally began approximately 5 days ago when he was attempting to climb a hill and noticed weakness in the left leg. Patient then states that he developed incoordination of the left face when attempting to brush his teeth this morning. Patient denies loss of sensation however states he has a tingling sensation diffusely over the left side of his body. There are no specific modifying factors. Severity of symptoms mild to moderate.

(alterations added). With regard to his neurological symptoms, petitioner's admitting physician Dr. Subash Viswanathan reported that petitioner was "unable to forcefully

closed [sic] left eye. Left face shows mild weakness. Otherwise cranial nerves 2-12 intact. There is subjective weakness of the left arm and left leg. However patient is able to move both extremities with good strength. There is no sensory deficit." (alteration added). Dr. Viswanathan also noted

> Pt [patient] had the "flu" 2 weeks ago, not receiving abx [antibiotics]. Denies recent travel or diarrhea. Was an URI. The past week first noted left leg weakness while climbing. Had presented to NSUH [North Shore University Hospital], where he works doing bench research on HIV [Human Immunodeficiency Virus] nephropathy, where he was admitted. CT [Computed tomography] chest was negative. After discharge he has been noting a weakness and numbness of the left face/arm/leg. He denies any vision change but there is some burning sensation in the left eye. He noted toothpaste dripping from the left mouth while brushing his teeth. He also complains of bloating and unable to make a BM. His BP [blood pressure] has been high.

(alterations added). CT scans of petitioner's brain and chest did not yield any significant abnormalities. Lab results indicated, however, that petitioner had the antibodies for the West Nile Virus, which indicated that he had contracted West Nile Virus at some point in the past.

On September 4, 2013, Dr. Michael Han, another treating physician, indicated "[m]uch of his [petitioner's] symptoms and findings are non-specific, though bifacial weakness is most prominent and perhaps most helpful in narrowing down differential. A major consideration would be AIDP [Acute Inflammatory Demyelinating Polyneuropathy]/GBS (Guillan [sic] Barre Syndrome) with all the above features, including potential autonomic dysfunction." (alterations added). Dr. Han also indicated that petitioner had suffered a "recent URI [upper respiratory infection] 2 weeks ago." (alteration added). During his stay at St. Francis Hospital, petitioner complained primarily of weakness. Petitioner also reported to Dr. Han that he had experienced flu like symptoms two weeks prior, and that he developed left leg weakness and difficulty climbing over a small hill near his home shortly thereafter.

On September 5, 2013, Dr. Teresa Deangelis, a neurologist, examined petitioner and reported that "[a] major consideration would be AIDP/GBS (Guillain Barre Syndrome)." Dr. Deangelis likewise noted that petitioner had experienced "recent URI 2 weeks ago." Dr. Deangelis' treatment notes indicate that she started petitioner on a five-day course of intravenous immunoglobulin therapy on September 5, 2013, which is a blood product used to treat patients with antibody deficiencies, including neurological disorders such as Guillain-Barré syndrome. On September 6, 2013, petitioner went through a rheumatology consult with Dr. William Given, who indicated that petitioner "states that he was well until about 2 weeks ago when he developed NP [nonproductive] cough, pharyngitis, malaise, and elevated temperature." (alteration added). Dr. Given

reported that it appeared that petitioner "developed weakness and paresthesias[[2]] following what appears to be a viral illness a couple of weeks ago." (alteration added). On the same day, September 6, 2013, petitioner had an infectious disease consult with Dr. Dava Klirsfield. Dr. Klirsfield's assessment indicated: "Patient with bell's palsy, left sided weakness and hyporeflexic, recent tetanus shot and flu-like illness, imaging shows a dermoid in occipital bone on right, suspect a demyelinating disorder[[3]] possibly post viral or post vaccine." (alteration added). Dr. Klirsfield's assessment also indicated that petitioner's positive West Nile Virus antibodies test had "unclear significance," and ordered additional laboratory testing. On September 10, 2013, following two consistent lumbar punctures, Dr. Doina Glodan diagnosed petitioner with "Guillain-Barre syndrome post recent viral URI." Petitioner remained at St. Francis Hospital until September 17, 2013, at which time he was discharged to Glen Cove Hospital, a rehabilitation facility in Glen Cove, New York. Petitioner's medical records from his date of discharge indicate that petitioner stated that he "[f]eels like he is getting better. No new complaints." While at Glen Cove Hospital, petitioner received physical therapy, occupational therapy, and commenced a speech therapy program.

On September 22, 2013, petitioner's medical records indicate that "he developed acute right facial weakness with right hemiparesis, and CAT scan of the head revealed no new acute pathology, and the patient after contacting primary neurology was transferred to North Shore University Hospital for further investigation and treatment." Treatment notes from North Shore University Hospital state that petitioner displayed increased lethargy, weakness, and right sided numbness and tingling that started two to three days prior, with trace reflexes and worsened right-side issues. Petitioner's admittance documents from North Shore University Hospital indicate that he was experiencing "new onset of R [right] side numbness/tingling weakness in the setting of recently diagnosed of [sic] AIDP." (alterations added).

On September 24, 2013, petitioner began plasmapheresis treatment.[4] Petitioner's treatment notes state that, as a result of the plasmapheresis treatment, petitioner exhibited "significant improvement" in strength and respiration. According to

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[2] Paresthesias is defined as "tingling or pricking ('pins and needles'), caused chiefly by pressure on or damage to peripheral nerves." Encyclopedia of Virology 738 (Dennis H. Bamford & Mark Zuckerman eds., 4th ed. 2021).

[3] "A demyelinating disorder is any condition that causes damage to the protective covering (myelin sheath) that surrounds nerve fibers in your brain, the nerves leading to the eyes (optic nerves) and spinal cord." Demyelinating disease: What can you do about it?, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/expert-answers/demyelinating-disease/faq-20058521 (last visited Feb. 10, 2023).

[4] Plasmapheresis "is a nonsurgical therapy that removes and replaces a patient's blood plasma." Plasmapheresis Program, UC SAN DIEGO HEALTH, https://health.ucsd.edu/specialties/apheresis/pages/plasmapheresis.aspx (last visited Feb. 10, 2023).

petitioner's medical records, thereafter, on September 26, 2013, petitioner saw a dietician who indicated in petitioner's medical history that petitioner had initially presented "with progressive weakness post tetanus shot 8 weeks ago." The dietician also noted that petitioner had reported that "he kept losing weight since after his tetanus shot despite adequate intake." On October 8, 2013, petitioner was discharged from North Shore University Hospital and returned to Glen Cove Hospital for further rehabilitation, where he stayed until October 21, 2013.

On October 21, 2013, petitioner was "discharged home with supervision from friends and family with a follow up with Dr. Han." Petitioner had an initial evaluation at Transitions Rehabilitation on October 23, 2013, when he stated that he was in "good health until September of this year." The following day, on October 24, 2013, petitioner was hospitalized at North Shore University Hospital after he was "FOUND LYING ON FLOOR AOX3 -LOC C/O SEVERE HEAD ACHE 10/10 PAIN SCALE, PT WAS JUST RELEASED MONDAY FROM REHAB FOR A NEUROLOGICAL REACTION TO A TETNUS SHOT 2 MONTHS AGO AND STARTED GETTING HEAD ACHE TONIGHT." (capitalization in original). Petitioner's medical records from North Shore University Hospital, dated October 24, 2013, indicate that he was "violently vomiting" and was experiencing "generalized weakness." A CT scan from the North Shore University Hospital Emergency Department of petitioner's head showed a "6 mm left extra-axial collection with mass effect, no shift. Denies any photophobia, vision loss, neck pain, increased weakness, fever/chills." On October 25, 2013, petitioner underwent a magnetic resonance imaging (MRI) scan of petitioner's brain, which revealed "[s]mall bilateral subacute subdural hematomas with diffuse dural enhancement," which "raise the possibility of intracranial hypotension." Petitioner also received a blood patch for suspected spinal tap CSF leak.[5] On October 27, 2013, petitioner underwent a repeat head CT scan, which revealed an interval increase in size in the left subdural hematoma. Petitioner was started on Dialudid and his previously prescribed Neurontin dose was increased. Neurosurgery advised that no intervention was necessary. Petitioner continued to follow up with Dr. Han through the end of 2013, and Dr. Han reported petitioner's overall improvement.

Petitioner did not visit Dr. Han again until September 2, 2014, at which time petitioner reported that he was still experiencing painful paresthesias in his feet, but no longer required a cane to walk. Petitioner also reported that "[h]is balance is still a bit off though he feels that he is 99% back to normal." Dr. Han advised petitioner to continue on his then-current course of medication and to see Dr. Han again in 4-6 months. Petitioner saw Dr. Han on November 24, 2015 and Dr. Han's treatment notes from the November 24, 2015 visit state that petitioner continued to experience "paresthesias," and Dr. Han theorized that "this still could be residual from Guillain-Barre," but that "we should not ignore the possibility of another neuropathic process such as diabetes or

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[5] A cerebrospinal fluid (CSF) leak occurs when there is a hole or tear in the outermost layer of the membranes surrounding the brain and spinal cord, which allows the fluid to escape. CSF Leak (Cerebrospinal fluid leak), MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/csf-leak/symptoms-causes/syc-20522246 (last visited Feb. 10, 2023).

borderline diabetes." Dr. Han ordered an electromyography (EMG) procedure and advised petitioner to continue with his previously prescribed Neurotonin. On December 4, 2015, petitioner underwent an EMG that "did not demonstrate the concern for possible axonal of demyelinating polyneuropathy." Dr. Han ordered an "MRI lumbosacral spine to rule out a significant herniated disc with nerve root compression," which petitioner went through on December 4, 2015.

On May 20, 2016, petitioner had an appointment with Dr. Adam Criss for "reevaluation of Guillain-Barre syndrome." Treatment notes indicate that petitioner "continues to do well although still has neuropathic pains associated with this syndrome. He'll continue with Neurontin 600/300/300. Weight loss and increased physical activity was encouraged. I will see him back in 6 months."

Procedural History

On August 11, 2016, petitioner filed a petition seeking compensation under the Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(C)(ii), alleging that the August 12, 2013 Tdap vaccination more likely than not caused his GBS, with the onset of the injury taking place on or about August 21, 2013. Special Master Mindy M. Roth was the Special Master initially assigned to petitioner's case. During the pendency of petitioner's case, he filed his medical records in nineteen exhibits and submitted two declarations. On February 23, 2017, respondent filed its Rule 4(c) report, pursuant to the Vaccine Rules, opposing compensation because "the medical records alone do not provide preponderant proof of a vaccine-related injury, and petitioner has not provided a reliable expert report in support of his claim." In addition, respondent stated that "the records also reflect that petitioner's treating physicians were immediately concerned that his symptoms were indicative of 'Guillain-Barre syndrome post recent viral URI.'" Respondent also argued that "petitioner has failed to rule out other potential causes for his injury. Petitioner had positive test results for both CMV [cytomegalovirus] and EBV [Epstein-Barr virus] infections, two known antecedents associated with GBS." (alterations added).

On March 22, 2017, Special Master Roth held a status conference with the parties, after which petitioner filed additional medical records and his first expert report authored by neurologist-immunologist Dr. Lawrence Steinman on August 4, 2017 in support of petitioner's case. On December 4, 2017, respondent filed its first expert report authored by immunologist Kathleen Collins, M.D., Ph.D. In her expert report, Dr. Collins stated that "the medical record better supported the conclusion that Petitioner's GBS was attributable to the 'influenza-like illness' that he appeared to have experienced in the interval between his vaccination and onset of neurologic symptoms." On February 20, 2018, petitioner filed Dr. Steinman's second expert report, in which Dr. Steinman characterized "Dr. Collins's ILI terminology as imprecise." On June 13, 2018, respondent filed Dr. Collins' second expert report and first response to Dr. Steinman's expert report. On December 28, 2018, petitioner filed Dr. Steinman's third expert report, which "'repeated his prior challenge to Dr. Collins's use of ILI." On May 7, 2019, respondent filed Dr. Collins' third expert report, in which Dr. Collins defended her theory of ILI as the more likely the cause of petitioner's GBS. On July 29, 2019, Special Master Roth held a status conference to discuss petitioner's aluminum adjuvant causation

theory. During the status conference, respondent expressed the implausibility of petitioner's aluminum adjuvant theory and Special Master Roth allowed petitioner to file and assert a new causation theory of molecular mimicry. On October 7, 2019, petitioner filed Dr. Steinman's fourth expert report, wherein Dr. Steinman proffered, for the first time, molecular mimicry as a new causation theory, which he contended co-existed with his prior aluminum adjuvant theory. As explained in the Chief Special Master's Entitlement Decision:

> Specifically, he [Dr. Steinman] (a) attempted to propose the degree of amino acid homology that would be necessary, arguing that five (and perhaps even four) out of a twelve amino acid string is sufficient (b) performed "BLAST"[[6]] searches with an online government database for the antigenic components of the Tdap vaccine, in order to identify the amino acids comprising them, and (c) compared them to identified GBS targets.

(internal references omitted; alterations added). Thereafter, respondent filed Dr. Collins' fourth, and final, expert report on January 23, 2020.

More than three years and seven months after petitioner filed his petition for compensation under the Vaccine Act, and following four expert reports filed by petitioner and four expert reports filed by respondent, on March 23, 2020, petitioner asked to retain an infectious disease expert in order to file another expert report, in addition to the expert reports previously filed by Dr. Steinman. Then on May 22, 2020, petitioner filed a formal motion for leave to file an expert report from an infectious disease specialist as well as an expert report from a specialist in biostatistics. Petitioner stated:

> Respondent's primary and persistent defense to petitioner's claim that the Tdap vaccine caused his Guillain Barré syndrome ("GBS") is the argument that petitioner had viral symptoms after his vaccination. Respondent argued in his Rule 4(c) Report that petitioner's symptoms "were indicative of 'Guillain-Barre syndrome post recent viral URI." [sic] Respondent presents several citations to the medical record purporting to support his argument. Respondent also argues in his Rule 4(c) Report that "petitioner has failed to rule out other potential caused [sic] for his injury. Petitioner had positive test results for both CMV [Cytomegalovirus] and EVC [Ellis-van Creveld] infections, two known antecedents associated with GBS."

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[6] As explained in a footnote to the Chief Special Master's Entitlement Decision:

> Basic Local Alignment Search Tool ("BLAST") is a medical/scientific internet resource that assists researchers in finding regions of similarity between biological sequences of amino acids. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance. BLAST, U.S. National Library of Medicine, https://blast.ncbi.nlm.nih.gov/Blast.cgi

(internal citations omitted; alteration added). Petitioner argued that respondent had previously "filed four expert reports from an expert in infectious disease," that pointed to an "influenza-like illness" as an "alternative cause" for petitioner's GBS. According to petitioner,

> [b]ecause the controversy in this case focuses in large part on respondent's claim that an infectious disease caused [K.A.]'s GBS and because respondent has relied on the opinion of a specialist in infectious disease, petitioner submits that it is appropriate for petitioner to file an expert report from a specialist in infectious disease.

(alterations added).

On June 12, 2020, Special Master Roth issued an Order which, in relevant part, denied petitioner's motion for file to file both the additional requested expert report from an infectious disease expert, as well as from a biostatistics expert. The text of Special Master Roth's Order stated:

> On May 22, 2020, petitioner filed a Motion for Leave to file an expert report from an infectious disease specialist and an expert report from a specialist in biostatistics. *See* ECF No. 71. Petitioner's Motion is hereby **DENIED**.
>
> On June 4, 2020, petitioner filed an unopposed Motion for Extension of Time until June 22, 2020, to file a supplemental expert report from Dr. Steinman. *See* ECF No. 72. Petitioner's Motion is hereby **GRANTED**. Petitioner shall file a supplemental expert report from Dr. Steinman by Monday, June 22, 2020.
>
> A status conference will be scheduled following the submission of Dr. Steinman's supplemental report.
>
> Based on the foregoing, the following is hereby ORDERED:
>
> 1) Petitioner shall file a supplemental expert report from Dr. Steinman **by no later than Monday, June 22, 2020.**

(capitalization and emphasis in original). Pursuant to Special Master Roth's Order, on June 22, 2020, petitioner filed Dr. Steinman's fifth, and final, expert report.

On January 27, 2021, the case was reassigned to Chief Special Master Corcoran. On April 26, 2021, petitioner renewed his request for leave to file expert reports from specialists in infectious disease and biostatistics, which request had been denied previously by Special Master Roth. Chief Special Master Corcoran issued an Order on April 27, 2021 directing petitioner to file his motion for a ruling on the record by June 29, 2021. On July 2, 2021, petitioner filed his motion for a ruling on the record in support of his entitlement to compensation under the Vaccine Act and his motion for leave to file additional expert reports from experts in infectious disease and biostatistics. On September 13, 2021, respondent filed its response to petitioner's motion for ruling on the record. On October 12, 2021, petitioner filed a reply brief which included a footnote which stated that "petitioner acknowledges the Court's authority to decide this

case without an evidentiary hearing during which the experts' presentations can be explored, in the context of the present case, where petitioner's theory is closely contested, a hearing would supply valuable elaboration of petitioner's case and a hearing should be conducted." Prior to issuing his Entitlement Decision, Chief Special Master Corcoran did not issue orders addressing petitioner's request for an evidentiary hearing or to allow petitioner to present additional experts.

On April 18, 2022, Chief Special Master Corcoran issued his Entitlement Decision in which he denied petitioner's claims in full. The Chief Special Master stated that petitioner had not established that he met the requirements to receive compensation based on the test in Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005).[7] Regarding the first prong of the Althen test, the medical theory causally connecting the vaccination and the injury, id. at 1278, the Chief Special Master noted: "Two causation theories were ultimately advanced in this case, but neither was preponderantly established." The Chief Special Master indicated that "[i]t was wise of Petitioner to "supplement" his case with a second causation theory, for the first one Dr. Steinman proposed—that alum included in the Tdap vaccine as an adjuvant can produce demyelination—was woefully inadequate," noting in a footnote, "[i]ndeed, Petitioner largely seems to have walked away from his first theory by the time of his reply brief." The Chief Special Master determined that "individual components of the [aluminum adjuvant] theory, as reliably established as they were, were not persuasively connected to *other* preponderant evidence to establish that the Tdap vaccine *likely* can cause GBS solely on the basis of the inclusion of the aluminum adjuvant." (emphasis in original; alteration added). Regarding petitioner's second causation theory, molecular mimicry, Chief Special Master Corcoran explained:

> Petitioner's second theory was one that, more often than not in Program cases, is the *primary* theory offered to explain how virtually any vaccine could produce an autoimmune disease—via molecular mimicry. But not only was it proposed late in the game, but it too was not preponderantly shown to be likely causal. All Dr. Steinman did was offer evidence suggesting a theoretic *possibility* of homology between Tdap vaccine components and locations in the nerve structures where an autoimmune attack might occur. But this is a relatively easy showing to make, given the prevalence of homology in nature. It does *not* amount to a showing that a

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[7] As described below, the United States Court of Appeals for the Federal Circuit in Althen explained:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her 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 at 1278.

> cross-reaction instigated by the Tdap vaccine resulting in GBS is "more likely than not." And Dr. Collins offered evidence and testimony raising reasonable questions about whether every variant of GBS inherently unfolds *only* from molecular mimicry causing the production of cross-reactive autoantibodies, or only at the identified myelin targets.

(emphasis in original). Therefore, for the first Althen prong, the Chief Special Master concluded that "neither of the causation theories offered was preponderantly established with sufficient reliable medical or scientific evidence, despite Dr. Steinman's ample credentials to opine on the subject."

Regarding the second Althen prong, the logical sequence of cause and effect showing that the vaccination was the reason for the injury, id., the Chief Special Master indicated that "[s]everal items of record evidence weigh against Petitioner's assertion that the Tdap vaccine he received likely 'did cause' his GBS. In particular, the majority of immediate treaters did not propose vaccination to be causal, finding far more significant the indisputable evidence of an intercurrent URI," and, furthermore, "the record reveals several instances in which treaters proposed that Petitioner's URI *did* play a role in his subsequent neurologic injury." (emphasis in original). The Chief Special Master concluded: "Overall, the medical records strongly support the conclusion that Petitioner's intercurrent URI likely caused his GBS—not that it was caused by the Tdap vaccine." Therefore, the Chief Special Master determined

> [p]etitioner has not preponderantly established that the Tdap vaccine can cause GBS, under either of the two causation theories ventured over the case's six-year life—and even if he had, the record demonstrates it is far more likely his GBS was attributable to an intercurrent upper respiratory infection ("URI") than vaccination.

Regarding the third Althen prong, the showing of a proximate temporal relationship between vaccination and injury, id., Chief Special Master Corcoran noted that "Petitioner's success in establishing that the timeframe for his onset of symptoms post-vaccination was medically acceptable (in terms of vaccine causation) is not consistent from theory to theory," and concluded that "because the claim fails on the first two Althen prongs, Petitioner's ability to preponderantly support the third prong does not avail him."

Chief Special Master Corcoran also indicated in the Entitlement Decision that an evidentiary hearing was not necessary and that "[t]he case was appropriately decided on the papers." In his Entitlement Decision, the Chief Special Master indicated that the parties had previously filed numerous expert reports, which Chief Special Master Corcoran characterized as a "back-and-forth between Drs. Steinman and Collins over Petitioner's initial causation theory." Chief Special Master Corcoran also stated:

> Notably (and after the case had existed for nearly three years), it was discussed during a July 2019 status conference (perhaps in reaction to questions about whether the case was likely to settle) that Respondent deemed Petitioner's causation theory implausible—prompting the special master formerly presiding over the case to order a deadline for Petitioner

> to file a new report, but this time "modifying" the theory to allege molecular mimicry as the causal mechanism. Scheduling Order, dated July 19, 2019 (ECF No. 59). Dr. Steinman did so by that fall, and another, shorter round of expert report filings occurred, with the final report (from Dr. Steinman) filed in June 2020.

On May 18, 2022, after Chief Special Master Corcoran issued his Entitlement Decision petitioner timely filed a Motion for Review of the Chief Special Master's Entitlement Decision in the United States Court of Federal Claims, in which petitioner puts forth three numbered objections:

> Numbered Objection One
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> 1. Denial of Petitioner's repeated requests to retain an infectious disease expert resulted in an unbalanced review of Petitioner's presentation of Althen Prong 2 and constituted an abuse of discretion under the circumstances of this case.
>
> Numbered Objection Two
>
> 2. In the case at bar, the Chief Special Master failed to recognize that the posited medical theory of molecular mimicry went well beyond the mere identification of homologies[[8]] between components of the Tdap vaccine and self-antigen such as human myelin protein, leading to GBS (Dec. at 40). The court's misconstruction of the record and incorrect application of the law requires vacatur of the Decision. The court compounded its error by holding that Petitioner's causal medical theory was "undercut" by epidemiological evidence as to causation for which an expert was denied to Petitioner despite repeated requests throughout the case (Dec. at 40-41).
>
> Numbered Objection Three
>
> 3. While Petitioner argued in the course of his Motion for Ruling on the Record that he had carried the burden of proof preponderantly for each prong of Althen, including prong 1, the court misinterpreted the law in rejecting an alternative argument that, in light of recent case law, Althen prong 1 could be properly established by a biologically plausible evidentiary showing founded upon a sound and reliable medical or scientific explanation.

(capitalization and emphasis in original; alteration added).

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[8] A "homology" is an antigenic similarity "between the vaccine's component and self neurologic structures." See Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 4100294, at *13 (Fed. Cl. Spec. Mstr. July 30, 2021), review denied, No. 17-79V, 2021 WL 6058835 (Fed. Cl. Dec. 3, 2021). In Caredio, Dr. Steinman, who offered expert testimony for the Caredio petitioner, "admitted that demonstrating a theoretical basis for homology is only the first step to establishing a possible causal association." Id.

On June 16, 2022, respondent filed its response to petitioner's Motion for Review, in which respondent argues that

> [b]ecause petitioner had a full and fair opportunity to present his case, including filing five expert reports over three years addressing the ILI/URI issue in the case and modifying his causation theory, the Chief Special Master appropriately decided this case on the existing record, as further input from an infectious disease expert for petitioner was neither required nor warranted.

Respondent also argues that "[t]he Chief Special Master properly applied the law, including Torday [v. Secretary of Health & Human Services, No. 07-372V, 2009 WL 5196163 (Fed. Cl. Spec. Mstr. Dec. 10, 2009)], and acted within his discretion in deciding this case without a hearing." (alteration added). In its response, respondent asserts that the Chief Special Master considered the appropriate and relevant evidence, "and stated a rational basis in concluding that petitioner failed to demonstrate how the Tdap vaccine can cause GBS via molecular mimicry under Althen prong 1." Finally, respondent argues that the Chief Special Master applied the correct evidentiary standard in evaluating whether petitioner preponderantly met the Althen prong 1, and that the "Federal Circuit precedent requires a petitioner to present more than a 'plausible theory' of vaccine causation." After the Motion for Review was fully briefed, this court held oral argument.

DISCUSSION

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition [filed under § 300aa-11] to the special master for further action in accordance with the court's direction.

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d 863, 867 (Fed. Cir. 1992) (alteration in original); see also 42 U.S.C. § 300aa-12(e)(2) (2018). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 101-386, at 516–17, reprinted in 1989 U.S.C.C.A.N. 3018, 3120 (alteration added).

In Markovich v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42

U.S.C. § 300aa-12(e)(2)(B).” Markovich v. Sec’y of Health & Hum. Servs., 477 F.3d 1353, 1355–56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1381 (Fed. Cir. 2021); Sharpe v. Sec’y of Health & Hum. Servs., 964 F.3d 1072, 1077 (Fed. Cir. 2020) (“This court thus performs the same task as the Court of Federal Claims and reviews the special master’s legal determinations *de novo*, fact findings under an arbitrary and capricious standard, and discretionary rulings for an abuse of discretion.” (citing Munn v. Sec’y of Health & Hum. Servs., 970 F.2d at 870-73, 870 n.10)); see also K.G. v. Sec’y of Health & Hum. Servs., 951 F.3d 1374, 1379 (Fed. Cir. 2020); Oliver v. Sec’y of Health & Hum. Servs., 900 F.3d 1357, 1360 (Fed. Cir. 2018) (citing Milik v. Sec’y of Health & Hum. Servs., 822 F.3d 1367, 1375–76 (Fed. Cir. 2016)); Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d 1363, 1366 (Fed. Cir.), reh’g and reh’g en banc denied (Fed. Cir. 2013) (The United States Court of Appeals for the Federal Circuit stated that “we ‘perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master’s findings were arbitrary or capricious.’” (alterations in original) (quoting Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))); W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1355 (Fed. Cir. 2013); Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008); Avera v. Sec’y of Health & Hum. Servs., 515 F.3d 1343, 1347 (Fed. Cir.) (“Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh’g and reh’g en banc denied (Fed. Cir. 2008); Althen v. Sec’y of Health & Hum. Servs., 418 F.3d at 1277; Faup v. Sec’y of Health & Hum. Servs., 147 Fed. Cl. 445, 458 (2019); Dodd v. Sec’y of Health & Hum. Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec’y of Health & Hum. Servs., 108 Fed. Cl. 807, 817 (2013). The abuse of discretion standard is applicable when the special master excludes evidence or limits the record upon which he or she relies. See Munn v. Sec’y of Health & Hum. Servs., 970 F.2d at 870. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the “not in accordance with law” standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Id. at 871 n.10; see also Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d at 1381 (“We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder” (citing Porter v. Sec’y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011))); Carson ex rel. Carson v. Sec’y of Health & Hum. Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec’y of Health & Hum. Servs., 717 F.3d at 1366; W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d at 1355; Griglock v. Sec’y of Health &

Hum. Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249 (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder" (citing Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)), reh'g and reh'g en banc denied (Fed. Cir. 2012); Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56. "[T]he special masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Hum. Servs., 141 Fed. Cl. 223, 229 (2018). As explained by the Federal Circuit:

> With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was "arbitrary and capricious."

Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B).

"'[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d at 1381 (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360); see also Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363 ("[I]f the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991))); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1253–54; Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Hum. Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Hum. Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" (quoting Motor Vehicle Mfrs. Association v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear

> that, on our review we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1366–67 (alterations in original) (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The United States Court of Appeals for the Federal Circuit has explained that the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1367 (modification in original) (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1363); see also K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d at 1379 ("With respect to factual findings, however, we will uphold the special master's findings of fact unless they are clearly erroneous." (citing Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278)); Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The United States Court of Appeals for the Federal Circuit has explained that:

> A petitioner can establish causation in one of two ways. Id. [Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1341] If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. Andreu [ex rel. Andreu] v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact.

Milik v. Sec'y of Health & Hum. Servs., 822 F.3d at 1379 (alterations added) see also W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1147–48 (Fed. Cir. 1992); Faup v. Sec'y of Health & Hum. Servs., 147 Fed. Cl. at 458; Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 467–68 (2012).

When proving eligibility for compensation for a petition under the Vaccine Act, a petitioner must establish by a preponderance of the evidence that he received a vaccine set forth in the Vaccine Injury Table and that injury caused by the vaccination occurred within the required amount of time. See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also 42 U.S.C. § 300aa-11(c)(1)(A). Regarding the preponderance of the evidence standard, the Vaccine Act requires "'the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor

of the party who has the burden to persuade the [judge] of the fact's existence.'" Moberly ex rel. Moberly v. Sec'y of Health and Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (alterations in original) (quoting Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602 (1993)). In demonstrating this preponderance of evidence, petitioner may not rely on his or her testimony alone to establish preponderant evidence of vaccine administration. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

In weighing the evidence, the Special Master has discretion to determine the relative weight of the evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); see also Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict).

> "Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."

Dodd v. Sec'y of Health & Hum. Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870 n.10); see also Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1349; Rich v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. at 467 ("So long as those findings are 'based on evidence in the record that [is] not wholly implausible,' they will be accepted by the court." (quoting Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d at 1363 (alteration in original))). "Determinations subject to review for abuse of discretion must be sustained unless 'manifestly erroneous.'" Heddens v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. 193 (2019) (quoting Piscopo v. Sec'y of Health & Hum. Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted)).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 728 (2009) (brackets added). As explained by a Judge of the United States Court of Federal Claims:

> "[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010)], he [or she] cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him [or her].'"

Paluck ex rel. Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. at 467 (quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011))) (alteration added). A Special Master is required to acknowledge that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," even if the possible link between the vaccine and the injury is "hitherto unproven." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280; see also Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1261. In that vein, "close calls regarding causation are resolved in favor of injured claimants." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280 (citing Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994)).

Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-13(a)(1)(A); see also LaLonde v. Sec'y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1322)); Hines v. Sec'y of Health & Hum. Servs., 940 F.2d at 1525. While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 473, 479 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d at 1379).

To establish causation in fact for a Non-Table claim, such as petitioner's claim in the above captioned case, a petitioner must satisfy all three of the elements established by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d at 1278. See Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th 1350 (Fed. Cir. 2022); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Hum. Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278, 1279–80; see also

Shapiro v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013). In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Federal Circuit in Althen v. Secretary of Health & Human Services, relied on Knudsen v. Secretary of Health & Human Services, 35 F.3d 543, 548–49 (Fed. Cir. 1994), in which the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1280. Rather, a petitioner must preponderantly establish that the vaccine at issue can cause the petitioner's injury by providing a "'reputable medical or scientific explanation' for its theory." Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Moberly ex rel. Moberly v. Sec'y of Health and Hum. Servs., 592 F.3d at 1322). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" Id. (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d at 548–49).

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353; Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). In Capizzano v. Secretary of Health and Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like-the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa–11(c)(1)–13(a)(1) (2006)); see also Cozart v. Sec'y of Health & Hum. Servs., 126 Fed. Cl. 488, 498 (2016) (quoting Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278).[9]

[9] The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, that there is "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1278; see also Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health and Human Services, when it noted that, "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 v. Sec'y of Health & Hum. Servs., 451 F.3d at 1358. "Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and

According to the Federal Circuit in Capizzano v. Secretary of Health and Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. See Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen III [Althen v. Sec'y of Health & Hum. Servs., 418 F.3d at 1274] prongs cannot overlap to satisfy another prong." (alteration added)). If a petitioner satisfies the Althen burden and meets all three prongs of the test, the petitioner prevails, "unless the government demonstrates that the injury was caused by factors unrelated to the vaccine." Sanchez v. Sec'y of Health & Hum. Servs., 34 F.4th at 1353 (alteration added) (citing 42 U.S.C. § 300aa-13(a)(1)(B)); see also Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d at 547 (brackets in original; quotation omitted).

As indicated above, in the case currently before the court, petitioner argues that denial by the Chief Special Master of his "repeated requests to retain an infectious disease expert resulted in an unbalanced review of Petitioner's presentation of Althen Prong 2 and constituted an abuse of discretion under the Circumstances of this Case." (capitalization in original). Petitioner also asserts that although

> [r]espondent argued in his responding brief that an influenza-like illness, an upper respiratory infection, or cytomegalovirus likely caused Petitioner's GBS. There exists no evidence in this case that a pathogen was present in [K.A.] prior to the onset of his GBS that supports Respondent's speculation about an infectious causal factor for [K.A.]'s GBS."

(alterations added). Petitioner continues:

> Chief Special Master Corcoran relied upon the existence of an intercurrent upper respiratory infection as the likely cause of onset of GBS in rejecting Petitioner's showing of Althen prong 2. Thus, in the court's own view, Petitioner could not have established his claim by a preponderance of the evidence without a more effective counterpoint to an unidentified infectious disease as causative agent.

Petitioner also asserts that "Chief Special Master Corcoran's slant in assessing the evidence was manifest in his pronouncement, not founded in the record, that [K.A.]'s initial symptoms, 'appear[ed] broader than the common post-vaccination malaise.'"

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the vaccination at issue under the 'but-for' prong of the causation analysis." Id. (citing Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d at 1326). The court notes that Chief Special Master's conclusions regarding the third prong of the Althen test was not one of the bases for petitioner's numbered objections in petitioner's May 18, 2022 Motion for Review of the Chief Special Master's Entitlement Decision, and, therefore, is not addressed in this Opinion. The court also notes that in the Chief Special Master's Entitlement Decision, the Chief Special Master indicated, "because the claim fails on the first two Althen prongs, Petitioner's ability to preponderantly support the third prong does not avail him."

(second alteration in original). Petitioner asserts that the "only undisputed diagnosis was the post-vaccination onset of GBS." Petitioner argues that

> [c]learly, the proposition that the initial symptoms, "appear[ed] broader" than would be induced by vaccination should have been addressed by an infectious disease expert retained by the Petitioner, who would be familiar with both symptoms of vaccination and infection. Multiple critical aspects of this case required clarification by – and even turned upon – the expertise and perspective of an infectious disease specialist presented by the Petitioner.

Only after more than three years and seven months after petitioner filed his petition for compensation and after petitioner filed the first four expert reports authored by Dr. Steinman did petitioner belatedly urge that an infectious disease expert could have "opined on the relationship" between petitioner's initial flu-like symptoms and those present at the onset of his GBS, despite the presence of URI symptoms, which, as the Chief Special Master noted, the majority of [petitioner's] treaters deemed the URI most likely causal." (alteration added).

Moreover, as noted above, Dr. Collins filed expert reports on December 4, 2017, June 13, 2018, and May 7, 2019, all of which addressed, and rejected, petitioner's initial causation theory that aluminum adjuvant in the Tdap vaccine caused petitioner's GBS. Further, even after Dr. Collins, in her fourth and final expert report dated January 23, 2020, addressed petitioner's alternate theory of molecular mimicry on behalf of the respondent, petitioner had an opportunity to file another expert report by Dr. Steinman on June 22, 2020.

With respect to the Chief Special Master's review by the expert reports authored Dr. Steinman offered by petitioner, petitioner argues that Chief Special Master Corcoran "characterized Dr. Steinman's challenge to Respondent's reliance upon an unidentified 'influenza-like illness' as mere 'quibbling.'" Petitioner argues that the Chief Special Master's "persistent criticism and denigration of Petitioner's lone expert implicates the harm that flowed from the Court's refusal, over the course of assignment to two special masters, to permit retention of the relevant experts." In the Motion for Review in this court, petitioner argues, "[w]hile Dr. Steinman has unparalleled qualifications in neurology and neuroimmunology and specific areas such as molecular mimicry, his singular focus upon the non-specificity of terms such as 'influenza-like illness' during his dialogue with Dr. Collins may reflect the limits of his expertise in the separate field of infectious disease." (citation omitted). Petitioner also stresses that the Chief Special Master criticized petitioner's expert for his lack of expertise in infectious diseases while denying petitioner the opportunity to retain an expert qualified in the field. Petitioner further states that "the presiding special masters[[10]] failed to afford each party a full and

[10] The court notes that petitioner's request "to file an expert report from an infectious disease specialist and an expert report from a specialist in biostatistics" was denied on June 12, 2020, by Special Master Roth before the case was transferred to the Chief Special Master. Chief Special Master Corcoran, however, also did not grant petitioner's

fair opportunity to present his case, failed to afford a hearing, and failed to create a record sufficient to allow review of the respective orders denying the retention of experts." (alteration added).

In response, respondent argues that the Chief Special Master, pursuant to Vaccine Rule 8(a), gave "each party a full and fair opportunity" to present their case, and also notes that a Special Master "will determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties.'" Respondent notes that, in the above captioned case, petitioner "filed five expert reports over three years, modified his causation theory, and now seeks, after an unexplained multi-year delay, additional experts to cover the same ground already covered by Dr. Steinman." (alteration added). Respondent also points out that petitioner's "medical record, filed between August 2016 and January 2017, is replete with references to petitioner's ILI/URI as a potential cause of his GBS." Respondent argues that in its February 23, 2017 Rule 4(c) report, respondent "specifically identified petitioner's ILI/URI as evidence against entitlement." Therefore, according to respondent, "petitioner, represented by experienced counsel, could have retained an infectious disease expert then. Instead, he chose to proceed with Dr. Steinman alone to address the ILI/URI issue until objecting at the 'eleventh-hour.'" In addition, according to respondent,

> in his five reports, Dr. Steinman variously discussed epidemiological studies, the "possibility of an infectious disease etiology," and opined that "the priority of the potential CMV or EBV infections in triggering disease is lower than the likelihood that the vaccination triggered the disease." Thus, not only did petitioner have both the time and opportunity before the case was adjudicated to retain an infectious disease expert, petitioner's expert actually did address the ILI/URI issue in regard to his GBS.

(internal citations omitted).

Further, respondent argues that the "Chief Special Master appropriately considered petitioner's own detailed reports of flu-like symptoms and the comments of his treating physicians regarding ILI/URI" because a Special Master "'is entitled to consider the record as a whole in determining causation, especially in a case involving multiple potential causes acting in concert, and no evidence should be embargoed from the special master's consideration[.]'" (quoting Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1380 (Fed. Cir. 2012)). Finally, respondent argues that "[t]he Chief Special Master correctly considered the ILI/URI evidence in evaluating the sufficiency of petitioner's proof that the Tdap vaccine did cause his GBS under Althen prong 2."

In reaching a conclusion in each vaccine case, the Special Master considers the factual and supporting record in a petitioner's case as filed before the Special Master including the petitioner's contemporaneous medical records, as well as expert reports, if any. The expert reports are reviewed by the Special Master for their content and for the

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renewed request for expert reports from an infectious disease specialist and a specialist in biostatistics.

expert's expertise and credibility. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d at 1348 (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d at 1528); see also Munn v. Sec'y of Health & Hum. Servs., 970 F.2d at 870. 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, their previous testimony and their previously filed expert reports.

In weighing the expertise and credibility of both petitioner's and respondent's experts, the Chief Special Master, in his Entitlement Decision, did "not give substantial, if any, weight to Dr. Steinman's objections that the term of art 'influenza-like illness' to describe Petitioner's URI is scientifically indeterminate—since filed record evidence from competent medical and scientific professionals employ the term in their own studies." In his Entitlement Decision, Chief Special Master Corcoran addressed Dr. Steinman's role as an expert for petitioner during the pendency of the case, as well as times he had previously testified in vaccine cases. For example, the Chief Special Master criticized Dr. Steinman's fifth and final report as "reflect[ing] the same bickering quality, or wholesale reproduction of prior arguments, that characterizes most of his prior reports filed in this case." Additionally, the Chief Special Master wrote in a footnote in his Entitlement Decision, that "Dr. Steinman also engaged in conduct I have in the past criticized him for: commenting on the standards governing Program cases, and elaborating on how he performs his role as expert, rather than simply providing the medical/scientific opinion for which he has been retained." In the above captioned case, Chief Special Master Corcoran also criticized what he called "Dr. Steinman's legal pronouncements" and correctly noted that expert witnesses are not allowed to interpret "the meaning of Program caselaw or the applicable legal standards." In this regard, the Chief Special Master wrote that "[n]one of Dr. Steinman's reports in this case were prepared while I was presiding over this matter—but in future cases in which Dr. Steinman is retained that are assigned to me, *I will not compensate time spent on opinions on legal issues that he is not qualified to address*." (emphasis in original). The Chief Special Master summarized his view of Dr. Steinman's role in the above captioned case by noting: "Altogether, Dr. Steinman offered more than 70 pages of expert opinion on this matter, (as discussed below and throughout this Decision), I do not conclude the significant effort was ultimately well spent."

The Chief Special Master, however, gave more credit to respondent's expert Dr. Collins. Chief Special Master Corcoran noted that in Dr. Collins' fourth and final expert report, "Dr. Collins also emphasized again her opinion that an influenza-like illness was a far more likely cause of Petitioner's GBS in this case," and determined that "Dr. Collins also persuasively showed that many facially-reliable studies had included 'influenza-like illness' as a potentially causal agent of GBS, despite Dr. Steinman's protestations."

All Special Masters have a responsibility to "afford[ ] each party a full and fair opportunity to present its case and create[e] a record sufficient to allow review of the special master's decision." See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d

1362, 1366 (Fed. Cir. 2020); see also Doles v. Sec'y of Health & Hum. Servs., 159 Fed. Cl. 241, 246 (2022) ("[T]he special masters *are* bound by an obligation to be fair to both parties, and to provide both parties the opportunity to present a case") (emphasis in original). A Special Master, however, also has the responsibility and authority to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case." Vaccine Rule 3(b)(2), 8(a) (2021). Although Chief Special Master Corcoran's choices of words regarding Dr. Steinman and his expert reports may have been pointed and critical, his comments as a veteran Special Master were based on Chief Special Master Corcoran's varied experiences in the Vaccine Program, including with Dr. Steinman as an expert witness. As explained by another Judge of the United States Court of Federal Claims:

> That the Special Master "was far more impressed and persuaded by the testimony of Dr. Wiznitzer" does not show any bias, and shows that the Special Master in fact did exactly what the Federal Circuit has admonished special masters to do in vaccine cases. See Porter, 663 F.3d at 1250 ("Indeed, this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."). The decision shows that the Special Master considered the testimony of both experts, and indeed, it recaps a significant amount of information from both experts, but in the end, the Master concluded that Dr. Wiznitzer was the more trustworthy. The Special Master, as fact finder, "has broad discretion in determining credibility because he saw the witnesses and heard the testimony." Bradley, 991 F.2d at 1575. For this reason, the Special Master's determination on credibility is "virtually unreviewable," Porter, 663 F.3d at 1251, and to the extent that it is reviewable, this Court sees nothing arbitrary or capricious in the Special Master's findings here.

Vaughan v. United States, 107 Fed. Cl. 212, 224 (2012).

After weighing all of the parties' submissions, including the numerous expert reports and petitioner's medical records, Chief Special Master Corcoran found Dr. Steinman's opinions less credible than those of Dr. Collins. The weight to be given to each expert is within the discretion of each trier of fact, based on the facts in the record in each case. See Porter v. Sec'y of Health & Hum. Servs., 663 F.3d at 1249. This court notes that initially Dr. Steinman offered a causation theory that the Tdap vaccine's aluminum adjuvant can cause GBS. Only in his fourth expert report did Dr. Steinman proffer molecular mimicry as a new causation theory, which he contended co-existed with his prior aluminum adjuvant theory. Petitioner tries to justify his delay for requesting to add an infectious disease expert late in the case, stating that "[w]hile Respondent argues that the issue of influenza-like-illness was already apparent, both the extent of that reliance and the ambiguity and limited value of that approach was not apparent until Respondent's expert, Dr. Collins, had made her case across her expert reports." Because petitioner's contemporaneous medical records from the time shortly after his Tdap vaccination, when he was medically examined, to the time the record was closed

prior to the Chief Special Master's review, and the issuance of his decision, there are repeated references to the existence of an influenza-like illness or upper respiratory illness, as a potential cause of petitioner's GBS. Petitioner, therefore, was on notice of the URI/ILI as a potential cause of his GBS well before he filed his petition with the Office of Special Masters. Moreover, respondent's Rule 4(c) report, filed on February 23, 2017, specifically identified petitioner's ILI/URI as evidence against entitlement, for petitioner to consider.

This court notes that petitioner's contemporaneous medical records, which receive great evidentiary weight, contained repeated references to his URI/ILI as a possible causation of his medical issues and a factor in his Guillain-Barré syndrome following his Tdap vaccination. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events."). In petitioner's case, a number of petitioner's contemporaneous medical records indicate, not only the existence of a URI/ILI, but that the URI/ILI was likely the cause of petitioner's GBS. Chief Special Master Corcoran specifically relied on these medical records when evaluating the likelihood that the Tdap vaccine caused petitioner's GBS. Chief Special Master Corcoran indicated that "not only is there incontrovertible evidence that Petitioner *first* experienced URI symptoms before neurologic-related symptoms, but also that the majority of his treaters deemed the URI most likely causal. The vaccine does not deserve greater weight simply because it is 'known' whereas the precise nature of the infection is not." (emphasis in original). The court notes that Chief Special Master Corcoran stated in his Entitlement Decision that in Dr. Collins' fourth and final expert report, "Dr. Collins also emphasized again her opinion that an influenza-like illness was a far more likely cause of Petitioner's GBS in this case."

Based on the contemporaneous medical records in the record before the Chief Special Master, the relative weight and credibility of the theories advanced by the expert witnesses for each party to the litigation, the decision issued by Chief Special Master Corcoran was reasonable and was supported by Dr. Collins' theory that petitioner's URI/ILI more than likely caused the GBS. Therefore, this court determines that Chief Special Master's decision not to grant to petitioner's request for additional experts, after petitioner filed numerous contemporaneous medical records, and five expert reports author by Dr. Steinman, did not result in denying petitioner a full and fair opportunity to present his case.

Although not one of his specific numbered objections, petitioner also asserts that the Chief Special Master's decision to deny a hearing in his case was unreasonable. Petitioner argues that the Chief Special Master's denial of a hearing constituted a failure "to afford each party a full and fair opportunity to present his case." Petitioner argues that a hearing was necessary because "Chief Special Master Corcoran has called into question the credibility of Dr. Steinman as a witness," and "a hearing would afford Dr. Steinman, a true expert in this area, the opportunity to clarify his position as to why the theory of molecular mimicry, in this case, addresses the issues of inflammation and

pathology and their relationship to Guillain Barre Syndrome (GBS)." The court notes that petitioner's first request for a hearing appears to have been made on October 12, 2021, after Dr. Steinman had submitted all five of his expert reports in the above captioned case. Petitioner argues that the denial of a hearing "prejudiced Petitioner in the proceedings" because it "limited the court's ability to assess the evidence proffered by Dr. Steinman, the Petitioner's sole expert witness." In response, respondent argues, citing Vaccine Rule 8(d) (2021), that "[i]t is well-established, however, that a special master 'may decide a case on the basis of written submissions without conducting an evidentiary hearing.'" Respondent also cites 42 U.S.C. § 300-aa-12(d)(3)(B)(v), stating that Special Masters have it within their discretion to allow "such hearings as may be reasonable and necessary." Respondent indicates that Chief Special Master Corcoran found that "a hearing was not needed to decide this case." Respondent argues:

> Since the filing of the Rule 4(c) report, petitioner has known respondent's position on petitioner's ILI/URI as a relevant factor regarding vaccine causation for his GBS. Petitioner cannot now reasonably object after initially agreeing to a ruling on the record by belatedly at the "eleventh-hour" requesting a hearing in his reply brief. C.f. Novosteel SA v. U.S., Bethlehem Steel Corp., 284 F.3d 1261, 1274 (Fed. Cir. 2002) ("Raising the issue for the first time in a reply brief does not suffice; reply briefs reply to arguments made in the response brief—they do not provide the moving party with a new opportunity to present yet another issue for the court's consideration."); see also In re Osterman, 296 F. App'x 900, 902 n.1 (11th Cir. 2008) ("[A] passing reference to an issue in a reply brief, offered without substantive argument in support, is insufficient to constitute raising the issue"). Because the Chief Special Master properly applied the law and acted within his discretion in deciding this case on the record, his Decision should be affirmed.

(alteration in original).

As noted above, petitioner's petition for compensation, dated August 11, 2016, and petitioner's initial brief, dated July 2, 2021, did not request for an evidentiary hearing. When he issued his Entitlement Decision, the Chief Special Master explained his decision "not to hold a hearing," which Chief Special Master Corcoran indicated he understood at the time was "a determination that the parties largely accepted." In a footnote, Chief Special Master Corcoran indicated:

> Petitioner's initial ruling on the record brief did not oppose deciding this case on the papers. On Reply, however, Petitioner included a footnote setting forth some process objections: that he was denied the opportunity to offer his own infectious disease expert (by the special master previously assigned to the case) to counter Dr. Collins's arguments, and that, although he noted my discretion to choose how best to decide the case, a hearing was warranted since the petitioner's theories were "closely

> contested."[11] Putting aside the underwhelming and somewhat eleventh-hour nature of this objection, I nevertheless determine (as explained herein) that the claim could be, and was, fairly adjudicated solely on the basis of the papers—and as already noted hearings are not held simply because the parties disagree on entitlement.

(internal reference omitted; alteration added). The Chief Special Master also indicated that "[d]etermining how best to resolve a case is a matter that lies generally within my discretion," and that "[i]t was wholly fair to both sides to resolve this case on the papers and after briefing by the parties." Chief Special Master Corcoran indicated that "[o]ver the case's nearly six years, Petitioner was afforded the opportunity to offer *five* written expert reports" and "was also permitted to modify his causation theory entirely, after Respondent voiced objections to its sufficiency." (emphasis in original). Moreover, the Chief Special Master concluded that petitioner's second theory of causation, molecular mimicry, is "one with which I have substantial familiarity—meaning I did not need to hear live testimony from Dr. Steinman to understand or react to it."

Courts review a Special Master's determination to deny an evidentiary hearing for an abuse of discretion. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d at 1364 ("We review a special master's decision to hold an evidentiary hearing for an abuse of discretion."); see also Munn v. Sec'y of Health & Hum. Servs., 970 F.2d 863 at 870 n.10. "Determinations subject to review for abuse of discretion must be sustained unless 'manifestly erroneous.'" Heddens v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. at 193 (quoting Piscopo v. Sec'y of Health & Hum. Servs., 66 Fed. Cl. at 53 (citations omitted)). Moreover, Special Masters have "wide discretion in determining whether to conduct an evidentiary hearing." Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d at 1365; see also Oliver v. Sec'y of Health & Hum. Servs., 900 F.3d 1357, 1364 n.6 (Fed. Cir. 2018) (holding that "Chief Special Master acted within her discretion in denying" the petitioner's request for a hearing); Burns v. Sec'y of Health & Hum. Servs., 3 F.3d at 417 (holding that "the special master acted within her discretion to determine that an additional [evidentiary] hearing on expert medical testimony was not necessary") (alteration added); Simanski v. Sec'y of Health & Hum. Servs., 671 F.3d 1368, 1371 (Fed. Cir. 2012) (noting that "the Vaccine Rules provide that the special masters can decide cases on written submissions, including, in appropriate cases, by summary judgment"). Nevertheless, the "special master's discretion to rule on the record is not without limitation." Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d at 1365. Because Special Masters are required to "afford[ ] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision," a special master "must determine that the record is comprehensive and fully developed before ruling on the record." Id. at 1366 (alterations in original) (citing

[11] A note in petitioner's October 12, 2021 reply brief stated that "petitioner acknowledges the Court's authority to decide this case without an evidentiary hearing during which the experts' presentations can be explored." Petitioner, however, also stated, "in the context of the present case, where petitioner's theory is closely contested, a hearing would supply valuable elaboration of petitioner's case and a hearing should be conducted."

Simanski v. Sec'y of Health & Hum. Servs., 671 F.3d at 1380 (finding that it was a violation of due process for a special master to rule on the record at "an early procedural stage" before respondent had "present[ed] its position with respect to the petition and the supporting evidence") (alteration added)); see also Oliver v. Sec'y of Health & Hum. Servs., 900 F.3d 1357, 1364 n.6 (Fed. Cir. 2018) (holding that because "the record was fully developed" and no legal or factual errors necessitated a hearing, it was within the Chief Special Master's discretion to deny the petitioner's request for an evidentiary hearing); Burns v. Sec'y of Health & Hum. Servs., 3 F.3d at 417.

Before Chief Special Master Corcoran, the record included petitioner's medical history prior to August 12, 2013 when petitioner received the vaccination at issue, his contemporaneous medical records from 2013 to 2016, as well as five expert reports that together spanned over seventy pages from petitioner's expert, Dr. Steinman, as well as four expert reports from Dr. Collins on behalf of respondent. The record also contained medical literature included with each of the experts' reports, including the results of Dr. Steinman's BLAST searches. Unlike in Simanski v. Secretary of Health & Human Services, 671 F.3d at 1380, in which the Federal Circuit found that it was a violation of due process for a special master to rule on the record at "an early procedural stage," the above captioned case was not at an "early procedural stage" based on the length of time from the filing of the case to when the parties submitted their respective briefs, which included the time to gather the relevant medical records of petitioner, to produce the numerous expert reports submitted by both experts, and for time for each expert to respond to the opposing expert. Moreover, petitioner had two years to file a request for additional expert(s) to challenge Dr. Collins' arguments that a URI/ILI caused petitioner's GBS. See Hines v. Sec'y of Health & Hum. Servs., 940 F.2d at 1526 (holding that "*principles of fundamental fairness to both parties*" were not violated when the petitioner had the opportunity to "discredit" and "rebut" the information (emphasis in original)).

Moreover, throughout the pendency of his case, petitioner received multiple extensions of time to file the expert reports authored by Dr. Steinman. In addition, on July 29, 2019, almost three years after the petition was filed, Special Master Roth held a status conference with the parties, during which the respondent indicated that petitioner's aluminum adjuvant causation theory was implausible. This prompted Special Master Roth to allow Dr. Steinman to submitted another expert report regarding petitioner's alterative causation theory regarding molecular mimicry as the causation mechanism, although denying petitioner's request to submit expert reports at such a late stage in the case from brand new experts.

Because a reviewing court should only overturn a special master's decision if it is "manifestly erroneous," see Heddens v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. at 193, and given the contemporaneous medical records in the record before Chief Special Master Corcoran when he issued his Entitlement Decision, as well as the numerous extensions and opportunities that petitioner was granted to supplement the record, and even to propose a second causation theory, it was not manifestly erroneous or an abuse of discretion for Chief Special Master Corcoran to deny petitioner's request to

submit additional expert testimony or to conclude that petitioner's case could be decided on the papers without an evidentiary hearing.

As to the Chief Special Master's rejection of petitioner's molecular mimicry alternative causation theory, the Chief Special Master reviewed Dr. Steinman's expert report on the subject in this case. Before this court, however, petitioner argues that

> the Chief Special Master failed to recognize that the posited medical theory of molecular mimicry went well beyond the mere identification of homologies between components of the Tdap vaccine and self-antigen such as human myelin protein, leading to GBS. The court's misconstruction of the record and incorrect application of the law requires vacatur of the Decision. The court compounded its error by holding that Petitioner's causal medical theory was "undercut" by epidemiological evidence as to causation for which an expert was denied to Petitioner despite requests throughout the case.

Petitioner argues that the "Chief Special Master held, *inter alia*, that Petitioner could not rely upon mere amino acid homologies identified through a BLAST search." (emphasis in original). Petitioner argues that Dr. Steinman's expert report went well beyond that standard and demonstrated how the homologies would produce an immune response. At the oral argument before this court, petitioner argued that when advancing a theory of molecular mimicry in vaccine cases, the standard is that it is insufficient to perform only a BLAST search to demonstrate potential homologies. Additionally, petitioner argues that Chief Special Master Corcoran's rejection of the petitioner's theory of molecular mimicry and the Chief Special Master's "undue reliance upon epidemiology in this context" constitutes an abuse of discretion. Petitioner asserts that the "Chief Special Master's Decision turned, in part, upon Baxter I [R. Baxter et al., <u>Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis</u>, 63 Clin. Infect. Diseases: An Official Publication of the Infectious Disease Soc. of Am., 1456 (2016) & II [R. Baxter et al., <u>Lack of Association of Guillain-Barre Syndrome with Vaccinations</u>, 57 Clin. Infect. Diseases: an Official Publication of the Infectious Diseases Soc. of Am. 197, 203 (2013)]." (alterations added). In the Entitlement Decision, the Chief Special Master found that "Epidemiologic evidence offered by Respondent also undercuts Petitioner's showing." (capitalization in original). In his Entitlement Decision, the Chief Special Master wrote:

> Baxter II—a large-scale study identifying no association between Tdap and GBS—was particularly harmful. It was far more relevant to Petitioner's claim herein than Baxter I (authored by almost all of the same individuals as Baxter II), which Dr. Steinman favorably cited but which only showed a possible association between Tdap and *ADEM* [acute disseminated encephalomyelitis]—a distinguishable central nervous system-impacting demyelinating disease. The very fact that Dr. Steinman chose to cite Baxter I is telling—if one epidemiologic study not fully on point is nevertheless supportive of his theory, how can a study *directly* on point (since it involved the injury at issue *in this case*), and written by largely the

> same group of scientific professionals, not *also* bear on the case's outcome?

(emphasis in original; alteration added).

Citing the legal analysis of one of his own, prior decisions, Yalacki v. Secretary of Health & Human Services, 14-278V, 2019 WL 1061429 (Fed. Cl. Spec. Mstr., Jan. 31, 2019), review denied, 146 Fed. Cl. 80 (2019), Chief Special Master Corcoran concluded that petitioner's molecular mimicry theory "was not preponderantly shown to be likely causal," and stated "that molecular mimicry is not a 'get out of jail free card' in the [Vaccine] Program, entitling claimants who hire Dr. Steinman (or someone else sufficiently conversant with molecular biology and the relevant databases) to compensation, merely because it has scientific reliability as a general matter." Chief Special Master Corcoran determined:

> Without some reason to further find that the relevant vaccine *can* be causal of the specific injury at issue—however that might be demonstrated—establishing a potentiality for molecular mimicry alone does not meet the preponderant standard of proof, no matter what degree of amino acid identity (sequential or not) Dr. Steinman can demonstrate with a BLAST search.

(emphasis in original).

Petitioner argues that Yalacki decision "does not appear to have considered the type of multi-layered, filtered investigation utilized by Dr. Steinman in establishing a theory of molecular mimicry in this case." Although petitioner appears to agree that the injury in Yalacki, like the injury here, involves autonomic dysfunction. Petitioner, however, attempts to distinguish the Yalacki case on the grounds that the petitioner's injury in Yalacki was "induced by a different vaccine" and the "evidence (and science) [in Yalacki] that the cross-reaction would target the self-antigen was undeveloped." Respondent does not specifically address petitioner's use of Yalacki v. Secretary of Health & Human Services other than to assert that "[t]he Chief Special Master properly applied the law."

Additionally, respondent argues that Dr. Steinman's efforts, "as correctly noted by the Chief Special Master, were wholly misplaced. Here, petitioner acknowledges he cannot rely on mere homologies to establish causation." Respondent continues that "Dr. Steinman never adequately addressed the central 'criticism of his theory'—namely, although homologies are common and pathogenic cross-reactions are uncommon, 'most human beings are not plagued by autoimmune pathology." Respondent further asserts that "Dr. Steinman never actually provided any relevant, reliable, persuasive evidence that identify what genetic or environmental factors 'are necessary before [ ] self-reactive immune responses to myelin might trigger GBS,' 'either theoretically or in [p]etitioner's specific case.'" (alterations in original). Respondent asserts that

> the Chief Special Master aptly observed, petitioner relied exclusively on mouse models studying experimental autoimmune encephalomyelitis ("EAE") to support the contention that the homologies found could cause

> neuroinflammation in humans. But EAE translates to ADEM in humans, "a neuroinflammatory demyelinating disorder that impacts the brain and spinal cord." Petitioner never explained how ADEM sufficiently compares to petitioner's specific "pharyngeal-cervical-brachial variant" of GBS, or even to GBS in general.

(capitalization in original; internal citations omitted).

Respondent, citing Andreu ex rel. Andreu v. Secretary of Health & Human Services, 569 F.3d at 1379, states that "the Chief Special Master appropriately considered the epidemiological evidence submitted by both parties." Respondent asserts that epidemiological evidence is not necessary to prove causation under the Vaccine Act, but that "'the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.'" Although petitioner alleges that the Chief Special Master erred in considering epidemiological evidence, both parties filed epidemiological evidence and analyses, and according to respondent, "epidemiology is considered by special masters in nearly every contested Vaccine Program case." Indeed, Dr. Steinman discussed epidemiological studies, the "possibility of an infectious disease etiology," but argued that "the priority of the potential CMV [cytomegalovirus] or EBV [Epstein-Barr virus] infections in triggering disease is lower than the likelihood that the vaccination triggered the disease." (alterations added). Respondent argues, therefore, that "[t]he Chief Special Master here acted within his discretion," in considering epidemiological evidence and deciding that petitioner did not meet his burden of proof on the first Althen prong.

In the case currently before the court, petitioner's expert, Dr. Steinman, presented epidemiological evidence by citing the Baxter I study, which the Chief Special Master found should necessarily allow him to look at the Baxter II study as well. Notably, epidemiologic evidence can be considered in a special master's Althen prong one determination, even though it is not required. See Taylor v. Sec'y of Health & Hum. Servs., 108 Fed. Cl. at 820 (finding that "the Special Master did not err in considering epidemiological evidence, along with the clinical record, expert testimony and other medical literature, to reach her informed judgment that Petitioner's theory of causation was more unlikely than not"); see also Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d at 1379 (finding that "where such [epidemiological] evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury" (alteration added)). As noted by a different Special Master in Pierson v. Secretary of Health & Human Services, a "petitioner must offer more than superficial invocation of molecular mimicry as the causal mechanism," and "[i]t also cannot be enough that a medical expert can simply identify homologous peptides from a generic BLAST search that are not, in any way, linked to the biological process that is dysfunctional or has suffered injury.'" Pierson v. Sec'y of Health & Hum. Servs., No. 17-1136V, 2022 WL 322836, at *25 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) (quoting Brayboy v. Sec'y of Health & Hum. Servs., No. 15-183V, 2021 WL 4453146, at *19 (Fed. Cl. Spec. Mstr. Aug. 30, 2011)).

The court notes that Dr. Steinman's molecular mimicry theories have had mixed success before different Special Masters. A number of Special Masters have determined causation was not met in instances in which Dr. Steinman argued a theory of molecular mimicry. See, e.g., Mason v. Sec'y of Health & Hum. Servs., No. 17-1383V, 2022 WL 600415, at *6, *26 (Fed. Cl. Spec. Mstr. Feb. 4, 2022) (Chief Special Master Corcoran found that Althen prong one was not met when Dr. Steinman argued that molecular mimicry could trigger chronic inflammatory demyelinating polyneuropathy even after his "BLAST searches revealed several common sequences, such as GSASGVSECRF (shared between MBP and the target antigen of the 2014-2015 flu vaccine), which had five of eleven identical amino acids, and he proposed as a result that this homology with vaccine components was sufficient for a damaging cross-attack by immune cells."); D.G. v. Sec'y of Health & Hum. Servs., No. 11-5777V, 2019 WL 2511769, at *128, *193 (Fed. Cl. Spec. Mstr. May 24, 2019) (Special Master Millman found no causation in fact when "Dr. Steinman said he talks a lot about molecular mimicry in this case, but he does not have a known molecular mimic that he can identify."); Chinea v. Sec'y of Health & Hum. Servs., No. 15-095V, 2019 WL 1873322, at *15 (Fed. Cl. Spec. Mstr. Mar. 15, 2019) (Chief Special Master Corcoran found no causation when "Dr. Steinman next proposed a mechanism by which the flu vaccine could have caused Mrs. Chinea's GBS."); Perez v. Sec'y of Health & Hum. Servs., No. 10–659V, 2015 WL 9483680, at *7, *13 (Fed. Cl. Spec. Mstr. Dec. 8, 2015) (Special Master Hamilton-Fieldman found petitioner did not meet Althen prong one when Dr. Steinman argued that molecular mimicry was the reason that petitioner's tetanus vaccine caused his GBS.); but see Pierson v. Sec'y of Health & Hum. Servs., 2022 WL 322836, at *12, *39 (Special Master Horner that causation-in-fact was proven preponderantly in cases in which "Dr. Steinman base[d] his theory of how the Prevnar 13 vaccine can cause GBS through the concept of molecular mimicry." (alteration added)); Koller v. Sec'y of Health & Hum. Servs., No. 16-439V, 2021 WL 5027947, at *8, *23 (Fed. Cl. Spec. Mstr. Oct. 8, 2021) (Special Master Gowan held that all three Althen prongs were met after Dr. Steinman used molecular mimicry to argue that the Prevnar 13 vaccine caused petitioner' GBS.). The court notes, of course, that each of above cited decisions of the Special Masters was based specifically on the medical histories and facts of the specific petitioners involved. Moreover, as explained by the Federal Circuit in Boatmon:

> To the extent the Court of Federal Claims required that special masters cite and distinguish the decisions of other special masters, it was incorrect. As the Court of Federal Claims itself acknowledged, "[a] Special Master is not bound to follow the opinions of other Special Masters." Id.; see also Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand."), aff'd, 191 F.3d 1344 (Fed. Cir. 1999). The government also acknowledges this on appeal. Appellee's Br. 18 n.1 ("The decisions of other special masters . . . are not binding precedent."); id. at 22 ("[S]pecial masters' decisions are non-binding."). By extension, special masters are not required to distinguish non-binding decisions of other special masters. That is, in part, because "[c]ausation in fact under the Vaccine Act is . . .

> based on the circumstances of the particular case." Knudsen, 35 F.3d at 548.

Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d at 1358–59 (alterations in original).

The court has reviewed petitioner's objection that the "Chief Special Master failed to recognize that the posited medical theory of molecular mimicry went well beyond the mere identification of homologies between components of the Tdap vaccine and self-antigen such as human myelin protein, leading to GBS." Petitioner did not offer reliable evidence to support the petitioner's theory that molecular mimicry between the Tdap antigens and self-structures associated with the initial attack on petitioner's nerves was the mechanism driving the autoimmune process. Therefore, based on the record before Chief Special Master Corcoran, this court finds that the Chief Special Master's decision that petitioner has not established by a preponderance of the evidence that the Tdap vaccine likely caused the production of antibodies associated with autonomic damage or interference sufficient to cause GBS and that those same antibodies did lead to a pathogenic process was not arbitrary or capricious, or an abuse of discretion.

Petitioner also argues that Chief Special Master Corcoran applied the wrong evidentiary standard to the first Althen prong, and argues that the correct legal standard is whether it is "biologically plausible," not whether petitioner has preponderantly established, that the Tdap vaccine could have caused GBS. In response, respondent argues "[t]he Chief Special Master properly required petitioner to present preponderant evidence in support of Althen prong 1, and correctly noted that Federal Circuit precedent requires a petitioner to present more than a 'plausible theory' of vaccine causation."

In his Entitlement Decision, Chief Special Master Corcoran noted:

> Before discussing the success of Petitioner's Althen prong one showing, review of his framing of the legal standard applicable is warranted. For Petitioner *fully misstates* that standard, proposing a version that, if adopted, would obliterate the existing distinction between Table and non-Table claims in the Vaccine Program. Reply at 3. As I noted above, the most recent controlling/precedential Federal Circuit caselaw directly addressing the subject states explicitly that the first Althen prong requires a preponderant showing—just like the other two prongs. Boatmon, 941 F.3d at 1359; LaLonde, 746 F.3d at 1339; see also Moberly, 592 F.3d at 1322.

(emphasis in original).

Consistent with petitioner's arguments before the Chief Special Master, in his Motion for Review in this court, petitioner cites to a decision of the Chief Special Master in Morgan v. Secretary of Health & Human Services, No. 15-1137V, 2019 WL 7498665 (Fed. Cl. Spec. Mstr. Dec. 4, 2019), review denied, 148 Fed. Cl. 454 (2020), aff'd, 850 F. App'x 775 (Fed. Cir. 2021)), a recent decision by a Judge of the United States Court of Federal Claims reversing Chief Special Master Corcoran's decision in J. v. Secretary

of Health & Human Services, 155 Fed. Cl. 20 (2021), and a recent, non-precedential Federal Circuit decision in Kottenstette v. Secretary of Health & Human Services, No. 2020-2282, 861 F. App'x 433 (Fed. Cir. 2021), in an attempt to argue that the current legal standard under the first Althen prong is whether it is biologically plausible petitioner's Tdap vaccine could have caused GBS. Despite the petitioner's attempts to refashion the first Althen prong standard, in 2019, the Federal Circuit in Boatmon v. Secretary of Health & Human Services, 941 F.3d 1351, reiterated the Federal Circuit's long standing holding that a petitioner bears the burden to prove actual causation by a preponderance of the evidence.[12] The Federal Circuit in Boatmon explained:

> In off-Table cases like this one, it is the petitioners' burden to prove actual causation by a preponderance of the evidence. Moberly, 592 F.3d at 1322. The Vaccine Act "relaxes proof of causation for injuries satisfying the Table[,] . . . but does not relax proof of causation in fact for non-Table Injuries." Id. (quoting Grant, 956 F.2d at 1148). A petitioner must provide a "reputable medical or scientific explanation" for its theory. Id. While it does not require medical or scientific certainty, it must still be "sound and reliable." Knudsen, 35 F.3d at 548–49.
>
> . . .
>
> We have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard. Moberly, 592 F.3d at 1322 (rejecting a "more relaxed standard" of whether the condition was "likely caused" by the vaccine and reiterating that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard"); see also LaLonde, 746 F.3d at 1339 ("However, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient

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[12] The court notes that the Federal Circuit appears to have issued one precedential decision on the issue of the correct legal standard for causation since the Boatmon decision. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378. In Kirby, the Federal Circuit observed that

> [t]he government relies on Boatmon v. Secretary of Health & Human Services, 941 F.3d 1351, 1359 (Fed. Cir. 2019), but that case is inapt because the special master there "articulated a lower 'reasonable' standard" in assessing the petitioners' medical theory of causation. Here, by contrast, the special master recited the correct legal standard. J.A. 33 ("[P]etitioners must provide a reputable medical theory . . . based on a sound and reliable medical or scientific explanation.") (internal quotation marks omitted).

Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d at 1384 (alterations in original).

> for a petitioner to meet her burden of proof." (quoting Moberly, 592 F.3d at 1322)).

Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d at 1359–60 (emphasis and alterations in original). Chief Special Master Corcoran properly cited to the Federal Circuit's precedential decision in Boatmon v. Secretary of Health & Human Services, to conclude that petitioner must present preponderant evidence to prevail under the first Althen prong. Therefore, this court finds that Chief Special Master Corcoran applied the correct legal standard for petitioner to meet the first Althen prong, which as determined above, petitioner failed to meet.

Petitioner also "seeks review of the Chief Special Master's conclusion that Torday v. Secretary of Health & Human Services, No. 07-372V, 2009 WL 5196163 (Fed. Cl. Spec. Mstr. December 10, 2009), is not 'useful' to disposition of the case at bar." (internal citation omitted). The court notes that the Chief Special Master only referenced Torday twice in his Entitlement Decision, both times in footnotes. The Chief Special Master noted in a footnote:

> As Respondent observed in his opposition brief, Dr. Steinman's misplaced reliance on Torday as requiring specification of a precise infection to counter the known quantity of a vaccination really invokes a Shyface-like analysis from a case where more than one factor was deemed potentially causal, leading the special master to give less weight to the unknown precise nature of the infection. Torday*,* 2009 WL 5196163, at *3–4.

Additionally, in a separate footnote, Chief Special Master Corcoran stated:

> Respondent herein also reacted directly to Dr. Steinman's non-medical exegesis into Vaccine Program legal standards, noting that the case he cited to defend his view that a known vaccine should be favored as causal over a non-specifically identified infection did not quite mean what he represented. Opp. at 27–28, citing Torday v. Sec'y of Health & Hum. Servs.*,* No. 07-372V, 2009 WL 5196163, at *3–4 (Fed. Cl. Spec. Mstr. Dec. 10, 2009). Torday*,* Respondent maintained, stood only for the proposition that when it was undisputed that the vaccine at issue *and* an unspecified illness could be causal, and the evidence was otherwise deemed close, it was reasonable to find the vaccine as causal. Here, by contrast, Dr. Collins and Respondent did *not* concede the Tdap vaccine was causal. Opp. at 28. Respondent's reading of Torday is superior to Dr. Steinman's—and it only underscores why medical/scientific experts like Dr. Steinman are better off not opining on the meaning of Program caselaw or the applicable legal standards (although as discussed in this Decision, I give no weight at all to Dr. Steinman's legal pronouncements, and do not otherwise deem Torday a useful guiding decision).

(emphasis in original).

Petitioner claims that "[w]hile Respondent has not conceded that the Tdap vaccine can be causal to Petitioner's development of GBS, a court may find that it can be causal and apply the logic of Torday here." Petitioner argues:

> All that is known about the days immediately after vaccination is that there were symptoms, which form the basis for Respondent's position in this case. It is not known to what these symptoms were attributable. There is no direct evidence that an infectious disease existed, at all. The symptoms may have been attributable to the formative stage of GBS, or perhaps another explanation. A court, in weighing a speculative, possibly non-existent infectious disease, without identification or specificity, could reasonably find recourse to the method employed in *Torday*, whereby preponderance was established, by just a feather's weight, to a known causal factor such as vaccination.

Respondent challenges petitioner's reading of Torday, and correctly points out that "Torday is nonprecedential, and the Chief Special Master is not bound by its analysis. Nevertheless, the Chief Special Master clearly considered Torday distinguishable from the present case." (citation omitted).

In Torday, the petitioner developed GBS after receiving the flu vaccine. See Torday v. Sec'y of Health & Hum. Servs., 2009 WL 5196163, at *1. Expert witnesses for petitioner Torday and the respondent disagreed as to whether the vaccine or an intervening upper respiratory infection caused petitioner Torday's GBS. See id. at *3. In Torday, then-Chief Special Master Golkiewicz indicated that "the issue to be decided is actually quite narrow" because both experts agreed that the vaccine or an upper respiratory infection could have caused petitioner's GBS and that both met the third Althen prong. See id. In Torday, then-Chief Special Master Golkiewicz stated:

> The preponderance of evidence standard is often described as 50 percent plus a feather. In this case, the undersigned interprets the experts' testimony to be that the vaccine and URI are potentially of equal culpability. However, when forced to choose, the experts disagree for the reasons stated as to which potential cause gets the feather. In resolving this case, the undersigned accepts and credits Dr. Steinman's logic that the known causative agent, the vaccine, should be weighted more heavily than the unknown agent causing the URI, which may or may not be a potential cause of GBS. Thus, the undersigned finds that the 50 percent and the feather goes to the vaccine as the cause of Mr. Torday's GBS.

Id. at *4 (alteration added). In the Torday decision, then-Chief Special Master Golkiewicz indicated that he ruled in favor of petitioner Torday "by the slimmest of margins." Id.

As noted above, in his Entitlement Decision for the above captioned case, Chief Special Master Corcoran indicated he did not "deem Torday a useful guiding decision."

Notably, the vaccine at issue in Torday, an influenza vaccination, was different than the Tdap vaccine administered to petitioner in the above captioned case.

As Chief Special Master Corcoran stated in his Entitlement Decision, "it is incorrect that evidence regarding possible alternative causes should not be included in a special master's weighing, absent definitive proof of the nature of the infection." In his Entitlement Decision, Chief Special Master Corcoran found that not only is there "incontrovertible evidence that Petitioner *first* experienced URI symptoms before neurologic-related symptoms, but also that the majority of [petitioner's] treaters deemed the URI most likely causal. The vaccine does not deserve greater weight simply because it is 'known' whereas the precise nature of the infection is not." (emphasis in original; alteration added). In his Entitlement Decision, Chief Special Master Corcoran, citing Randolph v. Secretary of Health & Human Services, No. 15-146V, 2021 WL 5816271, at *21 (Fed. Cl. Spec. Mstr. Nov. 12, 2021), indicated that "medical science cannot always test for or identify a specific infection." According to Chief Special Master Corcoran,

> [t]here are circumstances where experts on both sides concede two or more factors could be causal of injury (including vaccination), resulting in entitlement for the petitioner if the special master concludes that the vaccine was at least a 'substantial' factor (even if not the primary or predominant factor). Deribeaux v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 583, 589 (June 4, 2012). But here, there was no concession by Dr. Collins that the Tdap vaccine *can* be causal at all—and I have found that Petitioner did not preponderantly establish this to the case. Thus, the mere fact that temporarily [sic] Petitioner received the Tdap vaccine before onset of his URI does not compel me into a Shyface determination that the URI was not likely *solely* causal.

(emphasis in original; alteration added). In fact, in her January 23, 2020 expert report, Dr. Collins stated,

> [t]he timing of [K.A.]'s symptoms in relationship to the Tdap vaccine is most likely coincidental. An influenza-like illness that followed the vaccine and preceded development of GBS is more likely than not the cause of [K.A.]'s GBS. There is no evidence that aluminum in the Tdap vaccination causes GBS, while conversely there is a known association between influenza-like infection and the development of GBS. Therefore, I do not believe the evidence in this case is supportive of the conclusion that the Tdap vaccine caused or substantially contributed to [K.A.]'s symptoms.

(alteration added).

After examining petitioner's medical records and all the expert reports, Chief Special Master Corcoran found that

> [p]etitioner has not preponderantly established that the Tdap vaccine can cause GBS, under either of the two causation theories ventured over the case's six-year life—and even if he had, the record demonstrates it is far

more likely his GBS was attributable to an intercurrent upper respiratory infection ("URI") than vaccination.

Chief Special Master Corcoran's analysis and conclusions and rejection of the Torday analysis as a basis for his Entitlement Decision was not arbitrary, capricious, or an abuse of discretion, given the facts of petitioner's medical records in the above captioned case.

CONCLUSION

This court finds that Chief Special Master Corcoran's examination of the record before the court in petitioner's case, including the multiple, albeit conflicting, expert opinions by Dr. Steinman and Dr. Collins, petitioner's contemporaneous medical records and the literature submitted, resulted in a decision which was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). The Chief Special Master's Entitlement Decision is affirmed. Petitioner's Motion for Review is **DENIED**. The Clerk of the Court shall enter **JUDGMENT** consistent with this Opinion.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge