

In the United States Court of Federal Claims

PORTIA EXUM,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

No. 21-1513V

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2025¹

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2025

Amber D. Wilson of Wilson Science Law, Washington, DC argued for Petitioner.

Mary Novakovic, United States Department of Justice, Civil Division, Torts Branch, Washington, D.C., argued for Respondent. With her on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, Washington, DC; *C. Salvatore D'Alessio*, Director, Torts Branch, Civil Division; *Heather L. Pearlman*, Deputy Director, Torts Branch, Civil Division; *Alexis B. Babcock*, Assistant Director, Torts Branch, Civil Division.

MEMORANDUM AND ORDER

Pending before this Court is Petitioner Portia Exum's Motion for Review of the Chief Special Master's decision denying her entitlement to compensation under the Vaccine Act. *See* Motion for Review (ECF No. 76) (Mot.);² *see Exum v. Sec'y of Health & Hum. Servs.*, No. 21-1513, 2024 WL 4291116 (Fed. Cl. Spec. Mstr. Aug. 29, 2024) (ECF No. 74) (Decision). Petitioner contends that the Chief Special Master erred by (i) articulating and applying an erroneous legal standard for

¹ On February 26, 2025, this Court issued a sealed version of this Memorandum and Order. ECF No. 82. On March 14, 2025, the parties filed a Notice indicating they had no proposed redactions to the Memorandum and Order. ECF No. 83. Accordingly, the sealed and public versions of this Memorandum and Order are identical, except for the publication date and this footnote.

² Citations throughout this Order correspond to the ECF-assigned page numbers, which do not always correspond to the pagination within the document.

Althen prong one, (ii) reaching conclusions on *Althen* prong two that were contrary to law, and (iii) failing to analyze *Althen* prong three. Mot. at 5. She urges this Court to set aside the Decision and grant entitlement, or, in the alternative, remand this matter to the Chief Special Master for further consideration under the proper standard of review. *Id.* Respondent Secretary of Health and Human Services urges this Court to affirm the Decision, arguing that Petitioner “has not shown that the Chief Special Master’s denial of entitlement was arbitrary, capricious, an abuse of discretion, or not in accordance with law,” and has thus not demonstrated reversible error. Response to Petitioner’s Motion for Review (ECF No. 79) (Resp.) at 8. Petitioner’s Motion is fully briefed, and this Court conducted Oral Argument on December 19, 2024. *See* Transcript, dated Dec. 19, 2024 (ECF No. 81) (OA Tr.). Having considered the parties’ briefs, arguments, and applicable law, Petitioner’s Motion (ECF No. 76) is **GRANTED IN PART** and accordingly the Decision is **VACATED and REMANDED** to the Chief Special Master for further action in accordance with this Memorandum and Order.

BACKGROUND

On June 25, 2021, Petitioner Portia Exum filed a Petition for Compensation under the National Childhood Vaccine Injury Act (Vaccine Act) for an off-table injury. Vaccine Act, 42 U.S.C. §§ 300aa-10–34; Petition for Compensation (ECF No. 1) (Pet.). Specifically, Petitioner alleged that the measles-mumps-rubella (MMR) and tetanus-diphtheria-acellular pertussis (Tdap) vaccines she received on August 20, 2018, caused her autoimmune hepatitis (AIH) and chronically elevated liver serum enzymes. Pet. ¶¶ 4, 21–22.³ To support her position, Petitioner filed expert

³ Paragraphs 21 and 22 appear on page 4 of the Petition. The numbering of paragraphs restarts at one in the paragraph following paragraph 20. For clarity, paragraph references to the Petition continue numbering the paragraphs following paragraph 20 as 21 through 30.

reports,⁴ medical literature,⁵ and medical records.⁶ Respondent filed competing expert reports⁷ and medical literature⁸ in support of its contention that Petitioner had not established that her AIH and chronically elevated liver serum enzymes were caused by the MMR and Tdap vaccines. On March 7, 2024, Chief Special Master Brian H. Corcoran held an Entitlement Hearing, in which Drs. Robert Gish, Jeffrey Crippin, and Andrew MacGinnitie testified. *See generally* Hr’g Tr.

I. Factual Background

Petitioner’s AIH diagnosis is undisputed. *See* Mot. at 6, 17, 20; Resp. at 9 (adopting Special Master’s factual findings); *see also Exum*, 2024 WL 4291116, at *5 (“Dr. Crippin [Respondent’s expert] agreed with Petitioner’s AIH diagnosis”); *see also* Resp. Post-Hr’g Brief (ECF No. 72) at 15 (“Respondent does not contest petitioner’s diagnosis of [AIH].”). On August 17, 2018,

⁴ Petitioner filed an opening and a rebuttal report from her expert, Dr. Robert Gish, along with supplemental pages and supporting exhibits. Pet. Ex. 16 (ECF No 18-1) (Gish Initial Report); Pet. Ex. 38 (ECF No. 28-1) (Gish Rebuttal Report); *see also* ECF No. 53-2 (Petitioner’s exhibit list). Dr. Gish testified at the Petitioner’s Entitlement Hearing (Entitlement Hearing). *See* Entitlement Hearing Transcript, dated Mar. 7, 2024 (ECF No. 64) (Hr’g Tr.). at 5:8–116:19.

⁵ *See* Pet. Exs. 17–23 (ECF Nos. 18-2–18-8); Pet. Exs. 25–26, 28–33 (ECF Nos. 19-1–19-2, 19-4–19-9); Pet. Exs. 34–35 (ECF No. 20-1–20-3); Pet. Ex. 24 (ECF No. 58-1); Pet. Ex. 27; (ECF No. 61-1).

⁶ Petitioner filed her medical records as Exhibits 1–10. *See* ECF Nos. 6–7. Petitioner filed a Statement of Completion on June 30, 2021, confirming the submission of all medical records required by 42 U.S.C. § 11(c). ECF No. 8. She later filed additional medical records marked as Exhibits 14–15 (ECF No. 16-1–16-2) and Exhibit 46 (ECF No. 53). She also filed updated medical records as Exhibits 4344 (ECF No. 45-1–45-2).

⁷ Respondent filed one expert report from each of its two experts, Dr. Jeffrey Crippin and Dr. Andrew MacGinnitie. *See* Resp. Ex. A (ECF No. 23-1) (Crippin Report); Resp. Ex. C (ECF No. 23-3) (MacGinnitie Report). Both Drs. Crippin and MacGinnitie testified at Petitioner’s Entitlement Hearing. *See* Hr’g Tr. 117:14–141:10, 141:25–192:17.

⁸ *See* Exhibit A, Tabs 1–19 (ECF Nos. 25-1–25-19); Exhibit C, Tabs 1–19 (ECF Nos. 26-1–26-19).

in preparation for a trip to Kenya and Tanzania, Petitioner received an anti-malarial medication, Malarone (Atovaquone-Proguanil), which she was instructed to begin taking beginning two days before she visited high-risk areas and continue taking until seven days after her departure. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3 (ECF No. 6-3), at 74; Pet. Ex. 4 at 8 (ECF No. 6-4). On August 20, 2018,⁹ she received the Tdap and MMR vaccines. *Exum*, 2024 WL 4291116, at *1; Pet. ¶ 4; Pet. Ex. 3, at 72. She traveled to Kenya and Tanzania from August 29, 2018 through September 8, 2018, and reported receiving four or five bug bites during the trip. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 4, at 35. When she returned, Petitioner reported feeling “extreme fatigue,” and by late September developed gastroesophageal reflux disease (GERD) symptoms and indigestion. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 57; Pet. Ex. 4, at 35. By October 2018, she was experiencing daily nausea. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 4, at 35.

On October 26, 2018—two months after receiving the Tdap and MMR vaccines—a routine physical revealed that Petitioner’s liver enzyme levels were abnormally high.¹⁰ *Exum*, 2024 WL 4291116, at *1; Pet. ¶ 5; Pet. Ex. 4, at 42. Prior to this test, her liver enzyme levels had been normal.¹¹ *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 268.

⁹ The first page of the Decision states that Petitioner received the vaccines on October 8, 2018. *Exum*, 2024 WL 4291116, at *1. However, the Petition and Petitioner’s medical records reflect that the vaccines were administered on August 20, 2018. Pet. ¶ 4; Pet. Ex. 3, at 72.

¹⁰ Petitioner’s tests for the Hepatitis C Virus and HIV during this visit were negative. Pet. Ex. 3, at 250–53.

¹¹ Testing performed during a visit to the Emergency Room (ER) on May 16, 2018—three months before receiving the vaccines at issue—indicated that Petitioner’s liver enzyme levels were normal. Pet. Ex. 3, at 268. Lab testing performed in July 2018 also revealed normal liver enzyme levels. Pet. ¶ 9.

Petitioner visited a gastroenterologist on November 28, 2018, reporting elevated liver enzyme levels, nausea, and gastrointestinal (GI) symptoms. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 280. Her abdominal exam did not reveal any signs of liver enlargement or tenderness, although Petitioner reported that she was experiencing “right-sided distress.” *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 282. A physician’s assistant (PA) referred Petitioner to a hepatologist for an MRI of her liver, and recommended that Petitioner undergo *H. pylori* testing, repeat liver function tests, take Pepcid, and make several changes to her diet. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 282–83. Tests results dated November 30, 2018, revealed that Petitioner’s liver enzyme levels were “extremely elevated”—even higher than her previous levels—but were negative for *H. pylori*. *Exum*, 2024 WL 4291116, at *1; Pet. Ex. 3, at 67–69.

On December 6, 2018, a gynecologist removed Petitioner’s inter-uterine device (IUD) to eliminate the IUD as a possible cause of her liver issues. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 242. The following day, Petitioner visited her primary care physician (PCP), because she was reporting “intermittent nausea, right abdominal discomfort, fatigue, and that her eyes appeared yellow.” Pet ¶ 9; Pet. Ex. 3, at 61; *Exum*, 2024 WL 4291116, at *2. Her abdominal exam was “unremarkable” and her viral hepatitis panel came back negative,¹² but her liver enzyme levels—including aspartate aminotransferase (AST) and alanine aminotransferase (ALT)—and her ferritin levels were elevated. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 62–63; Pet. Ex. 4, at 31–33. Petitioner’s PCP referred her to a hepatologist. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 62–63; Pet. Ex. 4, at 31–33.

¹² Specifically, Petitioner tested negative for hepatitis A, B, and C. Her tests for antibodies including antinuclear (ANA), antismooth muscle, antimitochondrial, and antiendomysial were negative. Testing for celiac disease was negative. Her Alpha-1-antitrypsin and ceruloplasmin levels were also normal. Pet. Ex. 3, at 64–66.

On December 11, 2018, Petitioner had an MRI of her liver. Pet. ¶ 10; Pet. Ex. 3, at 239; Pet. Ex. 4, at 28–29. The MRI revealed two hyper-intense lesions (abnormal growth of cells or tissue in the liver) interpreted to be adenomas versus focal nodular hyperplasia (FNH), and asymmetric dilation of the left renal vein. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 235–36. Radiologists recommended that she see a hepatologist for the hepatic lesions. Pet. Ex. 4, at 28.

Petitioner returned to her PCP on December 14, 2018, because she was concerned that she may have contracted malaria or another insect-borne disease during her trip to Africa. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 57. He ordered liver enzyme testing, which again revealed abnormally high levels of AST and ALT but excluded the possibility of an active hepatitis infection. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 57–58. Petitioner’s PCP also referred her to an infectious disease specialist. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 59.

On December 19, 2018,¹³ Petitioner was evaluated by a hepatologist, who noted that she had no signs of decompensated liver disease and that her abdominal exam did not reveal abnormalities. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 232–38. Lab results indicated that her AST and ALT levels remained elevated but did not indicate acute liver failure or an active hepatitis infection. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 232, 237; Pet. Ex. 8 (ECF No. 6-8), at 73. Her differential diagnosis noted her elevated results from liver function tests and the possibility of hepatic adenoma versus FNH. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 237. Petitioner represented that her lifestyle did not present risk factors for liver disease (e.g., alcohol consumption, drug use), but acknowledged taking anti-malarial medication during her recent trip to Kenya and Tanzania. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 232. She also reported that

¹³ Though the Decision states that this visit occurred on December 19, 2019, Petitioner’s medical records indicate that this hepatology visit occurred on December 19, 2018. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 232.

reishi mushrooms were the only other over-the-counter medication or supplement she was taking. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 232. The hepatologist recommended that Petitioner have a liver biopsy and another liver MRI in six months. *Exum*, 2024 WL 4291116, at *2; Pet. ¶ 11; Pet. Ex. 3, at 237.

Petitioner had a liver biopsy on January 3, 2019, which showed moderate interface and lobular hepatitis. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 229. The liver biopsy “raise[d] a broad differential diagnosis” consistent with infections, AIH, hepatitis secondary to the effects of medications or supplements, and Wilson’s disease (a genetic disorder that causes copper build up in the body). Pet. Ex. 3, at 229; *Exum*, 2024 WL 4291116, at *2. The following day, Petitioner was evaluated by a hematology and oncology specialist for evaluation of her elevated ferritin levels. Pet. Ex. 3, at 222; Pet. ¶ 12; *Exum*, 2024 WL 4291116, at *2. He concluded that this elevated level was due to “obvious liver disease” and diagnosed her with hepatitis. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 222; Pet. ¶ 12 (quoting Pet. Ex. 7 (ECF No. 6-7) at 29).

A follow-up evaluation by an infectious disease specialist on January 24, 2019, confirmed Petitioner’s AIH diagnosis.¹⁴ Pet. Ex. 4, at 6–8; *Exum*, 2024 WL 4291116, at *2.¹⁵ During this visit, Petitioner discussed her 2018 international travel including “that she had entered bodies of water, received several insect bites, and felt extreme fatigue upon return,” and that she was taking a four- to six-week course of prednisone, which she had begun on January 19, 2019. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 4, at 6–8. Testing indicated that Petitioner had previously (at an undetermined time) had an Epstein-Barr viral infection and that her liver enzyme levels were

¹⁴ Specifically, the infectious disease specialist agreed that a diagnosis of AIH was most likely; the specialist spoke with a hepatitis specialist, who agreed with the diagnosis. Pet. Ex. 4, at 12–13.

¹⁵ While the Decision notes that this visit occurred on January 29, 2019, the medical records indicate that it occurred on January 24, 2019. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 4, at 6.

improving but remained abnormally high. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 4, at 12; Ex. 3, at 201–08. Petitioner was also treated for thrush and a kidney stone in January. Pet. ¶¶ 14–15; Pet. Ex. 3, at 52; Pet. Ex. 2, at 32–36; Pet. Ex. 4 at 12.

During February and March 2019, Petitioner’s liver enzyme levels continued to improve, but remained elevated. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 42–51. Petitioner took “kidney-oriented medication” (azathioprine) and prednisone for her liver issues. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 197. In April 2019, when Petitioner returned to her PCP to discuss symptoms unrelated to her AIH (throat, thrush, chest pains), her PCP indicated that Petitioner’s AIH was “improving.” *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 36–37. Petitioner also returned to her hepatologist, reporting similar symptoms. Pet ¶ 16; Pet. Ex. 10 (ECF No. 7-1), at 6; *Exum*, 2024 WL 4291116, at *2. Her liver enzyme levels were improving but had not returned to normal. *Exum*, 2024 WL 4291116, at *2; Pet ¶ 16; Pet. Ex. 3, at 195; Pet. Ex. 10, at 10. The hepatologist recommended increasing her dose of azathioprine and decreasing her dose of prednisone. Pet. Ex. 3, at 195; Pet. Ex. 10, at 10.

On August 26, 2019, Petitioner again returned to her hepatologist. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 162–65. Testing performed during that visit revealed that her liver enzyme levels were no longer improving and instead were elevated relative to previous levels,¹⁶ notwithstanding the fact that she was taking the maximum dose of azathioprine. Pet ¶ 17; Pet. Ex. 3, at 165. Her hepatologist advised that Petitioner continue taking her medication (at an increased dose) and ordered a metabolite screen to confirm that Petitioner was not suffering from hepatotoxicity from the azathioprine. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 165. Testing

¹⁶ In an appointment with a nutritionist days later on August 30, 2019, the nutritionist noted that the increased liver enzyme levels correlated with Petitioner’s tapering off of her prednisone prescription. Pet. Ex. 3, at 32.

performed in September 2019 showed improved liver enzyme levels that were slightly elevated. *Exum*, 2024 WL 4291116, at *2; Pet. Ex. 3, at 20–31.

On January 27, 2020, Petitioner’s hepatologist noticed that Petitioner was experiencing increased fatigue and myalgias, that her liver enzyme levels had returned to baseline, and no evidence of decompensated liver disease. Pet. ¶ 18; Pet. Ex. 10, at 56. Although her “liver concerns had mostly resolved,” Petitioner’s hepatologist instructed her to continue taking azathioprine and to have her serum enzymes tested every two to three months. *Exum*, 2024 WL 4291116, at *3; Pet. ¶ 18; Pet. Ex. 10, at 61.

At a follow-up appointment six months later on July 27, 2020, Petitioner’s liver enzyme levels were again normal. Pet. ¶ 19; Pet. Ex. 3 at 154. She was advised to continue taking azathioprine until 18 months after her diagnosis, at which point she could stop taking the drug, assuming her liver biopsy did not indicate significant inflammation. Pet. ¶ 19; Pet. Ex. 3 at 154. Other than a February 2021 liver biopsy which revealed “chronic hepatitis with minimal interface activity and mild portal fibrosis (stage 1 of 4),” Plaintiff’s testing from mid-2020 through 2022 indicated normal liver enzyme levels. *Exum*, 2024 WL 4291116, at *3; Pet. Ex. 14 (ECF No. 16-1), at 41; Pet. Ex. 15 (ECF No. 16-2) at 83, 149. A March 2022 hepatology visit did not indicate any signs of liver disease; her hepatologist noted that her liver function tests were stable and that she was not experiencing side effects related to her immunosuppression. Pet. Ex. 15, at 149; Pet. Ex. 14, at 36–41. As of November 2023, Plaintiff was not indicating any markers of liver disease. *Exum*, 2024 WL 4291116, at *3; Pet. Ex. 46 (ECF No. 53-1), at 6–7.

Petitioner indicates that she “has had to drastically change all of her prior nutrition and lifestyle habits due to suffering from a chronic illness” and that she “continues to require regular

care and monitoring from specialized physicians of her [AIH] and chronically elevated liver enzymes.” Pet. ¶¶ 20–21.

II. Expert Opinions

In addition to the referenced medical records, the Chief Special Master reviewed four expert reports filed by three different experts: Dr. Robert Gish, Dr. Jeffrey Crippin, and Dr. Andrew MacGinnitie. *See generally* Gish Initial Report; Crippin Report; MacGinnitie Report; Gish Rebuttal Report. All three experts testified at the Entitlement Hearing. *See generally* Hr’g Tr.

A. Petitioner’s Expert

1. Dr. Robert Gish

The Petitioner’s expert, Dr. Robert Gish, filed an initial and supplemental report and testified as an expert witness on behalf of Petitioner. *See generally* Gish Initial Report; Gish Rebuttal Report; Hr’g Tr. Dr. Gish is a clinical adjunct professor of medicine at the University of Nevada School of Medicine and University of California at San Diego Skaggs School of Pharmacy and Pharmaceutical Science and serves as the Medical Director of the Hepatitis B Foundation. Gish Initial Report at 1. He actively sees patients, consults with hepatology and liver centers nationwide, and performs clinical research. *Id.* at 1–2. Dr. Gish’s areas of expertise include internal medicine, gastroenterology, and hepatology. *Id.*; *Exum*, 2024 WL 4291116, at *3; Hr’g Tr. at 91:11–15. Dr. Gish acknowledges that he “do[es] not identify as an immunologist.” Hr’g Tr. at 91:11–15. He testified that approximately 10 of his patients in the past 30 years have developed AIH after receiving a vaccine. Hr’g Tr. 14:8–17. One of those cases involved the MMR vaccine, and none attributed AIH to the Tdap vaccine. *Id.* at 14:8–17, 89:5–90:10.

Dr. Gish opined that “the pathogenesis of [Petitioner’s] AIH is more probable than not attributed to the administration of her multiple vaccine dosing.” Gish Initial Rep. at 8. Dr. Gish offered several theories supporting this opinion. He theorized that the vaccines could have caused

Petitioner's AIH through molecular mimicry (an antigen-specific mechanism) and through several other immune activation mechanisms. *Id.* at 18–22; *see also* Hr'g Tr. at 42:22–44:18.

Dr. Gish posited that the live, attenuated measles virus in the MMR vaccine could have caused Petitioner to experience an autoimmune response resulting in AIH. Gish Initial Rep. at 18–20; Hr'g Tr. at 36:13–37:18. He relied on several studies in support of this theory, including an animal study indicating the specific immune cells that the measles vaccine targets (dendritic cells).¹⁷ Hr'g Tr. at 38:15–39:14; Pet. Ex. 33, Linda J. Rennick, et al., *Live-Attenuated Measles Virus Vaccine Targets Dendritic Cells and Macrophages in Muscle of Nonhuman Primates*, 89 *J. Virology* 2192 (2015) (ECF No. 19-9) (Rennick); Pet. Ex. 18, U. Christen & E. Hintermann, *Pathogens and Autoimmune Hepatitis*, 195 *J. Clinical & Experimental Immunology* 35 (2019) (ECF No. 18-3) (Christen & Hintermann); Pet. Ex. 29, D.A. Robertson et. al., *Persistent Measles Virus Genome in Autoimmune Chronic Active Hepatitis*, *The Lancet* (1987) (ECF No. 19-5) (Robertson); *see also* Gish. Initial Rep. at 10–11, 19.

Further, Dr. Gish relied on a study of *ex vivo* human T cells to support the proposition that wild-type measles infections and the attenuated measles vaccine cause immunosuppression. Hr'g Tr. at 40:21–42:21; Pet. Ex. 31, Ralph Nanan, et al., *Measles Virus Infection Causes Transient Depletion of Activated T Cells From Peripheral Circulation*, 12 *J. Clinical Virology* 201 (1999) (ECF No. 19-7) (Nanan); *see also* Pet. Ex. 32, Thomas Munyer et al., *Depressed Lymphocyte Function After Measles-Mumps-Rubella Vaccination*, 132 *J. Infectious Diseases* 75 (1975) (ECF No. 19-8); Gish Initial Report at 19. Dr. Gish testified that during this immunosuppressed state, the measles infection triggers measles-specific and “bystander” immune cells. Hr'g Tr. at 42:10–

¹⁷ Dr. Gish testified that he believed Rennick was relevant to the measles component of Petitioner's causation theory, despite that it was performed in an animal model. Hr'g Tr. at 38:15–39:14.

21 (discussing Gish Initial Report at 19). Using this bystander activation theory, Dr. Gish theorized that Petitioner’s MMR vaccine (which includes a live, attenuated measles vaccine infection) could have caused immunosuppression, activating both measles-specific and non-measles-specific (“bystander”) immune cells.¹⁸ *Id.* at 46:12–49:11; 59:24–60:2. The activation of those immune cells caused a cross-reaction of T cells, which caused a breaking of Petitioner’s self-tolerance to hepatic autoantigens. *Id.* at 53:21–54:12; 58:7–59:20. That, in turn, caused an autoimmune reaction. *Id.* at 59:15–20.

According to Dr. Gish, the Tdap booster could have activated Petitioner’s memory T cells because she had previously received the tetanus and diphtheria vaccines, which “amplif[ied] a normal immune response.” *Id.* at 62:7–63:2; Gish Initial Report at 23; Gish Rebuttal Report at 6.; *see also* Gish Initial Report at 10 (citing Pet. Ex. 19, Christine S. Benn et al., *A Small Jab – A Big Effect: Nonspecific Immunomodulation by Vaccines*, 34 Trends in Immunology 431 (2013) (ECF No. 18-4) (Benn)). He also testified that because she had previously had the Hepatitis A vaccine, memory T cells from those vaccinations could also have been the bystander immune cells that triggered an amplified immune response, noting that “there is a strong suggestive data in the medical literature” that AIH patients suffer from abnormalities associated with their T regulatory cells. Hr’g Tr. at 64:15–65:18; *see also* Gish Initial Report at 22 (arguing that given her Tdap and MMR vaccines “were both booster vaccines, Mrs. Exum likely suffered a sufficient immune

¹⁸ On cross-examination, Dr. Gish explained the apparently contradictory idea that suppression of the immune system can lead to AIH, a condition involving overactivation of the immune system. Hr’g Tr. at 112:7–113:10. He explained that the adaptive immune system compensates for the innate immune system, which activates a wide variety of cells, causing “off-target” effects that stimulate other parts of the immune system. *Id.*

response to increase her risk of immune dysfunction and clinical expression of autoimmune hepatitis disease.”).¹⁹

Similarly, Dr. Gish theorized that Petitioner’s prior whole cell pertussis vaccine could have caused her to display “polarization to Th1 and Th17 responses” when administered a booster with acellular pertussis, which is one component of the Tdap vaccine. Gish Initial Report at 21–22. Citing studies from 2018 and 2010, Dr. Gish explained that Th17 cells “induce inflammation and aid B cell production of antibodies” and “are believed to play an important role in the development of a variety of autoimmune diseases.” *Id.* (first citing Pet. Ex. 34, Ricardo da Silva Antunes et al., *Th1/Th17 Polarization Persists Following Whole-Cell Pertussis Vaccination Despite Repeated Acellular Boosters*, 128 J. Clinical Investigation 3853 (2018) (ECF No. 20-1) (Antunes); and then citing Pet. Ex. 35, Fouad Lafdil et al., *Th17 Cells and Their Associated Cytokines in Liver Diseases*, 7 Cellular & Molecular Immunology 250 (2010) (ECF No. (20-2) (Lafdil)).²⁰

Dr. Gish stated that medical literature supported a causal connection between the MMR and Tdap vaccines and AIH and cited numerous case reports to support his theory. Hr’g Tr. at 27:22–25; Gish Rebuttal Report at 3; *see* Pet. Ex. 21, Walid R. Saliba & Mazen Elias, *Acute Hepatitis Following MMR Vaccination*, 16 Euro. J. Internal Med. 379 (2005) (ECF No. 18-6) (Saliba & Elias); Pet. Ex. 23, PA Berry & G Smith-Laing, *Hepatitis A Vaccine Associated With Autoimmune Hepatitis*, 13 World J. Gastroenterology 2238 (2007) (ECF No. 18-8) (Berry &

¹⁹ *See* Pet. Ex. 3, at 72–73 (Petitioner’s vaccine history). As relevant here, Petitioner had previously received the DTP, Hepatitis A, Hepatitis B, MMR, Td, Tdap, Tetanus, and Yellow Fever vaccines. *Id.*

²⁰ In addition to the theories described above, Dr. Gish also theorized that the aluminum adjuvant in the Tdap vaccine could have caused Petitioner’s AIH. Gish Initial Rep. at 23. However, at the Entitlement Hearing, he expressly stated that he was “setting aside” that theory. Hr’g Tr. at 60:3–15.

Smith-Laing); Pet. Ex. 24, Ganesh R. Veerappan et al., *Vaccination-Induced Autoimmune Hepatitis*, 50 Digestive Diseases & Scis. 212 (2005) (ECF No. 58-1) (Veerappan); Pet. Ex. 25, Sruthi Kapliyil Subramanian, et al., *Postinfectious Autoimmune Hepatitis-Induced Liver Failure: A Consequence of Hepatitis A Virus Infection*, 7 ACG Case Reps. J. 1 (2020) (ECF No. 19-1) (Subramanian); Pet. Ex. 26, Marline A J van Gemeren, et al., *Vaccine-Related Autoimmune Hepatitis: The Same Disease as Idiopathic Autoimmune Hepatitis? Two Clinical Reports and Review*, 52 Scandinavian J. Gastroenterology 18 (2017) (ECF No. 19-2) (van Gemeren); Pet. Ex. 27, Ponni Perumalswami, et al., *Vaccination as a Triggering Event for Autoimmune Hepatitis*, 29 Seminars in Liver Disease 331 (2009) (ECF No. 61) (Perumalswami); Pet. Ex. 28, Tokio Sasaki, et al., *Autoimmune Hepatitis Following Influenza Virus Vaccination*, *Medicine*, July 2018 (ECF No. 19-4) (Sasaki); Pet. Ex. 30, Giorgina Mieli-Vergani, et al., *Measles and Autoimmune Chronic Active Hepatitis*, *The Lancet*, Sept. 16, 1989, at 688 (ECF No. 19-6) (Mieli-Vergain); Pet. Ex. 45, Jorch, et al. (1984) (Jorch), cited in Institute of Medicine, *Committee to Review Adverse Effects of Vaccines: Evidence and Causality* 39–430 (Kathleen Stratton, et al., eds., 2012) (ECF No. 45-3) (IOM).

During cross-examination, however, Dr. Gish acknowledged that the cited case reports differed from Petitioner's case because most of the reports didn't involve the MMR and Tdap vaccines. Hr'g Tr. at 97:14–107:22.

ECF No.	Case Report	Vaccine(s)	Related Illness
18-6	Pet. Ex. 21, Saliba & Elias (2005)	MMR	Acute hepatitis ²¹
18-8	Pet. Ex. 23, Berry & Smith-Laing (2007)	Hepatitis A	Acute liver injury consistent w/ AIH
58-1	Pet. Ex. 24, Veerappan (2005)	Typhoid, Hepatitis A, Td, oral polio, MMR	Flu-like symptoms then AIH
19-1	Pet. Ex. 25, Subramanian (2020)	N/A; wild acute Hepatitis A infection	AIH
19-2	Pet. Ex. 26, van Gemeren (2017)	Hepatitis A, Hepatitis B	AIH
19-2	Pet. Ex. 26, van Gemeren (2017)	Hepatitis A, diphtheria, whooping cough, ²² tetanus	AIH
61	Pet. Ex. 27, Perumalswami (2009)	Hepatitis A and yellow fever	AIH
19-4	Pet. Ex. 28, Sasaki (2018)	Flu	AIH
19-6	Pet. Ex. 30, Mieli-Vergain et al. (1989)	N/A; wild measles infection ²³	AIH
45-3	Pet. Ex. 45, Jorch, et al. ²⁴	MMR	Meningoencephalitis

²¹ According to Dr. Gish’s testimony, the difference between acute hepatitis and AIH, which is chronic, is duration. Hr’g Tr. at 46:19–47:15. Acute hepatitis lasts less than six months, but chronic hepatitis persists for longer than six months. *See Id.* at 100:18–101:3 (Dr. Gish explaining that chronic hepatitis means the patients has “documented elevated liver tests” for six months). Although the criteria for AIH was not published until 2008—several years after the Saliba & Elias report was published—the Saliba & Elias patient’s hepatitis fit the “acute” description because “the patient’s viral hepatitis testing was negative and spontaneously the liver function tests normalized after 4 weeks.” Gish Initial Report at 14.

²² The van Gemeren case report specifically mentions that the patient was vaccinated for whooping cough, but does not clarify the specific vaccine she received. It is unclear whether this patient received the Tdap vaccine. *See van Gemeren* at 3; Hr’g Tr. 106:7–22.

²³ While the Mieli-Vergain case report states that eight of the twelve child patients in this study “had received measles vaccination,” it does not specify which vaccine those patients received. *See Mieli-Vergain* at 1. The study further states: “Our data show[s] that in children [Autoimmune Chronic Hepatitis] develops despite measles vaccination, and that they have low measles antibody titres raise questions about a causative link between measles and this autoimmune condition, at least in childhood.” *Id.*

Dr. Gish theorized that when multiple vaccines are administered at the same time, the combination of a “[g]enetic predisposition to the immune stimulation of hepatitis A” and an environmental trigger (e.g., multiple vaccines administered concomitantly, plus adjuvants) “can stimulate a very robust immune response that may not be able to be brought under control until [the patient] start[s] immunosuppressants.”²⁵ Hr’g Tr. at 62:10–22, 69:7–14. Dr. Gish concluded that this is “a very, very good . . . theory” as to what occurred in Petitioner’s case. *Id.* at 62:23–63:2. Dr. Gish acknowledged, however, that no genetic testing supported this proposition; instead, Dr. Gish based his theory, that Petitioner may have a genetic predisposition that made her susceptible to AIH, on the contention that this kind of genetic predisposition is common. *Id.* at 96:7–97:13 (Dr. Gish testifying that “very large studies, with thousands and thousands of patients . . . have found very powerful statistical correlations with genetic diseases, genetic abnormalities, genetic mutations”).

Dr. Gish’s Initial Report also stated that Petitioner’s AIH diagnosis was “medically certain,” based on Petitioner’s medical history, medical records, and the specific sequence of events that led to her AIH. Gish Initial Report 2–7. In support, Dr. Gish discussed Petitioner’s pre-vaccination medical history, noting that prior to the vaccine, she did not appear to have liver issues, nor did her history indicate any alternative cause (other than the vaccine) for her condition.

²⁴ This case report is mentioned in the excerpt of a publication by the Institute of Medicine filed by Petitioner as Exhibit 45. See Pet. Ex. 45, Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* (ECF No. 45-3).

²⁵ To support his theory of genetic predisposition, Dr. Gish cited the Vento study, found in Subramanian, which followed family members of AIH patients to determine whether they would develop an AIH infection after developing a Hepatitis A infection. Because some individuals did develop AIH following this sequence of events, Dr. Gish asserted that this study supports the general idea that a “[g]enetic predisposition to the immune stimulation of hepatitis A” can contribute to AIH. Hr’g Tr. at 69:7–14.

Hr'g Tr. at 14:21–16:6. Specifically, he noted that her physical examinations did not indicate liver issues; her liver panel testing was normal; no lifestyle factors creating a risk of liver disease were present; and she tested negative for Hepatitis B and C. *Id.* at 15:17–16:6; 19:13–22:22.²⁶

At the Entitlement Hearing, Dr. Gish addressed potential alternative causes to Petitioner's AIH, as raised by the Respondent's experts. Dr. Gish noted that the specialists who had treated Petitioner at the Emory Travel Clinic "concluded that her travel history [did] not suggest an alternative infectious cause to her elevated liver enzymes." Gish Rebuttal Report at 8 (citing Pet. Ex. 4, at 7). Dr. Gish acknowledged that Petitioner's anti-malarial medication could be a risk factor for AIH, but asserted that the timing did not support a connection, and that antimalarial medications typically do not cause long-term or chronic autoimmune conditions. Hr'g Tr. at 22:9–14; 82:11–86:25 (discussing Resp. Ex. A, Tab 10, Benedetta Terzoli Beretta-Piccoli et al., *Atovaquone/Proguanil-Induced Autoimmune-Like Hepatitis*, 1 *Hepatology Commc'ns* 293 (2017) (ECF No. 25-10) (Beretta-Piccoli)). Further, although Petitioner was taking other supplements, the fact that her liver enzyme levels did not normalize after she stopped taking the supplements suggested to Dr. Gish that they were not the cause of her liver issues. *Id.* at 80:9–81:12. Relatedly, since Petitioner ceased taking reishi mushroom supplements after she learned that her liver enzyme levels were elevated, and saw no change in her liver enzyme levels as a result, Dr. Gish posited that this, too, could be eliminated as a potential cause of her AIH. *Id.* at 80:9–81:8. Additionally, Dr. Gish characterized the possibility that Petitioner's history of small intestinal bacterial overgrowth (SIBO) could have contributed to her AIH as very remote, because SIBO is associated

²⁶ Dr. Gish also noted that Petitioner's medical records showed no positive tests for the Epstein-Barr Virus (EBV); however, Dr. Crippin noted that Petitioner's medical records did contain evidence of a prior EBV infection at an undetermined time. Hr'g Tr. 21:19–22:4; Crippin Report at 4; Pet. Ex. 3, at 207 (positive tests for EBV Viral Capsid Antigen IGG and EBV Nuclear Antibody).

with a different autoimmune condition. *Id.* at 94:6–23. Thus, according to Dr. Gish, by process of elimination Petitioner’s MMR and Tdap vaccines causally contributed to her AIH. *Id.* at 22:23–23:19.

In addition, citing various studies including Rennick, Saliba & Elias, and Berry & Smith-Laing, Dr. Gish concluded that “[t]he sum of clinical evidence supports that a general acceptable timeframe to infer causation is when onset of symptoms occurs within one to five months of receipt of vaccination.” Gish Initial Report at 23–24; *see also* Pet. Ex. 22, McMahon et al., *Measles Vaccine Virus RNA in Children More than 100 Days After Vaccination*, 11 *Viruses* 636 (2019) (ECF No. 18-7) (reporting that measles vaccine virus RNA was detected in children more than 100 days after receiving a measles-containing vaccine). According to Dr. Gish, Petitioner’s case fit within a “general acceptable timeframe to infer causation” because Petitioner’s testing showed elevated liver enzymes 68 days post-vaccination and her AIH diagnosis was confirmed five months post-vaccination. Gish Initial Report at 24; *see also* Gish Rebuttal Report at 9–11.

In sum, Dr. Gish’s “elevator pitch” of Petitioner’s case was that the vaccine administration; the timing of her symptom onset, within 10 weeks of vaccine administration; her laboratory tests, which indicated fluctuating liver enzyme levels in 2018 through 2019; and her liver biopsy, which was consistent with recent AIH onset, taken together, indicated that the MMR and Tdap vaccines more likely than not caused her AIH. Hr’g Tr. at 70:6–77:1, 81:25–82:9. While Dr. Gish testified that AIH “needs an environmental trigger,” he acknowledged that Petitioner’s AIH could have been idiopathic (i.e., had no identifiable cause), and noted that he only identifies a trigger in approximately half of his AIH cases. *Id.* at 52:9–15, 95:6–22.

B. Respondent's Experts

1. Dr. Jeffrey Crippin

Respondent's Expert, Dr. Jeffrey Crippin is the Marilyn Bornefield Chair in Gastrointestinal Research and Treatment, Professor of Medicine, Department of Medicine, Division of Gastroenterology at the Washington University in St. Louis School of Medicine. Crippin Report at 1. He also serves as the Vice Chair for Clinical Programs for the Department of Medicine. *Id.* Dr. Crippin concluded that Petitioner's diagnosis of autoimmune hepatitis was reasonable, but challenged Dr. Gish's conclusion that Petitioner's Tdap and MMR vaccines led to her AIH diagnosis. *Id.* at 3; Hr'g Tr. at 125:9–130:12.

Dr. Crippin asserted that Dr. Gish failed to acknowledge the other factors in Petitioner's medical history that could also cause AIH, including: (1) evidence that Petitioner previously (but at an undeterminable time) had an Epstein-Barr Virus; (2) that Petitioner could have had other potential viral infections transmitted by the bug bites during her travels (although her records did not include evidence of other infections); (3) that Petitioner took an anti-malarial medication, which is associated with AIH; (4) Petitioner's history of SIBO; (5) Petitioner's travel to foreign countries,²⁷ which could have increased her exposure to new bacteria; (6) that Petitioner regularly took over-the-counter supplements, including mushroom extracts; and (7) that Petitioner was using an IUD. Hr'g Tr. at 125:9–130:12, 135:13–16. In sum, Dr. Crippin posited that “there are a number of factors” that could have led to Petitioner's AIH diagnosis, and “the interaction of multiple factors, both genetic and environmental” could have caused her AIH. Crippin Report at 4–6.²⁸

²⁷ Petitioner traveled to 21 countries within a four-year timeframe. Pet. Ex. 11 ¶ 16.

²⁸ Dr. Gish conceded that “based on the case report and biological understanding of AIH pathology that other causal agents could be plausible.” Gish Rebuttal Report at 4.

Dr. Crippin cited numerous case reports and studies in support of the potential alternative causes of Petitioner's AIH. See Resp. Ex. A, Tab 4, Haoran Peng et al., *Autoimmune Hepatitis Following Epstein-Barr Virus Infection: A Diagnostic Dilemma*, British Med. J. (2019) (ECF No. 25-4) (case report concluding that AIH has a potential association with Epstein-Barr Virus infection); Resp. Ex. A, Tab 5, Claudia Caglioti et al., *Chikungunya Virus Infection: An Overview*, 36 New Microbiologica 211 (2013) (ECF No. 25-5) (article describing mosquito-transmitted Chikungunya virus infection); Resp. Ex. A, Tab 6, MK Huntington et al., *Emerging Vector-Borne Diseases*, 7 Am. Fam. Physician 551 (2016) (ECF No. 25-6) (article describing mosquito-borne viral infections such as West Nile Virus, Chikungunya, Zika, Ehrlichiosis, Rickettsial, Dengue, Lyme Disease, Malaria); Resp. Ex. A, Tab 7, A. Arturo Leis et al., *West Nile Virus Infection and Myasthenia Gravis*, 49 Muscle & Nerve 26 (2013) (ECF No. 25-7) (retrospective case series associating the West Nile Virus with Myasthenia gravis, an autoimmune disease); Resp. Ex. A, Tab 8, P. Karagianni et al., *West Nile Virus Infection Triggering Autoimmune Encephalitis: Pathophysiological and Therapeutic Implications*, 207 Clinical Immunology 97 (2019) (ECF No. 25-8) (case report associating West Nile Virus with autoimmune encephalitis); Resp. Ex. A, Tab 9, Amir Tanay, *Chikungunya Virus and Autoimmunity*, 29 Current Op. in Rheumatology 389 (2017) (ECF No. 25-9) (Tanay) (study associating Chikungunya virus with inflammation and immune activation "not unlike those seen in rheumatoid arthritis," an autoimmune disease); Beretta-Piccoli (case report associating anti-malarial drug Malarone (Atovaquone-Proguanil) with AIH²⁹); Resp.

²⁹ As Dr. Crippin explains in his Report, the case described in Beretta-Piccoli differed from Petitioner's because the patient in the case report took Malarone in conjunction with azithromycin, which caused jaundice and acute hepatitis, and her symptoms resolved in two weeks. Approximately a year later, the patient took Malarone again and developed AIH. See Crippin Report at 5. In other words, the patient developed AIH in response to re-administration of Malarone. However, the case report was similar to Petitioner's case because the patient in the case report traveled to Tanzania and "need[ed] prolonged therapy with corticosteroids/prednisone." *Id.*

Ex. A, Tab 11, Yusuke Kinashi & Koji Hase, *Partners in Leaky Gut Syndrome: Intestinal Dysbiosis and Autoimmunity*, 12 *Frontiers in Immunology* (2021) (ECF No. 25-11) (study discussing the connection between intestinal dysbiosis, leaky gut syndrome and autoimmune disease); Resp. Ex. A, Tab 12, Muhammed Yuksel et al., *A Novel “Humanized Mouse” Model for Autoimmune Hepatitis and the Association of Gut Microbiota With Liver Inflammation*, 62 *Hepatology* 1536 (2015) (ECF No. 25-12) (animal study finding that significant gut microbiota of mice with AIH was significantly different from mice without AIH³⁰); Resp. Ex. A, Tab 13, Rui Lin et al., *Abnormal Intestinal Permeability and Microbiota in Patients with Autoimmune Hepatitis*, 8 *Int’l J. Clinical & Experimental Pathology* 5153 (2015) (ECF No. 25-13) (study associating leaky gut and microbiome imbalance with AIH); Resp. Ex. A, Tab 14, Francesca Motta et al., *Mushrooms and Immunity*, 117 *J. Autoimmunity* (2021) (ECF No. 25-14) (review of studies discussing biochemical changes induced by different mushroom compounds); Resp. Ex. A, Tab 15, Muthukumaran Jayachandran et al., *A Critical Review on the Impacts of β -Glucans on Gut Microbiota and Human Health*, 61 *J. Nutritional Biochemistry* 101 (2018) (ECF No. 25-15) (review summarizing *in vitro*, *in vivo*, and clinical studies on β -glucans and bacteria in gut microbiome); Resp. Ex. A, Tab 16, Mohamad O. Khawandanah et al., *Autoimmune Hemolytic Anemia and Thrombocytopenia Attributed to an Intrauterine Contraceptive Device*, 55 *Transfusion* 657 (2015) (ECF No. 25-16) (case report associating an IUD with Evans Syndrome manifested by autoimmune hemolytic anemia and thrombocytopenia).

³⁰ Dr. Crippin noted in his Report that “a causative relationship was thought to deserve further investigation.” Crippin Report at 5.

In addition, Dr. Crippin noted that AIH is often idiopathic, and that no case reports in published medical literature support that either the MMR or Tdap vaccines—independently or together—“trigger or are associated with [AIH].” Crippin Report at 3–4, 6; Hr’g Tr. at 130:3–12, 133:7–16, 137:3–13, 140:22–141:5. He explained that the MMR vaccine has been associated with idiopathic/immune thrombocytopenia and arthritis in children, and joint pain and inflammation, but it is “is not clear” whether that is RA. Crippin Rep. at 6 (citing Resp. Ex. A, Tab 17, U Nieminen, et al., *Acute Thrombocytopenic Purpura Following Measles, Mumps, and Rubella Vaccination. A Report on 23 Patients*, 82 *Acta Paediatr* 267 (1993) (ECF No. 25-17)); Resp. Ex. A, Tab 18, C M Benjamin et al., *Joint and Limb Symptoms in Children After Immunisation with Measles, Mumps, and Rubella Vaccine*, 304 *British Med. J.* 1075 (1992) (ECF No. 25-18)). Further, case reports associated the Tdap vaccine with joint and muscle pain, a skin rash, and type 1 diabetes. Crippin Rep. at 6 (citing Resp. Ex. A, Tab 19, N. Ruhrman-Shahar et al., *Autoimmune Reaction After Anti-Tetanus Vaccination—Description of Four Cases and Review of the Literature*, 65 *Immunological Rsch.* 157 (2017) (ECF No. 25-19)).

In his report and at the Entitlement Hearing, Dr. Crippin distinguished Petitioner’s case from the Saliba & Elias study. Crippin Report at 4 (citing Saliba & Elias). Dr. Crippin noted several key differences between Petitioner’s case and the patient in Saliba & Elias, including that the patient in Saliba & Elias suffered from *acute* hepatitis as opposed to AIH, and no liver biopsy was performed; the patient in Saliba & Elias had recently given birth, and pregnancy can cause immune suppression; and the patient in Saliba & Elias developed symptoms of her liver condition within two weeks after vaccination, whereas Petitioner’s symptom onset occurred around six to eight weeks. Hr’g Tr. 130:22–132:21.

2. Dr. Andrew MacGinnitie

Respondent's Second Expert, Dr. Andrew MacGinnitie is an Attending Physician as well as the Clinical Chief for the Division of Immunology at Boston Children's Hospital overseeing clinical operations for Allergy/Immunology, Rheumatology and Dermatology, and is also an Associate Professor of Pediatrics at Harvard Medical School. MacGinnitie Report at 1. In his view, Petitioner's AIH was "unrelated to" her MMR and Tdap vaccinations, and Dr. Gish's theory was unreliable. *Id.* at 12; Hr'g Tr. at 148:4–10.

Dr. MacGinnitie asserted that the case reports cited by Dr. Gish failed to establish causality between MMR, Tdap, and AIH. Hr'g Tr. at 149:17–156:18; MacGinnitie Report at 6–7. Dr. MacGinnitie noted that AIH can occur after vaccination "by coincidence." MacGinnitie Report at 6. He further asserts that, given the widespread nature of vaccination and because vaccines are recommend for patients with AIH, the cases Dr. Gish cited were "likely coincidental." *Id.* at 6–7, 11; Hr'g Tr. at 155:11–20. Further, Dr. MacGinnitie opined that case reports in general are "unable to really provide evidence of causation." Hr'g Tr. at 150:2–3.

Further, Dr. MacGinnitie challenged Dr. Gish's molecular mimicry theory, because Dr. Gish had not identified a potential homology between the MMR and Tdap vaccines and liver antigens. MacGinnitie Report at 7 (citing Resp. Ex. C, Tab 2, Institute of Medicine, *Committee to Review Adverse Effects of Vaccines: Evidence and Causality* (Kathleen Stratton, et al., eds., 2012) (ECF No. 26-2))³¹; Hr'g Tr. at 156:4–18, 157:22–158:7. Dr. MacGinnitie also contended that Dr. Gish had failed to explain how either vaccine otherwise could have caused Petitioner's AIH. MacGinnitie Report at 7–11. Dr. MacGinnitie further contends that the bystander activation

³¹ This is a different portion of the same IOM publication cited by Petitioner. *See* Pet. Ex. 45, IOM.

theory, that Dr. Gish opined would cause the relevant cross-reaction, “is not a commonly accepted mechanism of [AIH].” Hr’g Tr. at 160:11–20.

With respect to Dr. Gish’s theories relating to the measles virus, Dr. MacGinnitie countered that the “[m]easles virus causes profound suppression which is not seen with vaccination.” MacGinnitie Report at 8–9 (emphasis omitted); Hr’g Tr. at 162:6–20. Although Dr. MacGinnitie agreed that the wild measles virus causes immunosuppression, he took issue with Dr. Gish’s position that the measles *vaccine* causes immune suppression. MacGinnitie Report at 8. Contrary to Dr. Gish’s assertion that “it is well understood” the measles vaccine induces temporary immunosuppression, Dr. MacGinnitie opined that “more contemporary literature stress the need for measles vaccination to *prevent* the immunosuppression triggered by wild-type infection.” *Id.* (emphasis added). Dr. MacGinnitie noted that the Nanan and Munyer articles on which Dr. Gish relied did not provide “clinically meaningful” evidence and were outdated, having been published in 1999 and 1975, respectively. *Id.* Instead, Dr. MacGinnitie cited a 2017 study which stated that measles vaccination prevents measles infection, thereby “prevent[ing] measles-associated short- and long-term immunomodulating effects.” *Id.* (citing Resp. Ex. C, Tab 3, Michael J. Mina, *Measles, Immune Suppression and Vaccination: Direct and Indirect Nonspecific Vaccine Benefits*, 74 J. Infection S10 (2017) (ECF No. 26-3)). The Mina study also posited generally that the MMR vaccine can protect against other diseases by stimulating the immune system. *Id.*; *see also* Resp. Ex. C, Tab 4, *Measles*, Committee on Infectious Disease, Red Book (2021) (ECF No. 26-4). Dr. MacGinnitie also noted the apparent contradiction of Dr. Gish’s theory that measles infections and potentially also measles vaccinations lead to autoimmune *suppression*. MacGinnitie Report at 8–9; Hr’g Tr. at 162:15–20. Dr. MacGinnitie concluded that since AIH is an autoimmune condition—an overactivation of the immune system—any immunosuppression triggered by MMR

would likely be “*protective* against development of AIH.” MacGinnitie Report at 7–8; Hr’g Tr. at 162:15–20.

Further, Dr. MacGinnitie contended that it was unlikely that the activation of Petitioner’s memory T cells from her prior vaccines would cause autoimmune disease. Hr’g Tr. at 189:25–191:7. Similarly, Dr. MacGinnitie rejected Dr. Gish’s Th17 theory, taking issue with his interpretation of the Antunes study. *Id.* at 170:14–173:24; MacGinnitie Report at 9–10. Dr. MacGinnitie also asserted that Dr. Gish failed to provide any evidence that Th17 disease would cause AIH; rather, the studies he cites simply listed Th17 as “one of many potential pathways toward development of AIH” and as Th17 cells are “found in healthy humans,” his Th17 theory was not a sufficient explanation for development of autoimmunity. MacGinnitie Report at 9–10 (citing Resp. Ex. C, Tab 10, S.A. Khader et al., *Th17 Cells at the Crossroads of Innate and Adaptive Immunity Against Infectious Diseases at the Mucosa*, 2 *Mucosal Immunology* 403 (Sept. 2009) (ECF No. 26-10)).³²

Dr. MacGinnitie also took issue with Dr. Gish’s position that the timing of the onset of Petitioner’s AIH supported her causal theory. Dr. MacGinnitie contends that Dr. Gish failed to support his assertion that symptom onset within one to five months of vaccination is generally acceptable to infer causation. MacGinnitie Report at 11; Hr’g Tr. at 173:25–174:25. Further, Dr. MacGinnitie asserted that onset of autoimmune diseases tends to occur weeks—not months—after infection or immunization. MacGinnitie Report at 11 (first citing Resp. Ex. C, Tab 16, Jonathon R. Carapetis, *Acute Rheumatic Fever and Rheumatic Heart Disease*, 2 *Nature Reviews: Disease Primers* (Jan. 2016) (ECF No. 26-16); and then citing Resp. Ex. C, Tab 17, Shaheen Sombans et

³² Dr. MacGinnitie also rejected Dr. Gish’s aluminum adjuvant theory, which Dr. Gish had “set[] aside” at the Entitlement Hearing. *See supra* note 20.

al., *A Case Report of Acute Rheumatic Fever and a Brief Review of the Literature*, Archives of Medical Science: Atherosclerotic Diseases (2018) (ECF No. 26-17)). Analogizing to a study he cited involving Guillain-Barré syndrome, Dr. MacGinnitie testified that he considers six weeks to be “the outer limit of what [he] would expect for a vaccine-triggered autoimmune injury.” Hr’g Tr. at 175:11–176:8 (discussing Resp. Ex. C, Tab 19, Thomas J. Safranek et al., *Reassessment of the Association between Guillain-Barre Syndrome and Receipt of Swine Influenza Vaccine in 1976-1977: Results of a Two-State Study*, 133 Am. J. Epidemiology (1991) (ECF No. 26-19)). To that end, Dr. MacGinnitie pointed out that in the case reports Dr. Gish cited, the onset of AIH occurred within one month (and often sooner) of the relevant vaccination. *Id.* at 173:25–174:25

Dr. MacGinnitie also opined, that vaccines are generally only “a minor immune stimulus.” MacGinnitie Report at 10–11. He noted that vaccines are recommended for patients with AIH. *Id.* at 11. Such a recommendation, he contends, would be illogical if vaccines “were generally believed to play a role in triggering AIH.” *Id.* He also noted that none of Petitioner’s doctors—in particular the hepatologist who treated her AIH—associated her AIH with her MMR and Tdap vaccines. *Id.* at 12.

III. The Decision

On March 7, 2024, Chief Special Master Brian H. Corcoran held an Entitlement Hearing, in which Drs. Gish, Crippin, and MacGinnitie testified. *See generally* Hr’g Tr. On August 29, 2024, the Chief Special Master held that Petitioner was not entitled to compensation, because she had failed to “preponderantly establish [*Althen*] prongs one and two.” *Exum*, 2024 WL 4291116, at *13. With respect to prong one, the Chief Special Master held that Petitioner had not preponderantly established that the MMR and Tdap vaccines can cause AIH. *Id.* First, the Chief Special Master noted several issues with Dr. Gish’s theory, including that Dr. Gish had opined on

immunological matters, when his expertise was hepatology. *Id.* Specifically, the Chief Special Master reasoned that Dr. Gish’s theory relied on (1) “a false equivalence between the impact of the measles wild virus and vaccine,”³³ (2) the “contradictory” idea that the same environmental trigger can cause both immune suppression and immune overactivation; (3) speculations about the Tdap vaccine, and (4) the “barely-plausible contention” that administering MMR and Tdap together increases risk of adverse effects. *Id.* Second, the Decision stated that Dr. Gish “could not imbue these contentions with reliability by drawing on immunologic expertise he lacks.” *Id.* Third, the Chief Special Master held that Dr. Gish failed to demonstrate “that the vaccines at issue could likely promote an autoimmune response resulting in AIH.” *Id.* He rejected Dr. Gish’s molecular mimicry theory because Dr. Gish failed to establish a homology between the relevant vaccine antigens and liver cells. *Id.* at *13–14. Fourth, the Chief Special Master also noted that case reports—on which Dr. Gish’s theory relied—generally are “known to be weak evidence of causation,” and only a few of the case reports cited by Dr. Gish involved a relevant vaccine. *Id.* at *14.

With respect to *Althen* prong two, the Chief Special Master concluded that nothing other than the timing of Petitioner’s symptom onset and the type of symptoms she experienced supported the conclusion that Petitioner’s vaccines caused her AIH. *Id.* The Chief Special Master reasoned that this evidence is insufficient to demonstrate causation because the Federal Circuit has held that temporal proximity cannot establish causation between a vaccine and an injury. *Id.* (citing *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Chief Special Master further reasoned that the multiple alternative causes identified by Dr. Crippin, which were

³³ Notably, Dr. Gish testified that a live vaccine infection is different from a wild-type infection because “the immune response [from a live vaccine infection] is initially less.” Hr’g Tr. at 36:19–23.

acknowledged by—but not all “persuasively limit[ed] or exclude[d]” by—Dr. Gish, undermined Petitioner’s theory that the vaccines caused her AIH. *Id.* Put another way, the Chief Special Master held that there were “too many other possible explanations to find the vaccines were a substantial factor” for Petitioner to succeed on *Althen* prong two. *Id.*

The Chief Special Master did not analyze the sufficiency of Petitioner’s evidence regarding prong three, because, under Federal Circuit precedent, “failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim’s dismissal.” *Id.* at *13 (citing *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 F. App’x 976, 980 (Fed. Cir. 2014)).

IV. Petitioner’s Motion for Review

On September 30, 2024, Petitioner filed her Motion for Review, urging this Court to set aside the Decision and grant entitlement, or, in the alternative, to remand this matter to the Chief Special Master “with direction on applying the proper legal standard.” Mot. at 24. Respondent filed its Response to Petitioner’s Motion for Review on October 30, 2024, and this Court conducted Oral Argument on December 19, 2024. *See generally* Resp.; OA Tr.

STANDARD OF REVIEW

Pursuant to 42 U.S.C. § 300aa-12(e)(2), when ruling on a Motion for Review, this Court may: “(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 to the special master for further action in accordance with the court’s direction.” 42 U.S.C. § 300aa-12(e)(2). This Court reviews a special master’s factual determinations under the arbitrary and

capricious standard; legal questions under the “not in accordance with law” standard; and any discretionary rulings under the abuse of discretion standard. *Munn v. Sec’y of Health and Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The scope of this Court’s review is deferential. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). This Court must uphold factual findings of a special master so long as they are “based on evidence in the record that [is] not wholly implausible.” *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe*, 219 F.3d at 1363). Particularly in cases in which medical evidence of causation is in dispute, this Court will not “second guess” a special master’s factual determinations. *Id.* This Court also must “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.” *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). If a special master “‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,’ then reversible error is ‘extremely difficult to demonstrate.’” *Milik v. Sec’y of Health & Hum. Servs.*, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting *Hines v. Sec’y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

A special master’s findings of fact also must be “supported by substantial evidence.” *Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton v. Sec’y of Health & Hum. Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996), *on remand from Shalala v. Whitecotton*, 514 U.S. 268 (1995)). However, a “finder of fact generally is not required to itemize every piece of evidence on an issue and adopt or reject it.” *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 540 (2011) (citations omitted). Indeed, even when a special master makes

no express reference to certain evidence, the Court nonetheless must presume that he considered that evidence. *Hazlehurst v. Sec’y of Health & Hum. Servs.*, 604 F.3d 1343, 1352 (Fed. Cir. 2010).

Despite this, a special master must clearly articulate its reasons for its conclusions. *See Hines*, 940 F.2d at 1528; *Stewart-Robinson v. Sec’y of Health & Hum. Servs.*, 173 Fed. Cl. 567, 576 (2024) (“[S]pecial masters are required to . . . articulate a rational basis for their decisions.”); *Doles v. Sec’y of Health & Hum. Servs.*, 163 Fed. Cl. 726 (2023), *reconsideration denied*, 163 Fed. Cl. 616, 731 (2023) (stating that special masters are “obligate[d]” to articulate the reasons for their decisions); *Olson v. Sec’y of Health & Hum. Servs.*, 135 Fed. Cl. 670, 675 (2017), *aff’d*, 758 F. App’x 919 (Fed. Cir. 2018) (“When evaluating a motion for review, it is the Court’s task to determine whether the Special Master . . . provided a reasoned explanation in his or her decision.”). A failure to do so may necessitate remand to the special master to clarify his or her rationale. *M.R. v. United States*, No. 16-1024V, 2023 WL 4930490 at *7 (Fed. Cl. Aug. 2, 2023) (finding “that the Chief Special Master’s Decision and record lack the clarity necessary for a thorough review of the Decision’s legal and factual bases” and remanding for further proceedings).

DISCUSSION

The Vaccine Act created the National Vaccine Injury Compensation Program to compensate parties presumed or proven to be injured by certain vaccines. 42 U.S.C. § 300aa–10 *et seq.* The Program was designed to “lessen the number of lawsuits against manufacturers and provide[] relative certainty and generosity of compensation awards in order to satisfy petitioners in a fair, expeditious, and generous manner.” *Cloer v. Sec’y of Health & Hum. Servs.*, 654 F.3d 1322, 1326 (Fed. Cir. 2011) (en banc) (internal citations and quotation marks omitted) (alteration in original); *see also K.G. v. Sec’y of Health & Hum. Servs.*, 951 F.3d 1374, 1380 (Fed. Cir. 2020)

(citing *Cloer*, 654 F.3d at 1325) (“The Vaccine Act is a pro-claimant regime meant to allow injured individuals a fair and fast path to compensation . . .”).

The Vaccine Act grants jurisdiction to the Office of Special Masters “over proceedings to determine if a petitioner . . . is entitled to compensation under the Program” for vaccine-related injuries or deaths and the amount of compensation owed. 42 U.S.C. § 300aa–12(a). Petitions alleging injuries are initially reviewed by a Special Master, who issues a decision on the petition. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (citing 42 U.S.C. §§ 300aa–11(a)(1), 12(d)(3)).

Section 300aa–12(e) of the Vaccine Act grants the United States Court of Federal Claims authority to review decisions of the Special Master upon a party’s motion. 42 U.S.C. § 300aa–12(e)(1); *see* Vaccine Rule 23. In reviewing a Special Master’s decision, this Court may

set aside any findings of fact or conclusion of law . . . found to 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 . . . remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2)(B)–(C); *accord* Vaccine Rule 27; *see Munn*, 970 F.2d at 867. Each standard of review referenced in the statute “applies to a different aspect of the judgment” and involves a different degree of deference given to the Special Master’s determinations. *Munn*, 970 F.2d at 870 n.10. “Fact findings are reviewed . . . 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.” *Id.*; *accord Markovich v. Sec’y of Health & Hum. Servs.*, 477 F.3d 1353, 1356 (Fed. Cir. 2007).

Petitioner may demonstrate eligibility for compensation in two ways: (1) by demonstrating that she received a vaccine listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within the statutorily prescribed time period; or (2) by demonstrating that the vaccine was the cause-in-fact of her condition where the injury is not on the Vaccine Injury

Table (an off-table injury). *Milik*, 822 F.3d at 1379; *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006) (citing *Munn*, 970 F.2d at 865); 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1). The parties agree here that Petitioner’s claims concern alleged off-table injuries. *See* Resp. at 10; Petitioner’s Post-Hearing Brief (ECF No. 73) at 1–2. Regarding off-table injuries, Petitioner must prove by a preponderance of the evidence that her vaccinations were “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (2006) (petitioner must prove by preponderant evidence “both that her vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination”). However, a petitioner need not prove that the vaccine was the “sole or predominant cause of her injury.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008) (citing *Walther v. Sec’y of Health & Hum. Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007)).

The Federal Circuit has distilled this actual causation inquiry into a three-part test. *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Petitioner must provide:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

Id.; *see Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1354–55 (Fed. Cir. 2019) (quoting *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321–22 (Fed. Cir. 2010)). In this context, the preponderance standard “simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.” *Moberly*, 592 F.3d at 1322 n.2 (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602, 622

(1993)). A petitioner must prove each *Althen* prong by a preponderance of the evidence; failure to establish any one prong is dispositive. *Boatmon*, 941 F.3d at 1355; *Oliver v. Sec’y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018); *Olson*, 758 F. App’x at 922; *Dobrydnev*, 566 F. App’x at 980.

At prong one, Petitioner must establish a “‘reputable medical or scientific explanation’ for [her] theory.” *Boatmon*, 941 F.3d at 1359 (quoting *Moberly*, 592 F.3d at 1322). The theory must be “sound and reliable,” though it “does not require medical or scientific certainty.” *Id.* (quoting *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). At prong two, Petitioner must demonstrate that “the vaccine caused [her] injury.” *Capizzano*, 440 F.3d at 1326 (citing 42 U.S.C. §§ 300aa–11(c)(1)–13(a)(1)). At prong three, Petitioner must demonstrate a temporal relationship between the vaccination and her injury. *See Pafford*, 451 F.3d at 1358; *see also id.* (citing *Capizzano*, 440 F.3d at 1326) (“Evidence demonstrating petitioner’s injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the ‘but-for’ prong of the causation analysis.”). Evidence used to satisfy one prong may be used to satisfy the requirements of another *Althen* prong. *Capizzano*, 440 F.3d at 1326.

“Once a petitioner establishes a prima facie case, the government then bears the burden of establishing alternative causation by a preponderance of the evidence.” *Cedillo*, 617 F.3d at 1335 (citing *Walther*, 485 F.3d at 1151). After such a burden shift, the respondent must demonstrate by a preponderance of the evidence that the injury described in the petition was caused by factors unrelated to the administration of the vaccine described in the petition. 42 U.S.C. § 300aa–13(a)(1)(B); *Althen*, 418 F.3d at 1278 (internal citation omitted). However, if Petitioner fails to establish a *prima facie* case, the burden does not shift to Respondent. *See Doe*, 601 F.3d at 1358.

Regardless of whether the burden shifts, the special master may consider evidence of alternative causation presented by the respondent in determining whether the petitioner has established a *prima facie* case, as the special master is to consider the record as a whole in determining causation where multiple possible sources of injury may exist. *Stone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“Our decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a *prima facie* showing has been made that the vaccine was a substantial factor in causing the injury in question.”).

“[S]pecial 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). In adjudicating a Petition, the Court of Federal Claims does “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.” *Porter*, 663 F.3d at 1249; *see also Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 17-792V, at 12 (Fed. Cl. Oct. 27, 2022) (ECF No. 79) (internal citations omitted), *aff’d*, No. 2023-1321, 2024 WL 3064398 (Fed. Cir. June 20, 2024). Additionally, this Court should refrain from “‘second guess[ing] the Special Master[’]s fact-intensive conclusions’ particularly in cases ‘in which the medical evidence of causation is in dispute.’” *Cedillo*, 617 F.3d at 1338 (second alteration in original) (quoting *Hodges v. Sec’y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). “[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 1378, 1381 (Fed. Cir. 2021) (alteration in original) (quoting *Lampe*, 219 F.3d at 1360).

In weighing the evidence, the special master has discretion to determine the relative weight of the evidence, including medical records. *Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *see Hibbard v. Sec’y of Health & Hum. Servs.*, 698 F.3d 1355, 1368 (Fed. Cir. 2012). A special master is “not required to discuss every piece of evidence or testimony in [his or] her decision,” as the special master is presumed to have considered the whole record. *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 728 (2009) (citing *Maza v. Sec’y of Health & Hum. Servs.*, 67 Fed. Cl. 36, 38 (2005)); *see Moriarty v. Sec’y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (internal citations omitted) (“We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision. However, this presumption does not apply, as in this case, where a special master indicates otherwise.”). The purpose of the Vaccine Act’s standard of proof 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 alleged link is “hitherto unproven in medicine.” *Althen*, 418 F.3d at 1280. Therefore, “close calls regarding causation are resolved in favor of injured claimants.” *Id.* (citing *Knudsen*, 35 F.3d at 549).

In the present action, Petitioner alleges an off-table injury; therefore, she must prove by a preponderance of the evidence that the MMR and Tdap vaccines caused her AIH. *Capizzano*, 440 F.3d at 1319–20; *see also* 42 U.S.C. §§ 300aa-13(a)(1), 11(c)(1)(C)(ii)(I). Petitioner contends that the Chief Special Master erred in his Decision by (i) articulating and applying an erroneous legal standard for *Althen* prong one, (ii) reaching conclusions on *Althen* prong two that were contrary to

law, and (iii) failing to analyze *Althen* prong three. In sum, Petitioner argues that the Chief Special Master committed reversible legal error with respect to each *Althen* prong.

As described more fully below, the Decision's analysis lacks the clarity, specificity, and clear rationales for its conclusions that are necessary to determine whether the Chief Special Master committed legal error. Accordingly, pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), the Court remands this action to the Chief Special Master to more thoroughly state the rationale for his rulings regarding *Althen* prongs one and two in accordance with applicable legal standards. After remand, it may be that the Chief Special Master either changes his ultimate conclusions or not; in either instance, any decision issued on remand must clearly and thoroughly state the rationale for each ruling with citation to the evidentiary and legal bases for each ruling, along with a clear statement of the legal standard being applied.

I. *Althen* Prong One

While the Decision articulated the correct legal standard for *Althen* prong one, it failed to articulate adequate rationale for the conclusions it reached. Accordingly, for the reasons stated below, the Court remands this action to the Chief Special Master to clearly articulate his *Althen* prong one analysis, stating any rationale for his conclusions and providing citations to record evidence.

A. The Decision Articulated the Correct Legal Standard for *Althen* Prong One.

At *Althen* prong one, a petitioner must demonstrate that the relevant vaccine can cause Petitioner's alleged injury. *Pafford*, 451 F.3d at 1355–56. Accordingly, to satisfy *Althen* prong one, a petitioner must provide “a medical theory causally connecting the vaccination and the injury.” *Althen*, 418 F.3d at 1278. This means that “a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” *See Trollinger v. Sec'y of*

Health & Hum. Servs., 167 Fed. Cl. 127, 136 (2023) (quoting *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010)). As noted, the Petitioner must satisfy *Althen* prong one by a preponderance of evidence. *Boatmon*, 941 F.3d at 1355. In evaluating whether a special master failed to recognize a proposed theory, the Court reviews whether Petitioner offered reliable evidence on the record to support the theory. *See Broekelschen*, 618 F.3d at 1350–51 (affirming a finding of failure at prong one where the evidence relied upon (literature review) was weak and there was little evidence in the record regarding whether the influenza vaccine could cause the asserted injury).

Petitioner argues that the Chief Special Master erred by “conflat[ing] the burden of proof linking a petitioner’s vaccine to injury – preponderant evidence – from the standard of certainty required of petitioner’s medical theory – plausibility.” Mot. at 7 (citing *LaLonde v. Sec’y of Health & Hum. Servs.*, 746 F.3d 1334, 1340 (Fed. Cir. 2014)). The parties agree, as they must, that Petitioner must prove *Althen* prong one by a preponderance of the evidence. Mot. at 8; Resp. at 12–13; *see also* 42 U.S.C. § 300aa-13(a). The crux of their dispute is what Petitioner had to demonstrate – and how she could make that showing – to meet this burden. Mot. at 7–8; Resp. at 12. Petitioner posits that “preponderantly proving a biologically plausible scientific explanation connecting the vaccinations and the injury can establish” *Althen*’s first prong. Mot. at 11.³⁴

³⁴ Petitioner takes issue with the Decision’s discussion of plausibility. Mot. at 6–8. While the Decision’s statement that “the Federal Circuit has consistently rejected the contention that [*Althen* prong one] can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*,” may be a slight overstatement, it is of no moment because the Decision clearly stated the proper legal standard for *Althen* prong one. *Exum*, 2024 WL 4291116, at *9 (citing *Kalajdzic*, 2024 WL 3064398, at *2); *Bechel*, 168 Fed. Cl. 602, 617–19 (2023). Indeed, the Decision even acknowledged that “[p]lausibility . . . in many cases may be enough to satisfy *Althen* prong one.” *Exum*, 2024 WL 4291116, at *9 (citing *Contreras v. Sec’y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017)).

Respondent contends that Petitioner must prove a reputable, sound, reliable, and persuasive theory. Resp. at 12, 19–20.

Federal Circuit precedent establishes that a petitioner must provide a reputable medical theory based on a sound and reliable medical or scientific explanation to satisfy *Althen* prong one. *Boatmon*, 941 F.3d at 1359 (first quoting *Grant*, 956 F.2d at 1148; and then quoting *Knudsen*, 35 F.3d at 548–49); *Kirby*, 997 F.3d at 1384–85. The Decision correctly articulated that standard here. Indeed, the Federal Circuit recently affirmed a different decision of the Chief Special Master in which he articulated the standard in nearly the same way. *See Kalajdzic*, 2024 WL 3064398, at *2.

Here, the Decision held that Petitioner had not “preponderantly established that it is likely that the MMR and Tdap vaccines—alone or in combination—*can cause* AIH.” *Exum*, 2024 WL 4291116, at *13. It explained that petitioners must provide a “reputable medical theory” based on a “sound and reliable medical or scientific explanation,” and noted that the theory need only be “legally probable, not medically or scientifically certain.” *Id.* at *9 (first quoting *Pafford*, 451 F.3d at 1355–56; and then quoting *Knudsen*, 35 F.3d at 548–49). These are correct statements of Federal Circuit precedent. *Boatmon*, 941 F.3d at 1359 (first quoting *Grant*, 956 F.2d at 1148; and then quoting *Knudsen*, 35 F.3d at 548–49); *Kirby*, 997 F.3d at 1384–85. Indeed, Vaccine Act petitioners must set forth some indicia of reliability to support their prong one theory. *Boatmon*, 941 F.3d at 1359–60. The standards the Chief Special Master articulated here plainly comport with that principle. Thus, the Decision articulated the proper standard at *Althen* prong one.

B. The Decision Did Not Sufficiently Articulate the Legal, Factual, and Evidentiary Rationales for its *Althen* Prong One Conclusion.

Although the Decision correctly articulated the legal standard for *Althen* prong one, Petitioner asserts that the Chief Special Master erred by incorrectly applying that standard.

Specifically, Petitioner contends that (1) the Chief Special Master’s application of the “sound and reliable” standard was legal error, and that he impermissibly required her to prove a persuasive theory; (2) the Chief Special Master erred by requiring her to “provide specific biological mechanisms”; and (3) the Chief Special Master improperly “disguise[d] the application of an improper burden” in terms of evidentiary persuasiveness and as a credibility determination. Mot. at 8–9, 13–14. Each of Petitioner’s arguments is an extension of the same contention—that the Chief Special Master held Petitioner’s *Althen* prong one theory to too high an evidentiary standard. The Court concludes that the Chief Special Master insufficiently articulated in the Decision his legal, factual, and evidentiary rationales for his conclusions related to *Althen* prong one, and accordingly, the action must be remanded.

The Chief Special Master’s prong one analysis involved two steps. *First*, he identified numerous weaknesses in the logical underpinnings of Dr. Gish’s theories, made factual findings based on those identified weaknesses, and concluded that Dr. Gish’s testimony alone could not “imbue” any of the missing pieces with credibility, as he is not an immunologist. *Exum*, 2024 WL 4291116, at *13–14. *Second*, the Chief Special Master found Petitioner’s case report evidence to be only minimally probative, due to the stated weakness of case reports as evidence generally and because only a few of the case reports in the record “involved a relevant vaccine.” *Id.* at *14. As explained further below, because the Chief Special Master’s analysis did not adequately engage with the medical literature and appeared to reject the case report evidence out of hand, it is unclear whether the Chief Special Master properly applied the proper legal standard—*i.e.*, evaluated the medical literature “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009).

The Chief Special Master’s analysis did not directly engage with specific items of medical literature filed in this case, other than one passing reference to Saliba & Elias.³⁵ *See Exum*, 2024 WL 4291116, at *13–15. For example, the Chief Special Master first found that “[Dr. Gish’s] points about the immune-suppressive character of the MMR vaccine . . . relied on a false equivalence between the impact of the measles wild virus and vaccine.” *Id.* at *13. However, his analysis does not provide a rationale for rejecting the Nanan and Munyer articles (two items of literature Dr. Gish cited in support of this theory); the Decision’s analysis merely asserts its conclusion on the basis that “this kind of argument has been rejected in the Program before.”³⁶ *Id.* at n.6. While it is not legal error for a special master to review medical literature and conclude that it does not support a petitioner’s theory, the special master should “provide[] logical reasoning for finding certain articles unreliable.” *K.L. v. Sec’y of Health & Hum. Servs.*, 134 Fed. Cl. 579, 607 (2017) (citing *Cedillo*, 617 F.3d at 1345–46) (“The Federal Circuit has found that it is not error for a Special Master to consider the medical literature offered by an expert witness . . . and after review find it does not support the petitioner’s theory of causation, so long as the Special Master

³⁵ Rather, the Decision describes the medical literature only in the context of summarizing of the hearing witnesses’ testimony. *See Exum*, 2024 WL 4291116 at *3–8.

³⁶ The Decision references this literature, but only in the portion of the Decision summarizing hearing witnesses’ testimony. *Exum*, 2024 WL 4291116 at *4, *7. Specifically, that summary describes how the Nanan and Munyer articles supported Dr. Gish’s theory. *Id.* at *4. The Decision also references Dr. MacGinnitie’s testimony that the Nanan and Munyer articles were “lacking in clinical value or [] outdated,” and cites the more recent medical literature Dr. MacGinnitie cited supporting that the distinction between the wild-type and vaccine measles infections is a meaningful one. *Id.* at *7. However, the Decision’s analysis section lacks any discussion of the rationale for crediting Dr. MacGinnitie’s testimony over Dr. Gish’s based on the merits of the relevant literature (including the Nanan, Munyer, and Mina articles, and the excerpt of the Red Book). To the extent the Chief Special Master is adopting Dr. MacGinnitie’s rebuttal of the Nanan and Munyer articles as his own, he should make that clear in his decision, and articulate his rationale for doing so.

provides logical reasoning for finding certain articles unreliable.”). Given the lack of any real discussion in the Decision regarding which items of medical literature the Chief Special Master found more persuasive and why, the legal standard he applied to come to his conclusion is unclear.³⁷ Indeed, while the Decision concluded that Dr. Gish “made assumptions about the impact of the Tdap vaccine . . . that rely more on supposition than independent evidence,” the Decision’s analysis did not address, for example, the Antunes article cited in support of Dr. Gish’s contentions about the Tdap vaccine.³⁸ Further, while the Chief Special Master’s conclusions were largely consistent with Dr. MacGinnitie’s testimony, the extent to which the Chief Special Master credited Dr. MacGinnitie’s testimony or why he did so was not clear on the face of the Decision.³⁹ *See Exum*, 2024 WL 4291116, at *13–14. Not only was the Decision’s analysis ambiguous as to whether it was wholly crediting Dr. MacGinnitie’s testimony, insofar as the Chief Special Master

³⁷ Additionally, in her Motion, Petitioner cites two items of medical literature that the Decision does not directly address—Rennick and McMahon. The Court recognizes that a special master need not address every piece of medical literature a petitioner files or references. *Hazlehurst*, 604 F.3d at 1352. However, under these particular facts, failure to mention apparently relevant studies adds to the lack of clarity regarding the standard under which the Chief Special Master evaluated the evidence before him.

³⁸ Like the Nanan and Munyer articles, the Decision references the Antunes article only in its discussion of the Hearing Witnesses’ testimony, and the Chief Special Master’s finding is consistent with Dr. MacGinnitie’s testimony criticizing the article and doubting its relevance to Petitioner. *Exum*, 2024 WL 4291116, at *7. To the extent that the Chief Special Master intends to adopt Dr. MacGinnitie’s position regarding this aspect of Dr. Gish’s theory on remand, the Decision must make that clear and provide a rational basis for doing so.

³⁹ Specifically, the Decision only directly credits Dr. MacGinnitie’s testimony with respect to two of the Chief Special Master’s factual findings. *Exum*, 2024 WL 4291116, at *13 (“In fact, *as Dr. MacGinnitie noted*, the measles vaccine’s impact is to make immune suppression less likely—and there is a contradictory quality to arguing that immune suppression would cause a disease reaction that occurs due to an uncontrolled immune response.”) (emphasis added); *id.* at *14 (“Dr. Gish has not made this showing [of a specific homology]—which, *as Dr. MacGinnitie noted*, is by itself not necessarily sufficient evidence to conclude an autoimmune process linked to vaccination has been established.”) (emphasis added).

was doing so, the Decision’s analysis section failed to sufficiently engage with the evidence in the record to explain why.

The Chief Special Master’s rejection of case report evidence adds to the lack of clarity regarding the legal standard he applied. It is well-established that a special master cannot “requir[e] conclusive evidence in the medical literature” connecting the relevant vaccine and the relevant injury. *Andreu*, 569 F.3d at 1378. While case reports “do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value . . . the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight.” *Echols v. Sec’y of Health & Hum. Servs.*, 165 Fed. Cl. 9, 17–18 (2023) (quoting *Paluck v. Sec’y of Health & Hum. Servs.*, 104 Fed. Cl. 457, 475 (2012), *aff’d*, 786 F.3d 1373 (Fed. Cir. 2015)). The Decision correctly noted only a few of the case reports cited by Petitioner involved a relevant vaccine. *Exum*, 2024 WL 4291116, at *14. However, other than brushing them aside as generally weak evidence of causation, the Decision’s analysis did not address the few case reports that do involve a relevant vaccine. *Id.* at *13–14. Indeed, the Decision could be interpreted as rejecting the case reports cited by Petitioner out of hand. *See id.* at *13 (finding that Dr. Gish’s contention “that both vaccines administered at the same time raise the risk of an aberrant response” was “barely-plausible” and “lack[ing] corroboration” in the record, notwithstanding filed case reports describing patients who developed AIH after receiving multiple vaccines concomitantly). Particularly considering Petitioner’s argument that these case reports are relevant because they involve either relevant vaccine antigens or patients who received multiple vaccinations concomitantly, the Chief Special Master must explain his rationale fully to the extent he continues

to find these case reports unpersuasive or distinguishable after reevaluation on remand.⁴⁰ *See* Mot. at 10, 21; *Exum*, 2024 WL 4291116, at *6–8.

Accordingly, the Court concludes that these aspects of the Chief Special Master’s analysis warrant remand as “the *Althen* prong one standard required him to evaluate the overall reputability, soundness, and reliability of the posited medical or scientific theory,” and it is unclear on the face of the Decision how the Chief Special Master applied that legal standard here.⁴¹ *Bechel*, 168 Fed. Cl. at 620. The Court recognizes that the Chief Special Master need not address every piece of medical literature a petitioner files or references, and “has discretion to determine the relative weight to give to evidence in the record, *provided he or she offers a rational basis.*” *K.L.*, 134 Fed. Cl. at 608 (emphasis added) (citing *Andreu*, 569 F.3d at 1379); *Hazlehurst*, 604 F.3d at 1352. The Court further does not intend to second-guess credibility determinations where the Decision articulates a rational basis for such determinations. *See K.L.*, 134 Fed. Cl. at 608. However, the Chief Special Master must provide a rationale for crediting or discrediting the medical literature filed in this case; such a rationale supporting any conclusions here is necessary to confirm that the

⁴⁰ The Court does not make any finding as to the strength of the case report evidence, particularly because the Court does “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.” *Porter*, 663 F.3d at 1249; *Echols*, 165 Fed. Cl. at 18; *but see Patton v. Sec’y of Health & Hum. Servs.*, 157 Fed. Cl. 159, 169 (2021) (concluding that a theory was sound and reliable where it was supported by “the expert opinion of an experienced neurologist, four case reports, three medical articles, and the diagnoses of four treating physicians”). Rather, the Court finds that it is necessary for the Chief Special Master to discuss the merits of the medical literature, or lack thereof, to ensure application of the proper legal standard.

⁴¹ While the Decision acknowledges that “[p]etitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory,” and states that the Chief Special Master “reviewed all of the medical literature submitted,” those statements do not resolve any lack of clarity with respect to how he evaluated the medical literature filed in this case, and any reasons for crediting certain articles over others. *Exum*, 2024 WL 4291116, at *9 (citing *Andreu*, 569 F.3d at 1378–79), *12.

prong one legal standard was correctly applied. In sum, the Decision did not sufficiently articulate the legal, factual, and evidentiary bases of its conclusion that Petitioner failed to carry her prong one burden. *See id.* at 607 (citing *Cedillo*, 617 F.2d at 1345–46). Under these circumstances, remand is appropriate to ensure that the Chief Special Master does not require more of Petitioner’s theory than the *Althen* prong one standard requires. Indeed, as “close calls regarding causation are resolved in favor of injured claimants,” the Court agrees with Petitioner that, on this particular record, remand is appropriate. *Althen*, 418 F.3d at 1280; *see* Mot. at 5.

Specifically, on remand, the Chief Special Master should provide a more fulsome explanation to the extent he makes conclusions regarding (1) the probative weight of the medical literature Petitioner cited, including Petitioner’s case reports involving relevant vaccines and vaccine antigens, (2) his rationale for accepting or rejecting that evidence; and, as necessary, (3) the extent to which he is crediting each expert’s testimony; and (4) his rationale for doing so. *Moberly*, 592 F.3d at 1326 (“What *Andreu* prohibited was for the finder of fact to reject evidence based on an unduly stringent legal test while characterizing the rejection as based on the reliability of particular evidence or the credibility of a particular witness.”). In other words, the Chief Special Master must support any analysis of conclusions on remand to provide a more fulsome discussion of the “quantity and quality” of the medical literature presented. *See, e.g., Howard v. Sec’y of Health & Hum. Servs.*, No.16-1592V, 2023 WL 4117370, at *6 (Fed. Cl. May 18, 2023) *aff’d*, No. 2023-1816, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (per curiam) (affirming the Chief Special Master’s application of prong one where “[t]he Decision grappled with the quality and quantity of the evidence—not its circumstantiality—and found both metrics lacking”); *Bechel*, 168 Fed. Cl. at 622 (“Given the extensive and well-reasoned analysis provided by the Chief Special Master, the Court rejects Petitioners’ argument that he improperly discounted evidence because it was

circumstantial rather than direct and improperly heightened the legal standard of the first *Althen* prong.”).

II. *Althen* Prong Two

Under *Althen* prong two, Petitioner must prove actual causation by a preponderance of the evidence. *Boatmon*, 941 F.3d at 1355. Specifically, to prevail on prong two, a petitioner must prove “a logical sequence of cause and effect showing that the vaccination was the reason for the injury” by a preponderance of the evidence. *Oliver*, 900 F.3d at 1361 (quoting *Althen*, 418 F.3d at 1278). This “means what it sounds like” – a petitioner’s “theory of cause and effect must be logical.” *Capizzano*, 440 F.3d at 1326.

A showing of a proximate temporal relationship between vaccination and injury, or a “simplistic elimination of other potential causes of the injury” is insufficient to prove actual causation. *Althen*, 418 F.3d at 1278; *see also Moberly*, 592 F.3d at 1323 (quoting *Althen*, 418 F.3d at 1278). Despite this, the law is clear that “a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order establish a prima facie case.” *Stone*, 676 F.3d at 1380.⁴² However, “when petitioners attempt to eliminate other possible causes to buttress their theory of causation, the special master should evaluate such evidence in determining whether a prima facie case has been established.” *Doe*, 601 F.3d at 1358.

Here, with respect to *Althen* prong two, the Chief Special Master concluded that the record does not support the assertion that Petitioner’s Tdap and MMR vaccinations caused her AIH for two reasons. *Exum*, 2024 WL 4291116, at *14. *First*, the Decision noted that “[n]othing in the medical record (beyond the symptoms Petitioner began to experience post-vaccination) tends to

⁴² The petitioner may, instead, “rule out possible alternative causes to prove causation-in-fact when evidence as to the *Althen* requirements is insufficient.” *de Bazan*, 539 F.3d at 1352 n.3 (citing *Walther*, 485 F.3d at 1149–50).

support the conclusion that the vaccines caused her AIH,” and declined to “elevate” the temporal proximity of the vaccine and injury into evidence of causation. *Id.* (citing *Grant*, 956 F.2d at 1148). In so holding, the Chief Special Master declined to give weight to Petitioner’s post-vaccination symptoms and the fact that she exhibited no evidence of liver disease or hepatitis pre-vaccination. *Id.* n.7. *Second*, the Chief Special Master considered the evidence of alternative causes of Petitioner’s AIH, including her post-vaccination foreign travel, anti-malarial medication, supplements, her IUD, and her Epstein-Barr infection. *Id.* at *5, *13–14. The Chief Special Master concluded that each of these causes were “reasonably-likely”; and therefore, (i) “there are too many other possible explanations to find the vaccines were a substantial factor as well,” and (ii) “collectively [the other possible explanations] further undermine Petitioner’s showing.” *Id.* at *14.

Petitioner contends that the Decision’s conclusions concerning prong two are contrary to law because (1) she preponderantly proved a logical sequence of cause and effect, (2) Respondent did not meet its purported burden to prove “that an alternative causal factor was principally responsible for causing [her] AIH illness,” and (3) the Chief Special Master’s consideration of alternative causes was improper. *Mot.* at 16–18.

First, Petitioner argues that the Decision’s conclusion that Petitioner failed to satisfy *Althen* prong two is contrary to law as Petitioner has preponderantly proven a logical sequence of cause and effect. *Mot.* at 17. Petitioner challenges the Chief Special Master’s conclusion that “[n]othing in the medical record (beyond the symptoms Petitioner began to experience post-vaccination) tends to support the conclusion that the vaccines caused her AIH” as legal error. *Exum*, 2024 WL 4291116, at *14; *Mot.* at 16. Specifically, she asserts that in addition to the mere temporal association between the vaccines and her AIH, (1) Dr. Gish’s testimony, (2) the medical literature,

and (3) Petitioner's medical records, each support her logical sequence of cause and effect. Mot. at 16–24.

The Decision reflects that the Chief Special Master considered Petitioner's evidence and found that it was not specific or persuasive enough to have probative weight at prong two. The Decision acknowledges Dr. Gish's testimony that "the timing of symptoms, the timing of laboratory tests, the liver biopsy, all fits a classic triggering event and onset of autoimmune disease." *Id.* at *4. The Chief Special Master's reference to this testimony, taken together with his ultimate conclusion that "[n]othing in the medical record (beyond the symptoms Petitioner began to experience post-vaccination) tends to support that the vaccines caused her AIH" indicates that he considered Dr. Gish's testimony but did not find it sufficiently probative of a logical sequence of cause and effect. *Id.* at *14. The Court declines to "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." *Porter*, 663 F.3d at 1249. However, Petitioner also emphasizes that her prong one theory supports her logical sequence of cause and effect at prong two; specifically, she points to the "relevance of the case report evidence supporting [her] factual circumstances," noting similarities in her case and the case reports, such as "receiving multiple vaccine antigens," including the antigens included in the Tdap and MMR vaccines, and that some studies were relevant to Petitioner given her "personal hepatitis A vaccine history." Mot. at 19–21. Thus, to the extent that, on remand, the Chief Special Master's analysis of prong one affects his findings pertaining to Petitioner's prong two logical sequence of cause and effect, the Chief Special Master should revise and explain those findings accordingly.⁴³

⁴³ The Court does not suggest or direct that, on remand, the Chief Special Master's analysis should or necessarily will result in a different outcome; rather, the Court reaches its decision based on the

Second, Petitioner contends that the Chief Special Master committed legal error because “[i]t cannot be preponderantly concluded that an alternative causal factor was principally responsible for causing [Petitioner’s] AIH illness.” Mot. at 17–18 (citing *Knudsen*, 35 F.3d at 549); OA Tr. 71:17–72:5. Under 42 U.S.C. § 300aa–13(a)(1)(B), compensation may only be awarded to a petitioner if, on the record as a whole, “there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.” 42 U.S.C. § 300aa–13(a)(1)(B) (noting that “[t]he special master or court may not make such a finding based on claims of a petitioner alone, unsubstantiated by medical records or by medical opinion”). The respondent carries the burden to prove that a “factor[] unrelated” to the vaccine was the sole cause of a petitioner’s injury. *Doe*, 601 F.3d at 1357. However, the burden only shifts to the respondent if the special master concludes that petitioner has proven her *prima facie* case. *Id.* at 1357–58 (first citing *Doe/II v. Sec’y of Health & Hum. Servs.*, 87 Fed. Cl. 1, 12 (2009); then citing *Pafford*, 451 F.3d at 1357–59; and then citing *Shyface*, 165 F.3d 1344). Thus, the Chief Special Master correctly did not shift the burden to Respondent here, because he concluded that Petitioner had failed to meet *Althen* prong one, and a petitioner must prove all three prongs of *Althen* to prove her *prima facie* case. *Oliver*, 900 F.3d at 1361.

Third, Petitioner argues that the Chief Special Master’s consideration of evidence of potential alternative causes for her ailment was legal error because he “applied an erroneous ‘reasonable theory’ legal standard to conclude that [Petitioner] ‘did not persuasively limit or exclude all’ other possibilities.” Mot. at 16–18 (quoting *Exum*, 2024 WL 4291116, at *14).

need for additional reasoning to confirm application of the correct legal standard, which could result in a different outcome.

Petitioner contends that the Chief Special Master cannot “deviate from the correct ‘reputable,’ ‘sound and reliable,’ standard and articulate a lower ‘reasonably-likely’ standard for alternate causation, to then erroneously conclude that [Petitioner] could not prove a *prima facie* case.” *Id.* at 18. As noted, the Chief Special Master can consider evidence of alternative causes in his evaluation of Petitioner’s *prima facie* case. *Doe*, 601 F.3d at 1358. However, the manner in the Decision considered this evidence gives the Court pause. Specifically, the Decision states, “[w]hile Dr. Gish did observe the absence of many risk factors for AIH relevant to Petitioner, he did not persuasively limit or exclude *all of them*.” *Exum*, 2024 WL 4291116, at *14 (emphasis added). In reaching this conclusion, the Chief Special Master also emphasized the importance of these possible alternative causes. *Id.* (“*More important* are the circumstances in which Petitioner received these vaccines.”) (emphasis added).

While the Federal Circuit has held that a “petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner’s other evidence on causation is insufficient,” and that the government may present evidence of alternative causes, the law is clear that “a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order establish a *prima facie* case.” *Walther*, 485 F.3d at 1149–50 (citing *Pafford*, 451 F.3d at 1359); *Stone*, 676 F.3d at 1380; *see Doe*, 601 F.3d at 1358. Although the Decision elsewhere acknowledges that “claimants are never obligated to rule out alternative causes as part of their initial burden,” its problematic framing of the alternative causation discussion can lead to a reasonable conclusion that the Chief Special Master may have violated that axiom. *Exum*, 2024 WL 4291116, at *14 (citing *Stone*, 676 F.3d at 1380).

Particularly, as noted, the Decision emphasized this aspect of the analysis—describing the failure to rule out alternative causes as “[*m*]ore important” than the weakness in Petitioner’s other

prong two arguments—and specifically noted that Petitioner did not “persuasively limit or exclude *all of*” the possible alternative causes. *Id.* (emphasis added). The Federal Circuit has recognized that there is a “fine line between a court properly considering evidence in the record, and improperly placing the burden on the petitioner to prove that her [injury] was not caused by [an alternative cause],” and the Court finds that, the Decision, as worded, may fall on the wrong side of that line. *Sharpe v. Sec’y of Health & Hum. Servs.*, 964 F.3d 1072, 1082 (Fed. Cir. 2020) (internal citation omitted). However, due to the lack of elaboration and conflict between the recitation of the legal standard in the analysis section of the Decision (which correctly noted that “claimants are never obligated to rule out alternative causes as a part of their initial burden”) and the analysis itself, it is unclear whether that line was definitively crossed. *Exum*, 2024 WL 4291116, at *14. Indeed, the Decision could potentially be read as proper, given its determination that the other evidence supporting Petitioner’s claim was insufficient—which *Doe*, *Walther*, and *Pafford* permit—but also could be understood as requiring Petitioner to “shoulder the burden of eliminating all possible alternative causes,” which *Doe*, *Walther*, and *Stone* forbid. The noted lack of clarity regarding prong one, that the Chief Special Master’s prong one analysis influenced his conclusion on prong two, and the Decision’s above-noted reference to Petitioner’s failure to rule out alternate causes, supports Petitioner’s request for remand. *See id.* (“In this context, there are too many other possible explanations to find the vaccines were a substantial factor as well (especially given the thin showing overall on the “can cause” prong)—and collectively they further undermine Petitioner’s showing.”).

On remand, the Chief Special Master must (1) revise his findings on prong two, only to the extent that his prong one analysis on remand affects those findings, (2) revise his analysis pertaining to alternative causes, insofar as he improperly required Petitioner to “persuasively limit

or exclude *all of them*,” and, importantly, (3) fully describe his rationale for all of his prong two conclusions in the remand decision.

III. *Althen* Prong Three

Petitioner argues that the Chief Special Master’s failure to analyze *Althen* prong three constituted legal error. Mot. at 24. As Respondent correctly notes, “it is well-established in the Vaccine Program that a petitioner’s failure to satisfy even a single *Althen* prong is dispositive. Resp. at 26 (citing *LaLonde v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 201 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014)); then citing *Trollinger*, 167 Fed. Cl. at 142; and then citing *Hibbard*, 698 F.3d at 1365). Petitioner must establish all three prongs of *Althen* by a preponderance of evidence, and failure to establish any one of them is dispositive. *Oliver*, 900 F.3d at 1361. Indeed, the Federal Circuit has repeatedly stated that a special master is not required to decide *Althen* prong three if he properly decided the Petitioner failed at prongs one or two. *See Henkel v. Sec’y of Health & Hum. Servs.*, No. 2023-1894, 2024 WL 3873569, at *1 (Fed. Cir. Aug. 20, 2024) (“Because we conclude that the special master’s finding on *Althen* prong three was not arbitrary or capricious . . . and because Appellants needed to prevail on all three prongs to have their petition granted, we affirm the petition’s denial without reaching the prong-two finding.”); *Koehn v. Sec’y of Health & Hum. Servs.*, 773 F.3d 1239, 1244 (Fed. Cir. 2014) (“Because [petitioner] failed to meet her burden under the third *Althen* prong, however, and failure to do so under any one of the *Althen* prongs is dispositive of this case, the Special Master correctly denied [petitioner’s] petition.”); *Broekelschen*, 618 F.3d at 1344, 1351 (affirming the special master’s decision where he determined the petitioner failed at prong one, and therefore declined to rule on prongs two and three); *see also Trollinger*, 167 Fed. Cl. at 142 (same); *Contreras v. Sec’y of Health & Hum. Servs.*, 107 Fed. Cl. 280, 295 (2012) (citing *Broekelschen*, 618 F.3d at 1350–51) (“[T]here

is no *per se* rule forbidding a special master to deny compensation upon a finding that a petitioner has failed to meet one of the *Althen* prongs”); *LaLonde*, 110 Fed. Cl. at 206 (affirming petitioner failed to prove causation where it failed at prongs one and two, but where the special master agreed “there was a clear temporal relationship”).

Accordingly, the Chief Special Master appropriately declined to consider *Althen* prong three in his Decision. On remand, he must only consider *Althen* prong three if his remand analysis of *Althen* prong one and prong two lead to a conclusion that Petitioner satisfied each of those prongs.

CONCLUSION

For the reasons stated above, Petitioner’s Motion for Review (ECF No. 76) is **GRANTED IN PART**. The Chief Special Master’s Decision (ECF No. 74) is **VACATED** and **REMANDED** for further action in accordance with this Memorandum and Order. Pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), the Chief Special Master shall issue a remand decision within 90 days. The parties are directed to **CONFER** and **FILE** a Notice within 14 days, attaching a proposed public version of this sealed Memorandum and Order.

IT IS SO ORDERED.



Eleni M. Roumel

ELENI M. ROUMEL
Judge

Dated: February 26, 2025
Washington, D.C.