In the United States Court of Federal Claims

PORTIA EXUM, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 21-1513 Filed Under Seal: September 18, 2025 Publication: September 30, 2025[1]

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

Mary Novakovic, of the United States Department of Justice, Civil Division, Washington, D.C., argued for Respondent. With her on the briefs were *Brett A. Shumate*, *C. Salvatore D'Alessio*, *Heather L. Pearlman*, and *Alexis B. Babcock*, of the United States Department of Justice, Civil Division, Washington, D.C.

MEMORANDUM AND ORDER

Petitioner Portia Exum seeks compensation under the National Vaccine Injury Compensation Program (Vaccine Act). 42 U.S.C. §§ 300aa-10 *et seq.*, alleging that she suffers from autoimmune hepatitis (AIH) caused by the measles-mumps-rubella (MMR) and tetanus-diphtheria-acellular pertussis (Tdap) vaccines she received on August 20, 2018.

This action has a lengthy history, a summary of which provides helpful context to the present dispute. Petitioner initially filed this action on June 25, 2021, and on August 29, 2024, the

[1] On September 18, 2025, this Court issued a sealed version of this Memorandum and Order. ECF No. 93. The Court informed the parties that any proposed redactions were to be submitted by September 29, 2025. *Id.* at 58. Having received no proposed redactions from the parties, the sealed and public versions of this Memorandum and Order are identical except for the publication date and this footnote.

Chief Special Master denied Petitioner's claim. ECF No. 1 (Petition or Pet.); ECF No. 74 (First Entitlement Decision). Subsequently, Petitioner moved this Court for review of the Chief Special Master's decision. ECF No. 76. Subsequently, this Court granted Petitioner's motion for review in part—remanding the action and instructing the Chief Special Master to provide a more fulsome explanation of his weighing of the record evidence. *Exum v. Sec'y of Health & Hum. Servs.*, 175 Fed. Cl. 681 (2025) (*Exum I*); ECF No. 85. On May 27, 2025, the Chief Special Master issued a thorough and well-reasoned second entitlement decision, again denying Petitioner's claim. ECF No. 88 (Remand Decision). Pending before the Court is Petitioner's Motion for Review of the Chief Special Master's second decision — the Remand Decision — denying her petition for compensation. ECF No. 87.

The difficulties associated with Petitioner's circumstances are not lost on this Court. Despite this, after repeated judicial consideration of the evidentiary record in her case, it is evident that Petitioner's arguments do not provide a sufficient legal basis for setting aside the Chief Special Master's Decision. The Chief Special Master thoroughly "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision"—comprehensively analyzing the record evidence and law relevant to this case. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1381 (Fed. Cir. 2021) (alteration in original) (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)); *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Accordingly, and for the reasons described below, Petitioner's Motion for Review is **DENIED**.

BACKGROUND

The Chief Special Master's Remand Decision, his First Entitlement Decision, and this Court's prior opinion contain thorough discussions of the evidence of record in this case, familiarity with which is presumed. ECF No. 88 (Second Entitlement Decision or Decision) at 2–

30; ECF No. 74 (First Entitlement Decision); *Exum I*, 175 Fed. Cl. 681.[2] What follows is a summary of the aspects of the record pertinent to issues raised in Petitioner's present Motion for Review.

I. Factual Background

A. Petitioner's Pre-Vaccination Medical History

Prior to the receiving the vaccines at issue in this case, Petitioner's medical history included gastrointestinal issues and kidney stones. Pet. Ex. 2 (ECF No. 6-2) at 9–12; Pet. Ex. 3 (ECF No. 6-3) at 273–75. On August 17, 2018, in preparation for a trip to Kenya and Tanzania, Petitioner received an anti-malarial medication, which she was instructed to begin taking beginning two days before she visited high-risk areas and to continue taking until seven days after her departure from those high risk areas. Pet. Ex. 3 at 74; Pet. Ex. 4 at 8 (ECF No. 6-4). On August 20, 2018, she also received the Tdap and MMR vaccines. Pet. ¶ 4; Pet. Ex. 3 at 72; Pet. Ex. 11 (ECF No. 7-2) (Exum Aff.) ¶ 7.

B. Petitioner's AIH Symptom Onset[3]

Petitioner traveled to Kenya and Tanzania from August 29, 2018 through September 8, 2018, and reported four or five bug bites during the trip. Exum Aff. ¶ 8; Pet. Ex. 4 at 35. When she returned, Petitioner reported feeling "extreme fatigue," and by mid-late September she had

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

[3] Petitioner's AIH diagnosis is undisputed. *See* ECF No. 87 (Motion or MFR) at 6 ("It is undisputed that Mrs. Exum developed autoimmune hepatitis (AIH) . . . ."); ECF No. 72 at 15 ("Respondent does not contest petitioner's diagnosis of [AIH].").

developed gastroesophageal reflux disease (GERD) symptoms and indigestion. Pet. Ex. 3 at 57; Pet. Ex. 4 at 35. By October 2018, she was experiencing daily nausea. 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. Pet. ¶ 5; Exum Aff ¶ 11; Pet. Ex. 4 at 42, 44. Prior to this test, her liver enzyme levels had been normal. Specifically, 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; Pet. Ex. 1 (ECF No. 6-1) at 22.

Petitioner visited a gastroenterologist on November 28, 2018, for reporting elevated liver enzyme levels, nausea, and gastrointestinal (GI) symptoms. Pet. Ex. 3 at 280–83. Her abdominal exam did not reveal any signs of liver enlargement or tenderness, although Petitioner reported that she was experiencing "right-sided distress." *Id.* at 282. A physician's assistant (PA) noted the "unclear etiology" of Petitioner's condition, referred her 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. *Id.* at 282−83. Those tests revealed that Petitioner's liver enzyme levels were "extremely elevated"—even higher than her previous levels—but were negative for *H. pylori*. *Id.* 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. *Id.* at 242–45. The following day, Petitioner visited her primary care physician (PCP), reporting epigastric pressure and discomfort (specifically on her right side), nausea, fatigue, and that her eyes appeared yellow. Pet ¶ 9; Pet. Ex. 3 at 61. Her abdominal exam revealed no enlargement of the liver or spleen, and her viral

hepatitis panel came back negative, but her liver enzyme levels—including aspartate aminotransferase (AST) and alanine aminotransferase (ALT)—and her ferritin levels were elevated. Pet. Ex. 3 at 62−65; Pet. Ex. 4 at 31−33. Petitioner's PCP referred her to a hepatologist. Pet. Ex. 3 at 63.

On December 11, 2018, Petitioner had an MRI of her liver. Pet. Ex. 4 at 28−30. The MRI revealed two hyper-intense lesions (abnormal growth of cells or tissue in the liver) and asymmetric dilation of the left renal vein. *Id.* Radiologists recommended that she see a hepatologist for the hepatic lesions. *Id.* at 28.

Petitioner returned to her PCP on December 14, 2018. 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. *Id.* at 57–58. Petitioner's PCP also referred her to an infectious disease specialist. *Id.* at 59.

On December 19, 2018, Petitioner was evaluated by a hepatologist, and the records associated with that visit noted that Petitioner had no signs of decompensated liver disease and that her abdominal exam did not reveal abnormalities. *Id.* at 232−38; *id.* at 235 ("GI/Abdomen: soft, nontender, nondistended, normoactive bowel sounds"); *id.* at 232–33 ("Patient has no evidence of decompensated liver disease . . . ."). Lab results indicated that her AST and ALT levels remained elevated but did not indicate acute liver failure or an active hepatitis infection. *Id.* at 232, 237; Pet. Ex. 8 (ECF No. 6-8), at 73. Petitioner represented that her lifestyle did not present risk factors for liver disease (*e.g.*, drug use, blood transfusions), but acknowledged taking anti-malarial medication during her recent trip to Kenya and Tanzania. Pet. Ex. 3 at 232. She also reported that reishi mushrooms were the only other over-the-counter medication or supplement

she was taking. *Id.* The hepatologist recommended that Petitioner have a liver biopsy and another liver MRI in six months. *Id.* at 237.

Petitioner had a liver biopsy on January 3, 2019, which showed moderate interface and lobular hepatitis. *Id.* at 229. The liver biopsy "raise[d] a broad differential diagnosis which includes but [was] not limited to" 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). *Id.* The following day, Petitioner was evaluated by a hematology specialist. *Id.* at 222. He concluded that this elevated level was due to "obvious liver disease, whose etiology is as yet unknown" and diagnosed her with hepatitis. *Id.*; Pet. Ex. 7 (ECF No. 6-7) at 29.

A follow-up evaluation by an infectious disease specialist on January 24, 2019, confirmed that a diagnosis of AIH was most likely. Pet. Ex. 4 at 6−8, 12–13. During this visit, Petitioner discussed her 2018 international travel, including that she had swam in the Indian Ocean, incurred several insect bites, and felt extremely tired fatigue upon her return; the records from that visit also noted that Petitioner was taking a four- to six-week course of prednisone, which she had begun earlier in January 2019. *Id.* at 6, 8. Testing indicated that Petitioner had previously (at an undetermined time) had an Epstein-Barr viral infection (EBV) and also showed that her liver enzyme levels were improving but remained abnormally high. *Id.* at 12 (noting that Petitioner was "EBV positive but indicative of a previous infection, not a current infection"); Pet. Ex. 3 at 201−08. In January 2019, Petitioner was also treated for thrush and a kidney stone. Pet. Ex. 3 at 52; Pet. Ex. 2 at 32−36; Pet. Ex. 4 at 12.

C. Petitioner's Treatment for AIH

During February and March 2019, Petitioner's liver enzyme levels improved, but remained elevated. Pet. Ex. 3 at 42−51. She took azathioprine and prednisone for her liver issues. *Id.* 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." *Id.* at 36−37. Petitioner also returned to her hepatologist, reporting similar symptoms. Pet. Ex. 10 (ECF No. 7-1) at 6. Her liver enzyme levels were improving but had not returned to normal. Pet. Ex. 3, at 195; Pet. Ex. 10 at 10–11. 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. 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.[4] *Id.* at 165. Petitioner's hepatologist instructed her to continue taking azathioprine and ordered a metabolite screen to confirm that Petitioner was not suffering from hepatoxicity. *Id.* Testing performed in September 2019 showed improved liver enzyme levels that were slightly elevated. *Id.* at 29.

On January 27, 2020, Petitioner reported increased fatigue and myalgias, but her hepatologist noted that her liver enzyme levels had normalized, and that she had no evidence of decompensated liver disease. Pet. Ex. 10 at 56, 61. Nevertheless, Petitioner's hepatologist instructed her to continue taking azathioprine and to have her liver serum enzymes tested every two to three months. *Id.* at 61.

At a follow-up appointment six months later on July 27, 2020, Petitioner's liver enzyme levels were normal. 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. *Id.* Other than a February 2021 liver biopsy which revealed "chronic hepatitis with minimal interface activity and mild portal fibrosis (stage 1 of 4),"

[4] 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.

Plaintiff's testing from mid-2020 through 2022 indicated normal liver enzyme levels. 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. 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 for management of her autoimmune hepatitis and chronically elevated liver serum enzymes." Pet. ¶¶ 20–21.[5]

II. Expert Opinions

In addition to Petitioner's 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* Pet. Ex. 16 (ECF No 18-1) (Gish Initial Report); Pet. Ex. 38 (ECF No. 28-1) (Gish Rebuttal Report); Resp. Ex. A (ECF No. 23-1) (Crippin Report); Resp. Ex. C (ECF No. 23-3) (MacGinnitie Report). All three experts testified at the Entitlement Hearing. *See generally* Entitlement Hearing Transcript, dated Mar. 7, 2024 (ECF No. 64) (Hr'g Tr.).

A. Petitioner's Expert

1. Dr. Robert Gish

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

[5] Paragraph 21 appears 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.

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.*; Hr'g Tr. at 91:11–15. Dr. Gish acknowledges that he does 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).[6] 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)

[6] 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.

(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 42:10–21 (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.[7] *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.

[7] On cross-examination, Dr. Gish addressed 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.*

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 response to increase her risk of immune dysfunction and clinical expression of autoimmune hepatitis disease.").[8]

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 administrated a booster vaccine, like Tdap, with an acellular pertussis component. 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

[8] *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.*

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)).[9]

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 & 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-Vergani I); Pet. Ex.

[9] 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.

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 numerous case studies presented did not involve the MMR and Tdap vaccines. Hr'g Tr. at 97:14−107:22.

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ECF No.	Case Report	Vaccine(s)	Related Illness
18-6	Pet. Ex. 21, Saliba & Elias (2005)	MMR	Acute hepatitis[10]
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, Tdap	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-Vergani I (1989)	N/A; wild measles infection[11]	AIH
45-3	Pet. Ex. 45, Jorch, et al.[12]	MMR	Meningoencephalitis

[10] 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.

[11] The Mieli-Vergani I case report states that eight of the twelve child patients in this study "had received measles vaccination." *See* Mieli-Vergani 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.*

[12] 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).

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."[13] 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 done on Petitioner 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 statistic[al] correlations with genetic diseases, genetic abnormalities, genetic mutations . . . and these different autoimmune diseases").

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. Hr'g Tr. at 14:21–16:6. Specifically, he noted that her physical examinations did not indicate liver

[13] 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.

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.[14]

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 with a different autoimmune condition. *Id.* at 94:6–23. Thus, according to Dr. Gish, by process

[14] 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).

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, 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.[15]

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

[15] 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.

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," or RA, which is an autoimmune disease); Beretta-Piccoli (case report associating anti-malarial drug Malarone (Atovaquone-Proguanil) with AIH[16]); Resp. 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

[16] 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 (an anti-malarial drug) 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.*

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 AIH[17]); 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).

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,

[17] Dr. Crippin noted in his Report that "a causative relationship was thought to deserve further investigation." Crippin Report at 5.

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 6−7 (noting that case reports and case series "don't consider factors such as the total number of individuals receiving the vaccine or the background rate of AIH in the population, making any assessment of causality impossible"). 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))[18]; 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 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."

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

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[es] 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)).[19]

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 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

[19] Dr. MacGinnitie also rejected Dr. Gish's aluminum adjuvant theory, which Dr. Gish had "set[] aside" at the Entitlement Hearing. *See supra* note 9.

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.

II. Procedural Background

As noted, on June 25, 2021, Petitioner filed a Petition for Compensation under the National Childhood Vaccine Injury Act (Vaccine Act), 42 U.S.C. §§ 300aa-10 *et seq.*, alleging an off-Table injury. *See* Pet. Specifically, Petitioner alleged that the measles-mumps-rubella (MMR) and tetanus-diphtheria-acellular pertussis (Tdap) vaccines she had received on August 20, 2018, caused her autoimmune hepatitis (AIH) and chronically elevated liver serum enzymes. *Id.* ¶¶ 4, 21−22. As noted, in support of her claim Petitioner filed expert reports,[20] medical literature,[21] and medical

[20] Pet. Ex. 16 (ECF No 18-1) (Gish Initial Report); Pet. Ex. 38 (ECF No. 28-1) (Gish Rebuttal Report).

[21] 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).

records.[22] Respondent filed competing expert reports[23] and medical literature[24] in support of its contention that Petitioner had not established that her illness was caused by the MMR and Tdap vaccines.

On March 7, 2024, Chief Special Master Brian H. Corcoran held an Entitlement Hearing, during which Drs. Robert Gish, Jeffrey Crippin, and Andrew MacGinnitie testified. *See generally* Hr'g Tr. Subsequently, on August 29, 2024, the Chief Special Master denied Petitioner's claim, concluding that she had failed to prove her off-Table claim. ECF No. 74 (First Entitlement Decision); *see Exum v. Sec'y of Health & Hum. Servs.*, No. 21-1513, 2024 WL 4291116 (Fed. Cl. Aug. 29, 2024).

A. Petitioner's First Motion for Review

Petitioner next moved this Court for review of the Chief Special Master's Decision, arguing that the Chief Special Master had erred 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.[25] ECF No. 76 at 5. The Court conducted oral argument on Petitioner's motion on December 19, 2024. ECF No. 81 (First OA Tr.) at 1; *see also* Minute

[22] 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 43–44 (ECF No. 45-1−45-2).

[23] Resp. Ex. A (ECF No. 23-1) (Crippin Report); Resp. Ex. C (ECF No. 23-3) (MacGinnitie Report).

[24] Exhibit A, Tabs 1−19 (ECF Nos. 25-1–25-19); Exhibit C, Tabs 1−19 (ECF Nos. 26-1–26-19).

[25] The "*Althen* prongs" refer to the three-pronged causation standard for off-Table claims set forth in *Althen v. Secretary of Health & Human Services*, explained in further detail below. 418 F.3d 1274 (2005); *see infra* Discussion.

Entry, dated Dec. 19, 2024. Upon review, this Court granted Petitioner's motion in part and vacated the Chief Special Master's decision, remanding the case back to the Chief Special Master with specific instructions. *Exum I*, 175 Fed. Cl. at 687. *First*, the Court instructed that, on remand, the Chief Special Master should provide a more fulsome explanation of his rationales for accepting or rejecting Petitioner's evidence as to prong one. *Id.* at 707–08. *Second*, the Court instructed the Chief Special Master to revise his findings on prong two, "only to the extent that his prong one analysis on remand affects those findings" and "insofar as he improperly required Petitioner to 'persuasively limit or exclude *all* [alternative causes],'" and to "fully describe his rationale for all of his prong two conclusions in the remand decision." *Id.* at 710. *Third*, this Court concluded that the Chief Special Master had properly declined to consider *Althen* prong three, and that he should only consider *Althen* prong three on remand if his analysis "of *Althen* prong one and prong two lead to a conclusion that Petitioner satisfied each of those prongs." *Id.* at 711.

B. The Remand Decision

On May 27, 2025, the Chief Special Master issued his decision on remand, again denying Petitioner's claim. ECF No. 88 (Remand Decision or Decision).[26] Before proceeding to his analysis, the Chief Special Master recounted the medical facts relevant to Petitioner's claim, thoroughly summarized the parties' experts' testimony at the Entitlement Hearing, and summarized every item of medical literature filed by Petitioner. *Id.* at 2−30.

[26] The Chief Special Master issued the Remand Decision on May 27, 2025. ECF No. 86. Pursuant to Rule 18(b) of Appendix B of the Rules of the Court of Federal Claims (Vaccine Rules), the Chief Special Master provided the parties 14 days to identify and move to redact medical or other information, "the disclosure of which would constitute an unwarranted invasion of privacy." *Id.* at 1 n.1; Vaccine Rule 18(b)(2). As neither party moved to redact any information, the Chief Special Master publicly reissued the Decision on July 8, 2025. ECF No. 88. For clarity and consistency, all references to the Chief Special Master's Decision are to the public version, docketed as ECF No. 88.

The Chief Special Master was similarly thorough in each step of his analysis. *First*, the Chief Special Master noted that within the Vaccine Program, "the trend seems to be against" causally attributing AIH to covered vaccines. *Id.* at 38 (citing *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242 (Fed. Cir. 2011)). He explained that the evidence filed in this case, too, did "not appear to embrace the concept that vaccines might in rare cases cause [AIH]." *Id.* The Chief Special Master further noted that most AIH-related claims within the Vaccine Program involved the hepatitis A and hepatitis B vaccines, and that there "are comparatively fewer cases involving the MMR or Tdap vaccines"—the vaccines at issue in this case—and the cases that do "are not favorable to Petitioner." *Id.* (citing *Rivas v. Sec'y of Health & Hum. Servs.*, No. 21-1683V, 2025 WL 551570, at *2 (Fed. Cl. Spec. Mstr. Jan. 24, 2025)).

Second, the Chief Special Master held that Petitioner had failed to carry her burden to establish causation—again concluding that she failed to satisfy *Althen* prongs one and two. *Id.* at 38−39. With respect to prong one, the Chief Special Master first took care to note that some aspects of Petitioner's theory "are wholly noncontroversial," but that her theory "*in its totality* lacks sufficient preponderant support." *Id.* at 39. He then proceeded to explain the underlying rationales supporting this conclusion:

> (1) Petitioner had not preponderantly demonstrated a link between the measles component of the MMR vaccine and AIH;
>
> (2) Evidence of a causal connection between the Tdap vaccine and AIH was weak or lacking;
>
> (3) Insufficient evidence was offered to establish the risk of receiving two vaccines at once;
>
> (4) Dr. Gish's molecular mimicry mechanism for driving AIH due to vaccination was inadequately corroborated;
>
> (5) Case reports are weak causation evidence, and those offered were largely unhelpful to Petitioner;

(6) Other proposed mechanisms were inadequately developed; and

(7) Respondent's experts were more persuasive than Dr. Gish on the question of vaccine causation.

Id. at 39−48 (citation modified). For all of those detailed reasons, the Chief Special Master concluded that Petitioner had not established that the Tdap vaccine and MMR vaccines, individually or together, can likely cause autoimmune hepatitis. *Id.* at 48.

Likewise, with respect to prong two, the Chief Special Master concluded that Petitioner had not carried her burden to show that the MMR and Tdap vaccines she received "did cause" her AIH. *Id.* at 48−51 (quoting *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1355 (Fed. Cir. 2019)). In particular, he noted that "Petitioner's medical records contemporaneous to her vaccination date are devoid of evidence that she experienced any close-in-time vaccine reaction." *Id.* at 48. Additionally, the Chief Special Master noted that Petitioner had never tested positive for inflammation biomarkers which could indicate that she was experiencing an inflammatory event prior to her elevated liver test values. *Id.* Further, Petitioner was not experiencing an active measles infection, a hepatitis infection, or any other kind of infection that would occur "in the wake of the alleged measles vaccine-caused immune suppression." *Id.* The Chief Special Master also noted that he had not identified in the medical records any instances of her treating physicians attributing her AIH to the MMR and Tdap vaccines. *Id.* Accordingly, the Chief Special Master reasoned that, absent that factual support, "[w]hat remains is the fact that Petitioner experienced some post-travel nonspecific symptoms which did not immediately merit treatment (and which arguably were consistent with her pre-vaccination health)." *Id.* And even to the extent those non-specific symptoms, such as fatigue, could be considered related to her AIH, the Chief Special Master concluded that this evidence was not a sufficient basis to connect the vaccines and Petitioner's AIH. *Id.* at 48–49. The Chief Special Master also noted the presence of several risk

factors for AIH in Petitioner's medical history, including her recent foreign travel, and that she took anti-malarial medications and other supplements. *Id.* at 49. Regarding Petitioner's anti-malarial medication specifically, the Chief Special Master noted that there was not enough evidence to conclude that this was the cause of Petitioner's AIH, but that it was "clearly something that had a demonstrated capacity to increase Petitioner's possible hepatitis risk, and she received it *after* vaccination (and hence closer in time to her possible onset)." *Id.* at 49–50. The Chief Special Master concluded that there are "simply too many confounding factors specific to Petitioner's experiences in the six-to-eight week post-vaccination period" to conclude that it is more likely than not that the vaccines caused her AIH. *Id.* at 51 ("The medical record simply does not contain sufficient facts suggesting the vaccines had anything to do with Petitioner's disease.").

With respect to prong three, the Chief Special Master concluded that, although it was unclear precisely when the onset of Petitioner's AIH occurred, she experienced "some clinical features of early AIH within six to eight weeks of vaccination, later corroborated by the LFT test results, and progressing to more concerning symptoms that led her to seek treatment in December," and that this aligned with Dr. Gish's theory. *Id.* at 52. The Chief Special Master noted that Dr. MacGinnitie agreed that the six- to eight-week time frame would have been medically possible, and that Petitioner's treating physicians seemed to believe that her overall course "reflected a single disease process." *Id.* The Chief Special Master concluded that, had he found that Petitioner carried her burden under prong one, he would have been able to conclude that this six- to eight-week time period for onset would be medically acceptable—satisfying prong three. *Id.* However, the Chief Special Master concluded that this ultimately "d[id] not matter," given that he did not find prong one had been met. *Id.*

Third and finally, in closing, the Chief Special Master explained how the preponderance standard applies in claims brought under the Vaccine Act. *Id.* at 52–54. Specifically, "[w]hat matters is the *individual reliability of the items of evidence offered*, coupled with how well each item knits together into an overall theory that does not amount to speculation or unreasonable extrapolation." *Id.* at 53. The Chief Special Master concluded by noting that here, "a preponderant evidentiary showing *has not been made*—and it was not a close case." *Id.*

C. Petitioner's Second Motion for Review

On June 26, 2025, Petitioner filed a second Motion for Review, this time seeking review of the Chief Special Master's Remand Decision. ECF No. 87 (Motion or MFR). Petitioner raises two objections to the Remand Decision. *Id.* at 5–6. *First*, that the Chief Special Master's assessment of Petitioner's medical literature evidence as to *Althen* prong one constitutes legal error. *Id.* *Second*, that the Chief Special Master's conclusions as to *Althen* prong two were contrary to law. *Id.* at 6. On July 28, 2025, Respondent filed its Response to Petitioner's Motion, contending 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 that this Court should affirm the Chief Special Master's Decision. ECF No. 89 (Response or Resp.). Petitioner requested a hearing on her second Motion for Review, and accordingly, on September 8, 2025, this Court conducted oral argument. *See* ECF No. 92 (OA Tr.) at 1; *see also* Minute Entry, dated Sept. 8, 2025; MFR at 24. Petitioner's Motion is now fully briefed and ripe for resolution.

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 & Hum. Servs.*, 970 F.2d 863, 870 & n.10 (Fed. Cir. 1992); *see also Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1119 (Fed. Cir. 2025) ("In Vaccine Act cases, the Court of Federal Claims reviews the factual findings of the special master under the arbitrary and capricious standard and reviews the legal rulings of the special master to determine whether they are in accordance with law.").

The scope of this Court's review is "uniquely deferential." *Milik v. Sec'y of Health & Hum. Servs.*, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). This Court is required to uphold the factual findings of a special master unless those findings are arbitrary or capricious. *Lampe*, 219 F.3d at 1360 (noting that, with respect to factual findings—particularly the "decision to credit the evidence"—"judicial review of the special master's decision is very limited"); *Munn*, 970 F.2d at 870 & n.10 (noting that the arbitrary and capricious standard is "well understood to be the most deferential possible").

"The Vaccine Act makes clear that [the Court] do[es] not 'second guess' the special master's fact-intensive conclusions that are 'based upon [his] accumulated expertise in the field.'" *Hinton v. Sec'y of Health & Hum. Servs.*, No. 23-2161, 2025 WL 763153, at *2 (Fed. Cir. Mar. 11, 2025) (quoting *Hodges*, 9 F.3d at 961). It is not this Court's role 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—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (noting that a special master has discretion to determine the relative weight of the evidence, including medical records). If the special master's conclusion is "based on evidence in the record that [is] not wholly implausible," this Court is "compelled to uphold that finding as not being arbitrary or capricious." *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (alteration in original) (quoting *Lampe*, 219 F.3d at 1363). "[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); *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

DISCUSSION

Congress enacted the Vaccine Act 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, 1325–26 (Fed. Cir. 2011) (en banc) (citation modified); *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 Court of Federal Claims and 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), 300aa−12(d)(3)). To obtain compensation under the Vaccine Act, a petitioner must prove that a vaccine caused an injury. *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005). There are two ways for a petitioner to do this: (1) by proving that he suffered a Table injury within the specified time window after vaccination—in which case, causation is presumed (a Table claim), or (2) by proving causation-in-fact (an off-Table claim). *de Bazan*, 539 F.3d at 1351.

Table claims are based on "a statutorily-prescribed presumption of causation" created by the Vaccine Injury Table. *Althen*, 418 F.3d at 1278; 42 U.S.C. § 300aa-14(a) (Vaccine Injury Table); 42 CFR § 100.3 (current Vaccine Injury Table). The Table identifies vaccines covered under the Vaccine Act, compensable injuries, and how soon after vaccination the first symptom or manifestation of onset must occur for purposes of receiving compensation. *Bruesewitz*, 562 U.S. at 228. If a petitioner can prove by a preponderance of the evidence that his injury meets the criteria in the Table, he has successfully made a Table claim and is "prima facie entitled to compensation." *Id.*; *de Bazan*, 539 F.3d at 1351. In other words, "[b]ring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting—causation is conclusively presumed." *Hodges*, 9 F.3d at 961.

Alternatively, where the petitioner alleges an off-Table claim—i.e., claiming an injury not listed in the Vaccine Injury Table, or which first appears outside of the time limits set by the Table—"the heavy lifting must be done by the petitioner" to prove causation-in-fact. 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *Hodges*, 9 F.3d at 961; *Althen*, 418 F.3d at 1278. This burden "is heavy indeed." *Hodges*, 9 F.3d at 961. To prove causation for such an off-Table claim, a petitioner must

prove by a preponderance of the evidence that his vaccine was "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). To make this showing, a petitioner must prove each of the three *Althen* prongs by a preponderance of the evidence:

(1) a medical theory causally connecting the vaccination and the injury;

(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and

(3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278; *Boatmon*, 941 F.3d at 1354–55 (quoting *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321–22 (Fed. Cir. 2010)); *Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018) (quoting *Althen*, 418 F.3d at 1278); *see also Henkel v. Sec'y of Health & Hum. Servs.*, No. 23-1894, 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.").

"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 v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007)). 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 (citing *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994)). However, if Petitioner fails to establish a prima facie case, the burden does not shift to Respondent. *See Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010). 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. *de Bazan*, 539 F.3d at 1353; *Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379–80 (Fed. Cir. 2012).

In her second Motion for Review, Petitioner raises two objections to the Chief Special Master's Remand Decision. MFR at 5−6. *First*, that the Chief Special Master's assessment of Petitioner's medical literature evidence offered in support of *Althen* prong one constitutes legal error. *Id.* *Second*, that the Chief Special Master's conclusions as to *Althen* prong two were contrary to law. *Id.* at 6.

Having once again considered the record evidence and law applicable to this case, for the reasons explained below, this Court rejects both of Petitioner's objections, and holds that the Chief Special Master's conclusions do not constitute legal error. The Chief Special Master's Decision is sustained.

I. The Chief Special Master's Appropriately Evaluated Petitioner's *Althen* Prong One Theory.

Petitioner broadly contends that the Chief Special Master's evaluation of her prong one theory constitutes legal error. MFR at 5−6, 12–22. This claim encompasses several more specific arguments. *First*, Petitioner argues that the Chief Special Master's "erroneous assessment of the medical literature evidence" constitutes legal error, as he (i) purportedly viewed the evidence through improper medical standards—rather than through the vantage point of the Vaccine Act's preponderance standard—and (ii) improperly rejected circumstantial evidence. *Id.* at 12–20. *Second*, Petitioner asserts that the Chief Special Master's credibility determinations were

improper. *Id.* at 20−22. *Third*, she contends that several of the Chief Special Master's factual findings are arbitrary and capricious.[27] *Id.* at 15.

Respondent argues that "[t]he Chief Special Master's conclusion that petitioner did not establish a reliable medical theory of vaccine causation under *Althen* prong one is well supported by the record," and that he "articulated and applied the correct legal standards, thoroughly considered the relevant evidence, and explained in detail the rationale behind his Decision." Resp. at 12−13.

The Chief Special Master's Decision makes clear that he appropriately applied the *Althen* prong one standard. Both the standard the Chief Special Master articulated and the manner in which he applied that standard reflect that he required Petitioner to prove a "reliable medical theory of causation specific to the vaccine and injury in question," as required by Federal Circuit precedent. *Cerrone*, 146 F.4th at 1121 n.3; Decision at 32 (stating that Petitioner's burden at prong

[27] Petitioner's first numbered objection asserts only legal error with respect to prong one, and did not include in any specific objections to the Chief Special Master's factual findings. MFR at 5–6. Accordingly, Petitioner waived such factual challenges. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006) ("Our law is well established that arguments not raised in the opening brief are waived."); *Hodge ex rel. Elson v. Sec'y of Health & Hum. Servs.*, 168 Fed. Cl. 117, 129 n.13 (2023) ("Because petitioner did not explicitly raise such an argument, she has waived it."); *Miller v. Sec'y of Health & Hum. Servs.*, 172 Fed. Cl. 762, 779 (2024) (concluding that the petitioner waived her challenge to a specific finding of the special master, where she "failed to state it as an objection or adequately raise it in her Motion for Review or Memorandum of Objections"); *see also* Vaccine Rule 24 (requiring that a motion for review of a special master's decision must "be accompanied by a memorandum of numbered objections to the decision" which "fully and specifically state[s] and support[s] each objection" to the special master's decision). Nevertheless, in her Motion, Petitioner describes several of the Chief Special Master's findings as "arbitrary." MFR at 15 ("[T]he Chief arbitrarily concluded that Dr. Gish's testimony did not 'adequately substantiate' the reliable mechanistic explanation." (citing Decision at 44)); *id.* ("The Chief [Special Master's] finding that 'other proposed mechanisms' were inadequate was arbitrary, as he recognized that bystander activation is 'another way' AIH might occur."). Accordingly, for comprehensiveness, the Court addresses these two factual issues Petitioner references in her Motion, despite that they were not properly raised as objections. *See* Vaccine Rule 24.

one is to provide a theory based on "sound and reliable medical or scientific explanation" which is "legally probable, not medically or scientifically certain" (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548−49 (Fed. Cir. 1994))); Decision at 16−30 (discussing the merits of each item of medical literature filed by Petitioner).[28]

As the Chief Special Master explained in his Decision, he simply required her to "knit[] together [] an overall theory that does not amount to speculation or unreasonable extrapolation." Decision at 53; *Cerrone*, 146 F.4th at 1122 ("The special master correctly explained that 'the evidence a claimant offers must, in totality, always accomplish one thing in the end: *preponderantly establish that the vaccine(s) at issue more likely than not can cause the relevant disease*.'" (emphasis in original)). This analysis is entirely consistent with the "heavy" burden the Vaccine Act imposes on petitioners raising off-Table claims. *Hodges*, 9 F.3d at 961 ("Bring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting—causation is conclusively presumed. Failing that, the heavy lifting must be done by the petitioner, and it is heavy indeed."); *Cerrone*, 146 F.4th at 1121 n.3. Accordingly, for the reasons explained below, the Court holds that Chief Special Master's well-reasoned analysis of Petitioner's prong one theory did not constitute legal error.

[28] The Court notes that Petitioner appears to understate in her brief what she must prove to satisfy *Althen* prong one. *See* MFR at 11 ("[O]ne reliable scientific methodology experts can use to establish a legally probable medical theory is to preponderantly prove that alleged vaccine causal relationship has biological credibility, *i.e.*, is supported by a plausible biological theory."); *see also id.* at 12 (describing prong one as "concluding a biological theory is plausible"). Petitioner's prong one burden is "to show a reliable medical theory of causation specific to the vaccine and injury in question, not merely one that is plausible." *Cerrone*, 146 F.4th at 1121 n.3. At Oral Argument, Plaintiff agreed that this is the correct standard. OA Tr. at 13:11−22. Indeed, the Federal Circuit has "repeatedly stated that 'simply identifying a "plausible" theory of causation is insufficient for a petitioner to meet her burden of proof.'" *Id.*

A. The Chief Special Master's Analysis of Petitioner's Medical Literature Did Not Constitute Legal Error.

Petitioner argues that the Chief Special Master's "erroneous assessment of the medical literature evidence" constitutes legal error. MFR at 12−20. *First*, she contends that the Chief Special Master assessed the evidence through rigorous medical standards—or "the lens of the laboratorian"—rather than "the vantage point of the Vaccine Act's preponderance standard." *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009); MFR at 12–13 (first citing *id.*; and then citing *Doles v. Sec'y of Health & Hum. Servs.*, No. 2023-2404, 2025 WL 1177875, at *6−8 (Fed. Cir. Apr. 23, 2025)). *Second*, Petitioner contends that the Chief Special Master improperly rejected circumstantial evidence supporting her prong one theory. MFR at 13–20. For the reasons stated below, the Court concludes that neither of these arguments provide a sufficient basis for setting aside the Decision.

1. The Chief Special Master Did Not Evaluate the Evidence "Through the Lens of the Laboratorian."

Petitioner argues that the Chief Special Master improperly assessed the evidence through rigorous medical standards—or "the lens of the laboratorian"—rather than "the vantage point of the [Vaccine] Act." *Andreu*, 569 F.3d at 1380; MFR at 12–13 (first citing *id.*; and then citing *Doles*, 2025 WL 1177875, at *6−8). The Court disagrees with Petitioner's contention.

As a general matter, Petitioner is correct that "[m]edical literature and epidemiological evidence must be viewed . . . not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380 (quoting *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991)). But this standard is best understood simply as contrasting the just over 50% likelihood required to make a preponderant showing with the "95% probability" required for attribution of causation in the medical field. *Andreu*, 569 F.3d at 1380; *Doles*, 2025 WL 1177875, at *3 ("So, a proffered medical

theory of causation is measured by preponderance of evidence, not by whether the theory satisfies the standards of medical research."); *Bunting*, 931 F.2d at 873 ("The standard of proof required by the Act is simple preponderance of evidence; not scientific certainty."). Although a "claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment . . . ." *Andreu*, 569 F.3d at 1379. This is precisely the role of the special master: to "judg[e] the merits of individual claims." *Hodges*, 9 F.3d at 961 ("Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims."); *Cerrone*, 146 F.4th at 1122 ("The special master correctly explained that 'the evidence a claimant offers must, in totality, always accomplish one thing in the end: *preponderantly establish that the vaccine(s) at issue more likely than not can cause the relevant disease*.'" (emphasis in original)). Indeed, "finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326.

Here, the Chief Special Master's thorough analysis was entirely consistent with this command. The Chief Special Master expressly recognized that "scientific evidence offered to establish *Althen* prong one is viewed 'not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard.'" Decision at 32 (quoting *Andreu*, 569 F.3d at 1380). Further, he dedicated almost two full pages of his analysis to explaining how the preponderance standard is applied in cases arising under the Vaccine Act. *Id.* at 52–54. In doing so, he made clear that his "evaluation of this claim [] does not amount to a

heightening of the preponderant burden, requiring certainty even though the evidentiary test does not." *Id.* at 53.

The Chief Special Master did not simply recite the proper standard; his application of this preponderance standard to the facts before him reflects that he considered the evidence through the proper "vantage point." *Andreu*, 569 F.3d at 1380; *see, e.g.*, Decision at 39 (acknowledging that "[s]ome elements of [Petitioner's] theory are wholly noncontroversial" but that "the theory, *in its totality* lacks sufficient preponderant support, even if some individually-reliable items of literature have been offered in this case"); *id.* at 42–43 (explaining that there were "too many missing links in the causation chain" to conclude that the Tdap vaccine likely leads to an AIH disease process, and explaining why the literature Petitioner provided in support of this claim did not ultimately "bridge th[e] evidentiary gap sufficiently").

Petitioner's citation to *Doles* does not support her argument. MFR at 7–9, 12–14. In *Doles*, the Federal Circuit held—on a narrow, fact-bound basis—that it was error to fault the relevance of a study "solely for the study's lack of *statistically significant* conclusions regarding patients identically situated to [the petitioner]." *Doles*, 2025 WL 1177875, at *8. There, the study in question involved the same injury and vaccines as those at issue in the case, and the Federal Circuit recognized that the study "contain[ed] circumstantial evidence which demonstrate[d] that [the petitioner's] vaccines" were capable of impacting her brain in the manner posited by her proposed medical theory. *Id.* at *4−5.

By contrast, here, the Chief Special Master did not exclude from his analysis or otherwise "fault" certain evidence simply because the data was not statistically significant. *See* Decision at 16–30 (discussing every item of medical literature Petitioner filed); *Doles*, 2025 WL 1177875, at *8. Rather, the Chief Special Master considered the totality of the evidence, and thoroughly

explained why, based on his judgment, the preponderance standard had not been met. *Id.* at 39 ("[Petitioner's] theory *in its totality* lacks sufficient preponderant support, even if some individually-reliable items of literature have been offered in this case." (emphasis in original)). This is precisely the sort of judgment which is squarely "within the purview of the fact finder." *Porter*, 663 F.3d at 1249 ("We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses . . . ."); *see R.J. ex rel. W.J. v. Sec'y of Health & Hum. Servs.*, 93 F.4th 1228, 1235 (Fed. Cir. 2024) ("It is within a special master's discretion to weigh evidence."); *Rogero v. Sec'y of Health & Hum. Servs.*, 748 F. App'x 996, 1001 (Fed. Cir. 2018) ("Determinations of relative weight of different evidence are generally for the trier of fact.").

Further, where the Chief Special Master declined to afford significant weight to certain items of evidence, he articulated a rational explanation for doing so. *Kirby*, 997 F.3d at 1381 ("[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." (alteration in original) (quoting *Lampe*, 219 F.3d at 1360)); *see, e.g.*, Decision at 40 (explaining the limitations of the Munyer, Nanan, Christen, Robertson, and Mieli-Vergani I articles as support for Petitioner's theory regarding the measles component of the MMR vaccine); *see also infra* Discussion § I.A.2. (discussing the Chief Special Master's analysis of Petitioner's case reports, and his reasons for declining to give those studies weight).

Petitioner also contends that because Respondent's experts reviewed the evidence through a medical lens, and the Chief Special Master relied heavily on their testimony, that the Chief Special Master, too, applied "rigorous" medical standards in assessing her prong one theory. MFR at 20. But the standard the *experts* applied has little to do with the standard the Chief Special

Master applied. This is especially true where, as here, the Chief Special Master so clearly explained how each item of evidence either supported or failed to support petitioner's theory. *See e.g.*, Decision at 42 (noting that da Silva Antunes "includes no discussion of AIH"); *id.* at 40 ("Christen, for example, only briefly mentions the measles vaccine, but notes that evidence connecting it to AIH was not corroborated over time."); *id.* at 46 ("Rennick has more to say about the function of the measles vaccine from an immunologic standpoint than it does about the vaccine's allegedly-pathogenic capacity (which is what is at issue in this case)."); *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360) ("[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.").

2. The Chief Special Master Did Not Improperly Reject Circumstantial Evidence.

Next, Petitioner argues that the Chief Special Master improperly declined to give weight to certain circumstantial evidence that she believes is relevant. MFR at 12−20 ("In his improper medical literature assessment, the Chief [Special Master], on the other hand, narrowly rejected every type of medical literature and scientific explanation provided, and then relying heavily on Respondent's opposing vantage point, assessed the evidence through the rigorous medical standards and narrowly concluded that the evidence was not scientifically or medically sufficient to meet the legally probable burden."). Respondent counters that "the Chief Special Master made clear that the problem with petitioner's evidence was not that it was circumstantial, but that it was insufficient to meet her burden." Resp. at 15–16. In Respondent's view, the Chief Special Master "clearly did not demand 'complete and direct proof.' He did, however, demand *preponderant* proof, which is required by statute and precedent, and which he rightly found to be lacking." *Id.* at 17 (citation omitted) (citing *Althen*, 418 F.3d at 1280)).

The Court agrees with Respondent. As an initial matter, Petitioner did not cite any evidence that the Chief Special Master failed to consider in his Decision. *See generally* MFR. Nor could she, as he addressed every piece of medical literature she had presented. Decision at 16–30, 39–48. But more to the point, as noted above, the Chief Special Master simply undertook the analysis which was required of him: determining whether Petitioner's evidence, "in totality . . . *preponderantly establish[es] that the vaccine(s) at issue more likely than not can cause the relevant disease*." *Cerrone*, 146 F.4th at 1122; *see, e.g.*, Decision at 41 n.24 (explaining that "the evidence of a more direct vaccine-AIH association is not evident (underscoring the degree to which Petitioner must rely on more indirect and circumstantial proof—and here, that proof too proves inadequate)"); *Olson v. Sec'y of Health & Hum. Servs.*, 135 Fed. Cl. 670, 679 (2017), *aff'd*, 758 F. App'x 919 (Fed. Cir. 2018) ("[A]s Petitioner offered evidence of a specific biologic mechanism, the Special Master was then required to consider it and evaluate its persuasiveness."); *Porter*, 663 F.3d at 1249; *R.J.*, 93 F.4th at 1235; *Rogero*, 748 F. App'x at 1001.

Here, the Chief Special Master provided detailed reasons for declining to afford significant weight to both certain items of medical literature and aspects of Petitioner's theory; his analysis and the rationales provided were rational, well-supported by the record, and thoroughly explained in the Decision. For instance, the Chief Special Master dedicated several pages of his analysis to the "primary thrust" of Petitioner's causation argument—that the measles component of the MMR vaccine caused immunosuppression which, in turn, "open[ed] the door" for her AIH. *See* Decision at 39–42; *see also id.* at 16, 21–24 (summarizing and analyzing each of the articles supporting this component of Petitioner's theory). In his analysis, the Chief Special Master explained that two of the articles Petitioner relied upon, Nanan and Munyer, were (i) dated and (ii) did not stand for the proposition that "that the studied patients experienced *meaningful* immune suppression, such that

any disease became more likely after receipt of the vaccine (let alone AIH)." *Id.* at 40 (emphasis in original). This analysis was reasonable, given the Chief Special Master's findings that Nanan did not offer evidence that the patients considered in the study "experienced any actual immune suppression sufficient to cause disease," and Munyer observed that "experimental stimulation of blood samples revealed an impairment in immune cells," but that "*actual, in vivo vaccination did not*." *Id.* at 23 (citing Hr'g Tr. at 163); *id.* at 24 (describing Munyer as "a single (and facially-outdated) 'brick' in the causation theory 'wall' Petitioner seeks to build," and noting that Munyer did not "itself establish vaccine-related pathology").

In her Motion, Petitioner specifically focuses on a bystander activation theory.[29] MFR at 13–20. Specifically, Petitioner faults the Chief Special Master for concluding that Dr. Gish's bystander activation theory was not "yoked to sufficient reliable proof." *Id.* at 13 (citing Decision at 47). However, the Chief Special Master's approach to this aspect of Petitioner's theory was reasonable. Decision at 46–47. The Chief Special Master explained that one of the articles on which Petitioner relied for this point, Benn, "focused on the *positive*, secondary effects of [] nonspecific immune stimulation, rather than supporting the contention that vaccine-associated bystander activation is harmful." *Id.* (emphasis added) (citing Benn at 432, 436–37); *see also id.*

[29] Petitioner contends that "Respondent's experts agree" that "bystander activation is a reputable biological mechanism" which is "the unexpected activation of immune cells." MFR at 13 (citing H'rg Tr. at 158−59). However, in the portion of the transcript Petitioner cites, Dr. MacGinnitie expressly stated that "no literature that was provided suggest[ed] that vaccination can cause bystander activation," and further that Petitioner's medical records did not show that she "had excessive inflammation immediately after vaccination." H'rg Tr. at 159:14–160:23. This testimony supported the Chief Special Master's conclusion that "Dr. MacGinnitie persuasively explained that usually bystander activation would only be thought to occur in the presence of active inflammation due to an infectious process," and—importantly—this "was never shown to have happened in this case." Decision at 46–47 (citing H'rg Tr. at 158–60); *Moberly*, 592 F.3d at 1324 (holding special master did not err in rejecting a theory of causation where "there was no evidence in the record suggesting that the proposed mechanism was at work in [the petitioner's] case").

at 17 ("Benn, however, primarily focuses on the *positive* rather than pathologic indirect effects of vaccination."(emphasis in original)). And more broadly, the Chief Special Master explained that although Dr. Gish's assertions were "consistent with how AIH likely unfolds," Dr. Gish had not provided enough proof that the vaccine "can be an aspect of the disease process." *Id.* at 47.

Petitioner also argues that the Chief Special Master "incorrectly discounted the probative relevance" of the case reports she presented. MFR at 17−20. This argument, too, is unavailing. The Chief Special Master "articulated a rational basis" for declining to give weight to the case report evidence cited by Petitioner. *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360).[30]

The Chief Special Master explained that many of Petitioner's case reports "do not involve the Tdap or MMR vaccines (or even comparable wild virus infections)," which "greatly saps such case reports of evidentiary value in the context of this case." Decision at 45. Therefore, in the Chief Special Master's view, "the paucity of case reports specific to the vaccines at issue and AIH do not appreciably add to the total picture." *Id.* at 46. In other words, he did not wholly discount the value of this evidence; he simply explained why, in this particular case, the case reports that were filed—many of which did not involve the relevant vaccine or disease at issue—did not lend much credence to Petitioner's causation theory. This conclusion was plainly rational, given that Petitioner's task is to demonstrate a theory that is "specific to the vaccine and injury in question." *Cerrone*, 146 F.4th at 1121 n.3; OA Tr. at 13:11−22; *see Herms v. Sec'y of Health & Hum. Servs.*,

[30] Although there is some disagreement regarding the evidentiary value of case reports, there does appear to be some consensus that they can provide evidence of association or correlation, but do not prove "causation definitively"—and accordingly there are limits to their evidentiary value. *Echols v. Sec'y of Health & Hum. Servs.*, 165 Fed. Cl. 9, 18 (2023) ("[C]ase reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value' . . . [but] 'the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight." (quoting *Paluck v. Sec'y of Health & Hum. Servs.*, 104 Fed. Cl. 457, 475 (2012)); *Broussard v. Sec'y of Health & Hum. Servs.*, No. 18-302V, 2024 WL 1829210, at *8–14 (Fed. Cl. Apr. 4, 2024).

No. 19-70V, 2024 WL 1340669, at *21 (Fed. Cl. Spec. Mstr. Mar. 4, 2024) ("Petitioner does not explain how data from other unrelated vaccines could be extrapolated to the vaccines at issue here and accordingly, the data is not persuasive."), *review denied*, 173 Fed. Cl. 1 (2024).

Petitioner again analogizes to *Doles*, asserting that "[l]ike the individual data relied upon in *Doles*, Dr. Gish relied on relevant, even if not medically certain case reports supporting a theory that the identical vaccine components, especially when administered in combination, are associated with onset AIH or acute hepatitis symptoms." MFR at 19−20 (citing *Doles*, 2025 WL 1177875, at *8). As explained above, this case was different from *Doles*, in that the study in question in *Doles* did include the vaccine and injury at issue, and the judge had faulted a study's relevance simply due to a lack of "*statistically significant* conclusions regarding patients identically situated to" the petitioner. *Doles*, 2025 WL 1177875, at *8 (emphasis in original). By contrast, here, the Chief Special Master observed that (i) case reports in general are not strong evidence of causation and (ii) here, as many of Petitioner's case reports involved different vaccines and injuries than those at issue, they merit even less probative weight. Decision at 45–46. The Chief Special Master did not wholly discount the value of this form of evidence—he reasonably acknowledged that case reports "may be the place to *start* a causation inquiry, but that effort must then build upon other evidence that suggests the temporal/coincidental observation of post-vaccination injury is scientifically meaningful." *Id.* at 46.

In sum, the Chief Special Master's analysis reflects that he carefully considered the medical literature Petitioner presented, and found certain articles to provide only weak evidence of causation because they were not sufficiently tethered to the concept of *vaccine* causation of the *disease at issue*. *Cerrone*, 146 F.4th at 1120–1122 & n.3; *Herms*, 2024 WL 1340669, at *21; *Porter*, 663 F.3d at 1249; *R.J.*, 93 F.4th at 1235; *Rogero*, 748 F. App'x at 1001. Accordingly,

Petitioner's argument that the Chief Special Master improperly rejected circumstantial evidence fails.

B. The Chief Special Master Did Not "Cloak the Application of an Erroneous Legal Standard in the Guise of a Credibility Determination."

Petitioner's next argument is an extension of her prior arguments. She argues that the Chief Special Master purportedly imposed a heightened burden at prong one by "disguising an impermissible legal burden" as a credibility determination, specifically by crediting Respondent's expert's theories over Dr. Gish's. MFR at 20−22. According to Petitioner, this determination is "squarely within this Court's review," because this aspect of the Chief Special Master's analysis amounted to "an improper evidentiary burden." *Id.* at 21. The Court rejects Petitioner's argument.

Special masters are "entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and if, appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1325–26; *see also Cerrone*, 146 F.4th at 1124–25 ("[C]redibility determinations are virtually unreviewable on appeal."); *Munn*, 970 F.2d at 871 ("[O]f course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."). "The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). Petitioner is correct that special masters cannot "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu*, 569 F.3d at 1379. But this simply means that the fact finder cannot "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." *Moberly*, 592 F.3d at 1326. That is not what occurred here.

Here, the Chief Special Master dedicated an entire section of his prong one analysis to explaining why he was more persuaded by Respondent's experts than Petitioner's. Decision at 47. First, the Chief Special Master recognized that Dr. Gish was "certainly *qualified* to offer an opinion in this case . . . given his expertise in hepatology." *Id.* However, the Chief Special Master explained that Dr. Gish lacked expertise in both "AIH's pathogenesis" and immunology, and that his contentions were "generalized and somewhat broad." *Id.* Further, Respondent's expert, Dr. Crippin—also a hepatologist—offered competing testimony, and Dr. Gish's opinions "were persuasively rebutted by Dr. MacGinnitie—*the sole immunologist* who testified" in the case. *Id.* The Chief Special Master also noted that it was difficult to follow Dr. Gish's theory, which the Chief Special Master described as "excessively wordy, meandering, and unclear in the theory it embraced," which "detract[ed] from the theory's persuasiveness." *Id.* n.26. For all of these reasons, the Chief Special Master gave Dr. Gish's contentions less weight than Respondent's expert. *Id.* at 47–48 ("Dr. Gish's theory did not add up, independent of his expertise as a hepatologist, and even if some of its components were individually reliable.").

The Court concludes that the Chief Special Master "articulated a rational basis" in support of his determination to afford less weight to Dr. Gish's testimony than that of Dr. Crippin and Dr. MacGinnitie. *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360). It was reasonable for the Chief Special Master to consider the experts' respective areas of expertise and to consider the clarity—or lack thereof—of the theories presented. *Olson v. Sec'y of Health & Hum. Servs.*, 758 F. App'x 919, 925 (Fed. Cir. 2018) ("The Special Master did not require evidence from an immunologist, but rather properly evaluated [the expert's] individual competence to opine on the matters at issue."). Petitioner's belief that there is "more than adequate objective evidence supporting Dr. Gish's opinion" is not a sufficient basis for finding that the Chief Special Master's

analysis of the expert testimony in this case was legal error. MFR at 21. Accordingly, the Court discerns no legal error in the Chief Special Master's weighing of the expert testimony in this case. *Cerrone*, 146 F.4th at 1124–25 (finding no error where the Chief Special Master concluded that petitioner's expert opinions were less credible and persuasive than those of respondent's expert); *Tullio v. Sec'y of Health & Hum. Servs.*, 149 Fed. Cl. 448, 475 (2020) ("Although the Special Master in his decision appears to give more credence to the respondent's experts than to petitioner's experts, he did carefully review all the evidence before him in reaching his ultimate conclusion denying compensation and was not arbitrary or capricious in doing so.").

C. The Chief Special Master's Factual Findings Were Not Arbitrary or Capricious.

In addition to the legal challenges discussed above, Petitioner also appears to challenge two of the Chief Special Master's factual conclusions. MFR at 15. *First*, she argues that the Chief Special Master's conclusion that Dr. Gish did not adequately substantiate molecular mimicry as a causal mechanism for AIH was arbitrary. *Id.* However, the Chief Special Master reasonably concluded that there is "very little evidence in this record that would support molecular mimicry due to vaccination as a mechanistic explanation for AIH," given that Dr. Gish did not (i) demonstrate a homology,[31] and (ii) "did not otherwise offer evidence suggesting that the vaccines or their wild viral counterparts are associated with any antibodies thought to drive AIH or be involved in its pathogenesis." *Id.* at 44. This conclusion was reasonable, particularly in view of Dr. MacGinnitie's testimony that he was not aware of any evidence in medical literature of molecular mimicry occurring between the components of the MMR and Tdap vaccines and liver antigens. *See* Hr'g Tr. at 156:4–18; *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1360–

[31] In the context of molecular mimicry, a "homology" is a similar sequence found in both a pathogenic or disease-causing protein and a human or "self" protein which would cause the immune system to "cross-react" (or attack) both. *See* H'rg Tr. at 156:19–157:24.

61 (Fed. Cir. 2013) (affirming rejection of petitioner's molecular mimicry theory where "[t]he special master reasonably considered the lack of evidence connecting the cross-reactivity observed by [the petitioner's study] to the facts of [the p]etitioner's case to weigh" against an expert's molecular mimicry theory); *Pierson v. Sec'y of Health & Hum. Servs.*, No. 17-1136V, 2022 WL 322836, at *25 (Fed. Cl. Jan. 19, 2022) ("[A] petitioner must offer more than superficial invocation of molecular mimicry as the causal mechanism.").

Second, Petitioner argues that "[t]he Chief [Special Master's] finding that 'other proposed mechanisms' were inadequate was arbitrary, as he recognized that bystander activation is 'another way' AIH might occur." MFR at 15 (quoting Decision at 46). However, as Respondent notes, in the portion of the Decision Petitioner cites, the Chief Special Master simply recounted Petitioner's argument with respect to bystander activation, and did not accept the theory himself. Decision at 46 ("Petitioner proposed bystander activation of nonspecific immune cells (and/or suppression leading to expansion of these immune cells) as another way AIH might occur."). As explained above, the Court finds that Chief Special Master's conclusions with respect to Petitioner's bystander activation theory were reasonable. *See supra* Discussion § I.A.2.

* * * * *

In sum, the Court concludes that the Chief Special Master properly evaluated Petitioner's prong one theory, and held her to her burden to "show a reliable medical theory of causation specific to the vaccine and injury in question, not merely one that is plausible." *Cerrone*, 146 F.4th at 1121 n.3. As another judge of this court has explained: "[This Court's] role in evaluating a special master's decision is not to quibble with the weight afforded certain pieces of evidence or substitute our determinations of credibility. Rather, we are empowered under the Vaccine Act only to act as a check on unreasonable decision-making." *Cerrone v. Sec'y of Health & Hum. Servs.*, 168 Fed. Cl. 745, 755 (2023), *aff'd*, 146 F.4th 1113.

Here, the Chief Special Master's decision-making in this case was reasonable and well-supported by the record. The Chief Special Master did not, as Petitioner contends, impose a heightened burden upon her prong one theory by any means—not by evaluating her evidence "through the lens of the laboratorian," not by improperly rejecting circumstantial evidence, and not by disguising a heightened burden as a credibility determination. *Andreu*, 569 F.3d at 1379–80. Rather, the Chief Special Master reasonably concluded that her theory "*in its totality* lacks sufficient preponderant support, even if some individually-reliable items of literature have been offered in this case." Decision at 39 (emphasis in original). Put another way, although Petitioner had offered several threads of evidence, those threads did not "knit[] together into an overall theory that does not amount to speculation or unreasonable extrapolation." *Id.* at 53−54 ("To meet the preponderant standard, sufficient evidence must be presented to allow for the conclusion that the vaccine 'more likely than not' acted as proposed. That was not accomplished in this case, even though Petitioner has offered some reliable evidence plus an experienced hepatologist to convey her causation opinion."). Accordingly, the Court rejects Petitioner's argument that the Chief Special Master's evaluation of her prong one theory constitutes legal error.

II. The Chief Special Master's Conclusions as to Prong Two Were Not Arbitrary, Capricious, or Otherwise Contrary to Law.

Petitioner next argues that the Chief Special Master's analysis of prong two warrants reversal for two reasons. *First*, she contends that his conclusion that "[t]he medical record simply does not contain sufficient facts suggesting the vaccines had anything to do with Petitioner's disease," was arbitrary and capricious. MFR at 22 (citing Decision at 51). *Second*, she contends that the Chief Special Master erred by "ignor[ing] case report evidence that is circumstantially on

point with Mrs. Exum's facts," along with other medical literature, which, she contends, "circumstantially support" a finding of vaccine causation in Petitioner's case.[32] *Id.* at 22–23.

Evidence offered in support of one prong can support the other *Althen* prongs. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("We see no reason why evidence used to satisfy one of the *Althen* [] prongs cannot overlap to satisfy another prong."). However, this does not in any way lessen Petitioner's burden to prove that the vaccine caused her injury *in her particular case.* The second prong of *Althen* "requires the petitioner to prove, by a preponderance of the evidence, that the medical theory was in fact the mechanism that *resulted in the injury at issue*." *Cerrone*, 146 F.4th at 1121 (emphasis added) (citing *Broekelschen*, 618 F.3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case . . . .")); *Capizzano*, 440 F.3d at 1327 ("The second prong of the *Althen* [] test is not without meaning."); *Nussman v. Sec'y*

[32] Petitioner also makes a passing suggestion that the burden had shifted to Respondent to prove that a "factor[] unrelated" to the vaccine was more likely than not the cause of Petitioner's AIH, and that Respondent failed to make that showing. *See* 42 U.S.C § 300aa-13(a); *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1357 (Fed. Cir. 2010) ("While the burden of proving a prima facie case is on the petitioner, the government has the burden of showing the injury or death was caused by a 'factor unrelated.'"). However, only "[o]nce *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 (emphasis added) (citing *Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007)). The Chief Special Master made this precise point in his analysis and then stated that he "ha[d] not found the burden should be, or was, shifted here." Decision at 50. To the extent that Petitioner argues that the Chief Special Master erred in denying her compensation because the Government could not prove that a factor unrelated was the cause of her AIH, her argument is necessarily unavailing. *Winkler v. Sec'y of Health & Hum. Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) ("[T]he failure to prove an alternate cause does not obviate the need for proof of causation by the vaccine."). Said differently, regardless of whether the Government can preponderantly prove that a factor unrelated to the vaccine caused the disease, the onus is always on the Petitioner to first prove her prima facie case. The Chief Special Master, in his thorough and well-reasoned opinion, concluded that Petitioner had not done so. Decision at 51 ("The medical record simply does not contain sufficient facts suggesting the vaccines had anything to do with Petitioner's disease. The second *Althen* prong has not been preponderantly established.").

of Health & Hum. Servs., 83 Fed. Cl. 111, 121 (2008) ("Proof of a medical theory explaining how a vaccine could cause an injury is analytically distinct from proof that a vaccine actually did cause the injury."). In other words, the Vaccine Act requires that Petitioner preponderantly prove a "logical sequence of cause and effect"—that the vaccine more likely than not "did cause" her illness *here*. *Boatmon*, 941 F.3d at 1359, 1362 (quoting *Althen*, 418 F.3d at 1278).

A. The Chief Special Master's Conclusion that Petitioner Did Not Prove a "Logical Sequence of Cause and Effect" Was Not Arbitrary and Capricious.

Petitioner broadly contends that the Chief Special Master's conclusion that "[t]he medical record simply does not contain sufficient facts suggesting the vaccines had anything to do with Petitioner's disease," was arbitrary and capricious. MFR at 22 (citing Decision at 51). The Decision, however, reflects that the Chief Special Master considered, appropriately weighed, and "dr[ew] plausible inferences and articulated a rational basis" for his conclusion with respect to prong two. *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360).

The Chief Special Master gave several reasons for his conclusion that Petitioner had not preponderantly proven a "logical sequence of cause and effect showing that the vaccination was the reason for the injury," as required to meet prong two. *Althen*, 418 F.3d at 1278; Decision at 48–51. *First*, he noted the "absence of objective record proof" in Petitioner's medical records that would support the inference that Petitioner had an aberrant reaction to the vaccines. Decision at 48. This was the primary basis for his conclusion. *Id.* *Second*, the Chief Special Master noted that he had not identified any instance in which one of Petitioner's treating physicians associated her AIH with the vaccines. *Id.* *Third*, the Chief Special Master explained that although the non-specific symptoms which manifested when she returned from her travel, such as fatigue, were likely related to her AIH, those symptoms were insufficient to carry her burden of proof. *Id.* at 48–49. *Fourth*, he noted the presence of risk factors for AIH—other than the vaccines—which

were present in Petitioner's medical history. *Id.* at 49–50. These included her use of anti-malarial medication, supplements, and foreign travel. *Id.* at 49.

This analysis was legally proper. Reversible error is "extremely difficult to demonstrate" where the special master has "considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Hines*, 940 F.2d at 1528; *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360). Here, the Chief Special Master clearly did so. His analysis—which spans roughly three full pages—makes clear that he considered the relevant evidence, and it was entirely plausible for him to infer a lack of a causal connection between the vaccine and Petitioner's AIH given the absence of evidence of such a connection in her medical records. *See, e.g.*, Pet. Ex. 3 at 282 (PA noting "unclear etiology" of Petitioner's condition on November 28, 2018); *id.* at 222 (hematologist diagnosing Petitioner with hepatitis on January 4, 2019 and noting that the "etiology [of her liver disease] is as yet unknown"); *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("Medical records, in general, warrant consideration as trustworthy evidence."); *Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting *Althen*, 418 F.3d at 1280)). The Chief Special Master even went so far as to explain the specific types of evidence that *would* indicate an aberrant response to the vaccines, such as inflammation or an infection. Decision at 48.

Petitioner focuses on the nonspecific symptoms that Petitioner had experienced, like fatigue and nausea, but the Chief Special Master reasonably explained that those symptoms "are not enough of a basis to conclude that the two vaccines Petitioner received 'did cause' her AIH." MFR at 22 (citing Decision at 52); Decision at 48. As the Chief Special Master noted, those

symptoms "did not immediately merit treatment" and "arguably were consistent with her pre-vaccination health." *Id.* ("I also have not ascertained any instance where any of Petitioner's treaters proposed the vaccinations explained her AIH (including Drs. Oloruntoba or Wu))." Petitioner otherwise does not appear to argue that these specific reasons the Chief Special Master gave for his decision were irrational, nor does she point to evidence in Petitioner's medical records that the Chief Special Master ignored. *See generally* MFR at 22–24. Indeed, when asked by the Court to "put aside all the medical literature for a moment and just focus[] on Ms. Exum's medical records" and explain "what, for purposes of [p]rong two, is evidence that is specific to Petitioner" that would support her case, Petitioner's counsel responded by continuing to discuss the case report evidence. OA Tr. at 37:22−38:5. At bottom, Petitioner simply takes issue with his ultimate conclusion—broadly asserting that "the totality of the medical literature evidence in combination with her medical facts, the logical progression of her medical sequence, the individual case report data, the biologically credible bystander activation theory, and the lack of any alternate causal factors . . . more than" satisfies the preponderance standard. *Id.* at 24. This Court, however, 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. In sum, the Chief Special Master plainly "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis" for his conclusion as to prong two. *Kirby*, 997 F.3d at 1381 (quoting *Lampe*, 219 F.3d at 1360).

B. Chief Special Master's Analysis of Petitioner's Medical Literature Did Not Constitute Legal Error with Respect to Prong Two.

Petitioner next contends that the Chief Special Master erred by "ignor[ing] objective case report evidence that is circumstantially on point with Mrs. Exum's facts," along with other medical

literature, which, she contends, circumstantially support a finding of vaccine causation in Petitioner's case. MFR at 22–23.

This argument is unavailing. Petitioner fails to point to specific studies that the Chief Special Master ignored, and also fails to explain precisely how these studies would lend support to the claim that Petitioner's vaccines caused her AIH *in her particular case*. *Id.* The Chief Special Master discussed every item of medical literature Petitioner filed in this case—summarizing and discussing the merits of each.[33] Decision at 16–30. Given the nature of the "did cause" inquiry at prong two, which is specific to each petitioner, it was not improper for the Chief Special Master to focus on the medical records and other evidence relating to Petitioner's specific case. *Cerrone*, 146 F.4th at 1121 (citing *Broekelschen*, 618 F.3d at 1345; *Capizzano*, 440 F.3d at 1327; *Nussman*, 83 Fed. Cl. at 121.

Petitioner argues that the medical literature on which Dr. Gish relied shows that "a vaccine causal theory is the most probable medical cause in [Petitioner's] AIH case." MFR at 23. However, this conclusory argument that a certain category of evidence, in general, supports Petitioner's prong two argument is insufficient to demonstrate any legal error. This is particularly true where, as here, Petitioner fails to point to *specific* evidence that the Chief Special Master failed to consider.

CONCLUSION

For the reasons stated above, the Court finds that the Chief Special Master's thorough examination of the record in Mrs. Exum's case resulted in a decision that was not contrary to law.

[33] Even if he had not done so, under Federal Circuit precedent, reviewing courts "generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016).

The Chief Special Master's Decision denying her petition is therefore **SUSTAINED**, and Petitioner's Motion for Review (ECF No. 87) is **DENIED**. The Clerk of the Court is **DIRECTED** to enter Judgment consistent with this Memorandum and Order. The parties are directed to **CONFER** and **FILE** a Notice by **September 29, 2025**, attaching a proposed public version of this sealed Memorandum and Order, identifying any information subject to redaction pursuant to Vaccine Rule 18(b).

IT IS SO ORDERED.

Eleni M. Roumel

ELENI M. ROUMEL
Judge