

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1937V

MICHAEL JOHNSON,

Petitioner,

Chief Special Master Corcoran

Filed: March 25, 2026

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.

James V. Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION¹

On September 30, 2021, Michael Johnson filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petition (ECF No. 1). Petitioner alleges his receipt of an influenza (“flu”) vaccine on October 28, 2020, caused him to develop “hemolytic anemia resulting in permanent tooth loss.” *Id.* at Preamble.

Although the matter had been set for hearing, the parties later opted to resolve the claim on the basis of the written record, and have filed briefs in support of their respective positions. Petitioner’s Brief, dated May 19, 2025 (ECF No. 68) (“Br.”); Respondent’s Response, dated Aug. 21, 2025 (ECF No. 70) (“Opp.”); Petitioner’s Reply, dated Sept. 25, 2025 (ECF No. 71) (“Reply”). Now, for the reasons set forth in greater detail below, I deny entitlement.

¹ Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual History

Vaccination and Early Reaction

Mr. Johnson was 50 years old when he received the flu vaccine on October 28, 2020, at Bon Secours Mercy Health Employee Health Services in Chesapeake, Virginia. Ex. 9 at 22; Ex. 5 at 1. At the time of vaccination, his medical history included stage 1 sarcoidosis,³ hypertension, hyperlipidemia, unstable angina, left bundle branch block, chronic fatigue syndrome, recurrent kidney stone, type II diabetes mellitus, idiopathic peripheral autonomic neuropathy, “dizziness and giddiness,” cervical disc disorder with radiculopathy, panic disorder, unspecified peripheral vascular disease, obstructive sleep apnea, anxiety, and smokeless tobacco abuse. *See* Ex. 1 at 456; Ex. 8 at 18, 23, 30, 35, 41, 50; Ex. 9 at 2. In addition, Petitioner is a veteran, and has a ten percent disability rating for traumatic arthritis attributable to his military service. Ex. 4 at 77.

Five days later, on November 2, 2020, Petitioner went to an urgent care center complaining of “[c]hest tightness, Chills, Body Aches, Hand tingling and Fatigue,” and reporting “Onset: 5 Day(s)” (meaning the same day as vaccination). Ex. 1 at 2–6. Petitioner stated that he “got a flu shot last week and for the last 5 days he has been extremely fatigued, with chest tightness with body aches, intermittent hand tingling, intermittent nausea, and chills.” *Id.* (Petitioner’s affidavit offered in support of his claim also maintains that he felt like he had caught the flu “[r]ight after receiving the vaccine,” and was experiencing chills, tingling in his hands, and was having difficulty walking. Ex. 6 at 1).

The physical exam performed at this time yielded normal results. Ex. 1 at 2–6. However, a complete blood count (“CBC”) was abnormal, including a low red blood cell (“RBC”) count of 2.16 (range: 4.14–5.8), low hemoglobin of 8 (range: 13–17.7), and low hematocrit of 22.3% (range: 37.5–51%). *Id.* at 10. Petitioner was assessed with weakness, myalgias, abnormality of RBCs, and anemia, and sent to the emergency department (“ED”) for further evaluation. *Id.* at 6–7. There, Petitioner appeared “pale and ill appearing.” Ex. 2 at 458. A second CBC test produced abnormal results, and direct antiglobulin testing (“DAT” or “Coombs test”)⁴ was positive for

³ “Sarcoidosis” is defined as “a chronic, progressive, systemic granulomatous reticulosis of unknown etiology, characterized by hard tubercles (q.v.). It can affect almost any organ or tissue, including the skin, lungs, lymph nodes, liver, spleen, eyes, and small bones of the hands and feet. Laboratory findings may include hypercalcemia and hypergammaglobulinemia. There is usually low or absent reactivity to tuberculin, and in active cases, the Kveim test is positive.” *Sarcoidosis*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=44637&searchterm=sarcoidosis> (last visited Mar. 25, 2026).

It is not evident from the filed record in this case how long Petitioner’s prior sarcoidosis diagnosis existed, or when it was first proposed by past treaters.

⁴ “Antiglobulin test” is “a test for the presence of nonagglutinating antibodies against red blood cells, using antihuman globulin antibody to agglutinate cells coated with the nonagglutinating antibody. The direct antiglobulin test detects antibodies bound to circulating red cells in vivo. It is used in the evaluation of autoimmune and drug-induced immune

immunoglobulin G (“IgG”) and C3b/C3d. *Id.*

Later that same day, Petitioner was admitted to Maryview Medical Center for treatment of anemia, and he remained hospitalized for five days. Ex. 2 at 455–64. On admission, hospitalist Nabeel Mohamed, M.D., noted Petitioner’s receipt of a “flu shot a week ago,” but proposed that the “[e]tiology of the anemia is uncertain at this point,” ordering additional work-up and a hematology consultation. *Id.* at 470. Later, internist Jacob Peterson, M.D., described Petitioner as suffering from a “warm autoimmune hemolytic anemia of unknown trigger.” *Id.* at 477. Dr. Peterson added that Petitioner was “not on any medications that are classically associated with hemolytic anemia, but recent nonspecific illness may represent a viral trigger.” *Id.* at 542.

Petitioner was also at this time evaluated by a hematologist, Dr. Moussa Sissoko, who assessed him with Coombs-positive hemolytic anemia, based on the “DAT . . . with positive IgG as well as positive C3 B/C3d.” Ex. 2 at 518, 542–48. It was proposed that Petitioner receive a tapering steroid treatment plus Rituxan (a monoclonal antibody treatment used for some autoimmune conditions). *Id.* at 548. Dr. Sissoko also opined that “[p]atient might need not to have flu shot anymore since he said that every time he has a flu shot [h]e gets sick. I would recommend in the future to have nasal flu instillation instead of IM.” *Id.* Mr. Johnson was discharged on November 7, 2020, in stable condition, with a diagnosis of hemolytic anemia. *Id.* at 464. Because of a slow response, his steroid treatment was extended, and another physician instructed Petitioner not to receive the flu vaccine in the future. *Id.* at 465, 469, 482.

That November, Petitioner had several follow-up visits as an outpatient with hematologist Tien Do, M.D. *See, e.g.*, Ex. 3 at 2–4. Petitioner reported having difficulty sleeping and feeling angry (likely a side effect of his steroid dosage), plus a rash. *Id.* A record from one of these visits indicated that he had experienced some kind of allergy to the flu vaccine causing an “[u]nknown” reaction, and Dr. Do noted that Petitioner had reported post-vaccination cough and aches. *Id.* at 2–4, 11. But Petitioner’s CBC labs were “slow[ly] improving from previous numbers,” and he was assessed with autoimmune hemolytic anemia requiring further treatment with steroids and Rituxan. *Id.* at 11.

At a subsequent visit with Dr. Do later in November 2020, Petitioner reported that “he had two blisters in his mouth that eventually popped and made him lose two teeth,” adding that when in the ED he had been informed that a mouth infection due to the medications he was receiving had likely occurred. *Id.* at 27–28. Petitioner “also complain[ed] of a tickle in this throat, heart pounding very ha[r]d then slowing way down, stiff fingers that he has to pull back into place, swelling in both feet, still not sleeping and terrible mood swings” that had “gotten worse.” *Id.* Dr.

hemolytic anemia and erythroblastosis fetalis. The indirect antiglobulin test detects serum antibodies that bind to red cells in an in vitro incubation step. It is used in typing of erythrocyte antigens and in compatibility testing (cross-match).” *Antiglobulin test*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=112414> (last visited Mar. 25, 2026).

Do prescribed some additional medications, and on that same day his Rituxan treatments were concluded. Ex. 2 at 203–07.

2021-22 Treatment and Cessation of Anemia Signs

In early January 2021, Petitioner was hospitalized at the Hampton Veterans Affairs Medical Center for “fever, malaise, chest tightness of one day duration.” Ex. 4 at 64. At this time, he tested positive for COVID-19. *Id.* at 66. Petitioner was discharged in stable condition with the diagnoses “[a]utoimmune hemolytic anemia on chronic steroid; Steatosis of liver; Sarcoidosis, pulmonary; Chronic fatigue syndrome; Obesity; Chronic post-traumatic stress disorder; Diabetes II likely [secondary to] chronic steroid use; Kidney stone, [status post] removal; sleep apnea, not on CPAP at this time.” *Id.* at 281. Later that month he returned to an emergency department reporting chest pain and ongoing COVID-19 symptoms, but was quickly discharged in stable condition, with the assessment that his symptoms were likely due to COVID. *Id.* at 220–26, 265–72.

Petitioner also continued to treat for his previously-diagnosed hemolytic anemia. He had a telephonic consultation in late-January 2021 with Dr. Do. Ex. 3 at 47–48. He now reported lingering symptoms he deemed related to his COVID infection,⁵ and Dr. Do addressed further steroid tapering, advising a follow-up with a dermatology specialist for any steroid-related rash. *Id.* Later that spring, serologic monitoring revealed improved CBC results (a slightly low RBC count of 4.4 (range: 4.7–6.1), normal hemoglobin of 14.7 (range:14–18), normal hematocrit of 44.2% (range:42–52%), and normal platelet count of 181 (range: 140–440)). Ex. 4 at 30.

Mr. Johnson saw Dr. Do again on March 29, 2021 (now five months post-vaccination), and complained of “swelling in the left leg, redness in both legs, rash on left arm that is itchy and SOB.” Ex. 3 at 60–61. A repeat CBC again yielded good results—a normal RBC count of 4.47 (range: 4.1–5.1), a normal hemoglobin of 14.6 (range: 12–16), normal hematocrit of 42.9% (range: 36–48%), and a normal platelet count 156 (range: 40–440). *Id.* at 65–66. By this time, Petitioner had completed his prednisone taper, and the plan was to continue to periodically monitor his CBC, to refer petitioner to a pulmonologist for his shortness of breath from COVID-19, and for Petitioner to follow-up with his dermatologist regarding his rash. *Id.* at 68.

Two months later, on May 19, 2021, Petitioner took himself again to a hospital emergency department, complaining of “left sided upper back/flank pain” for one week, plus evaluation of abrasions from a fall the prior day. Ex. 4 at 152, 159, 165. A repeat CBC performed at this time again yielded normal results (RBC count of 4.86 (range: 4.7–6.1), hemoglobin of 15.4 (range:14–18), hematocrit of 46.4% (range:42–52%)), but a slightly low platelet count of 137 (range: 140–

⁵ Throughout this timeframe, Petitioner received other kinds of treatments associated with his ongoing COVID infection recovery, but they do not bear on this claim’s outcome.

440). *Id.* at 30. Petitioner was prescribed pain medication and discharged in stable condition. *Id.* at 165. Another CBC performed in early June was also normal. *Id.* at 30.

On August 30, 2021, Mr. Johnson’s primary care physician consulted an infectious disease physician related to the “risk/benefit of COVID vaccines.” Ex. 10 at 372. At this time, Petitioner’s documented history included “severe autoimmune hemolytic anemia after flu vaccine.” *Id.* However, the specialist’s opinion was that “[a]utoimmune hemolytic anemia has not been reported as a common adverse reaction,” with at most a possible association with the COVID vaccine. *Id.*

Over three months later, in mid-December 2021, Petitioner again underwent a CBC that produced normal results. Ex. 10 at 194–95. Petitioner at this time also continued to receive treatment for other concerns (and the possibility that they related to his prior COVID infection). *Id.* at 192–93. It was proposed at this time that he should not receive a COVID vaccine, given his prior “severe autoimmune hemolytic anemia after flu vaccine.” *Id.* at 196.

In January 2022, Petitioner had a hematology consultation with a nurse practitioner. Ex. 10 at 101–06. It was noted at this time that his prior CBC labs had not been concerning for anemia. *Id.* A work-up for his history of autoimmune hemolytic anemia was ordered, and the treater advised Petitioner to follow-up in two months. *Id.* No other medical records relevant to the claim have been filed.

II. Expert Reports

A. *Petitioner’s Expert – Dr. Clinton F. Merrill, Jr.*

Dr. Merrill prepared two written reports for Petitioner. Report, dated Oct. 5, 2023, filed as Ex. 16 (ECF No. 37-1) (“First Merrill Rep.”); Report, dated Aug. 6, 2024, filed as Ex. 25 (ECF No. 45-1) (“Second Merrill Rep.”).

Dr. Merrill graduated from the University of Wyoming with a Bachelor of Science in Chemistry, and received his medical degree from Creighton University School of Medicine. *See* Curriculum Vitae, filed as Ex. 17 (ECF No. 37-2) (“Merrill CV”) at 1. Thereafter, he completed his internship and residency in Internal Medicine at St. Joseph Hospital, followed by a fellowship in Hematology and Medical Oncology at Michigan State University College of Human Medicine. *Id.* He currently holds an active hospital staff position at the Wyoming Medical Center and maintains an active practice in both Internal Medicine and Medical Oncology and Hematology. First Merrill Rep. at 7. Dr. Merrill is board certified by the American Board of Internal Medicine in Internal Medicine, Medical Oncology and Hematology. Merrill CV at 2. In addition, he is an active member of several professional societies, including the American Society of Clinical Oncology, the American Society of Hematology, the American Medical Association, and the

International Society on Thrombosis and Hemostasis. *Id.* at 3.

First Report

Dr. Merrill began with a brief summary of Petitioner’s relevant medical history (although he provided a fairly truncated evaluation of the substantial comorbidities Petitioner was suffering from at the time of vaccination). First Merrill Rep. at 1–3. He then provided an explanation of Petitioner’s diagnosis of warm autoimmune hemolytic anemia (“AIHA”). *Id.* at 3–4. He deemed AIHA a rare disease, in which autoantibodies attack red blood cells/erythrocytes. *Id.* at 3. AIHA is associated with a number of other conditions, including likely autoimmune diseases such as lupus. *Id.* at 3–4. It can also be triggered by infection or certain drugs, but in such cases is more likely short-lived. *Id.* at 4. AIHA is diagnosed with serologic testing, and is treated with steroids and Rituxan (the same medications used for Petitioner’s AIHA). *Id.* at 4.

Next, Dr. Merrill considered some of the possible pathologic mechanisms for how AIHA might occur (partially depending on the instigating agent). First Merrill Rep. at 4–5. All would involve an autoimmune process—reflecting some combination of “a cross-reaction between antigens of infectious agents and self-molecules (named ‘molecular mimicry’), reduction of immune tolerance (thus allowing immune aberrant responses), production of autoantibodies specifically capable of cross-reaction with self, and/or foreign antigen “modification of erythrocyte membrane.” *Id.* at 4. The immune system can mistakenly “recognize” self-antigens as foreign (through production of autoantibodies) in different ways—whether due to existing cell apoptosis/necrosis (in which intracellular contents are released in the body), a neoplastic process, or due to mimicking similarity between the foreign and self-antigens. *Id.* at 4–5. Individual susceptibility may also play a role. *Id.* at 5. Regardless, once produced the autoantibodies “activate the complement cascade, and mainly destroy erythrocytes via antibody dependent cellular cytotoxicity and phagocytosis.” *Id.*

Vaccines could also trigger such a process, and Dr. Merrill evaluated that possibility within the context of “drug-induced AIHA.” This kind of AIHA cause, he maintained, was very rare, and arises as a result of either “antibodies that activate an immune response only while the drug is present,” or where the drug itself more generally impacts the disease process (but with less certainty as to how). First Merrill Rep. at 5. Many pharmaceutical treatments have (usually via case reports) been associated with AIHA—including vaccines. *Id.* As evidence, he noted the existence of VAERS⁶ reports establishing what he deemed to be 90 instances of vaccine-associated

⁶ The Vaccine Adverse Event Reporting System (“VAERS”) is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, <https://vaers.hhs.gov/about.html> (last visited Mar. 13, 2026). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation, unless supplemented with other reliable evidence—since

AIHA, including six cases involving the flu vaccine. W. Barcellini, *Drug-Induced Hemolytic Anemia*, in UpToDate (R. Brodsky & J. Timauer, eds., 2022), filed as Ex. 22 (ECF No. 38-5) (“Barcellini”) (identifying various drugs (approximately 150) to be associated with AIHA). (At the same time, however, Dr. Merrill also proposed that “[t]he actual incidence of AIHA following vaccination is also most likely extremely under reported,” since only when symptoms were significant would any consideration of possible explanations be undertaken. First Merrill Report at 6).

More generally, Dr. Merrill noted that vaccines have been recognized as likely antecedents to certain autoimmune disease processes, via several reliable pathogenic mechanisms, including molecular mimicry. First Merrill Rep. at 6 (citing Y. Pacheco et al., *Bystander Activation and Autoimmunity*, 103 J. of Autoimmunity 1, 1 (2019), filed as Ex. 23 (ECF No. 38-6)). All things being equal, vaccines were likely to initiate autoimmune processes in a manner comparable to a wild infectious process (even though ironically the vaccine’s intent is to prevent a wild infection). M. Vadala et al., *Vaccination and Autoimmune Diseases: Is Prevention of Adverse Health Effects on the Horizon?*, 8 EPMA J. 295, 305 (2017), filed as Ex. 24 (ECF No. 38-7) (“Vadala”).

Thus, Dr. Merrill opined that the elements of causation could be met in this case. He admitted that “the pathogenesis of autoimmune cytopenias as well as autoimmunity in general remain poorly defined,” and that vaccine-induced AIHA was likely quite rare. First Merrill Rep. at 6. Nevertheless, because AIHA was autoimmune in nature, because “exogenous factors” could trigger it, and because vaccines were known occasionally to be such factors, it was likely the flu vaccine could cause AIHA. *Id.* at 7. In addition, there were no other possible explanations for Petitioner’s AIHA, “consistent with the opinions of his treating providers,” some of whom had opined he should not in the future receive the flu vaccine. *Id.* And the onset timeframe (measured from date of vaccination) was reasonable, although Dr. Merrill in this report did not expand on why that was so. *Id.*

Second Report

Dr. Merrill’s supplemental report largely responded to the opinions contained in the report of Respondent’s expert, Dr. You-Wen He. First, Dr. Merrill attempted to rebut Dr. He’s arguments that AIHA has not generally been considered even a possibly vaccine-associated adverse event. Second Merrill Rep. at 2–3. Dr. Merrill maintained that the 2012 IOM Report did not specifically look for AIHA or anemia. *Id.* at 2. In addition, he noted the existence of several more recent case reports⁷ in which AIHA was observed to occur post-vaccination (although he primarily referenced

a VAERS report only establishes a temporal, post-vaccination occurrence, and does not independently confirm the reported adverse event either.

⁷ See, e.g., S. Montagnani et al., *Autoimmune Hemolytic Anemia Following MF59-Adjuvanted Influenza Vaccine Administration: A Report of Two Cases*, 45 The Annals of Pharmacotherapy e8 (2011), filed as Ex. 11 (ECF No. 58-

for this point a study specific to the COVID vaccine, rather than the flu vaccine at issue in this matter). *Id.* at 2–3; J. Jacobs et al., *Autoimmune Haemolytic Anaemia and Immune Thrombocytopenia following SARS-CoV-2 and non-SARS-CoV-2 Vaccination: 32 Years of Passive Surveillance Data*, 201 Br J Haematol. 227 (2023), filed as Ex. 33 (ECF No. 60-1) (“Jacobs”) (finding a total of 863 AIHA and immune thrombocytopenic purpura (“ITP”) reports following vaccination). Later, Dr. Merrill repeated his “underreporting” contention, maintaining that only individuals suffering from the most severe form of AIHA would ever be evaluated in studies relevant to causation, and that passive surveillance systems like VAERS inherently missed likely vaccine-associated adverse events. Second Merrill Rep. at 4–5).

Second, Dr. Merrill endeavored to defend the relevance of his proposed autoimmune mechanisms against Dr. He’s argument that no specific evidence had been offered showing that the flu vaccine itself could likely cause AIHA via those mechanisms. Second Merrill Rep. at 3–4. Dr. Merrill stressed that Dr. He had not disputed the general scientific reliability/acceptance of the proposed mechanisms, and added that there was to his knowledge no requirement in the Vaccine Program that covered vaccines be shown to likely cause a given injury via any particular mechanism (and that to look for this was to seek virtual certainty of causation). *Id.* at 3. At bottom, “the pathogenesis of AIHA is complex and still not fully understood,” and therefore it was enough to posit *possible* mechanisms for how vaccine-induced AIHA might occur. *Id.* at 4.

Dr. Merrill then discussed Dr. He’s contention that Petitioner’s pre-vaccination sarcoidosis could be the cause of his subsequent anemia. Second Merrill Rep. at 5–8. As a threshold matter, Dr. Merrill contested the strength of this sarcoidosis diagnosis, observing that it stemmed from records pertaining to treatment more than 15 years before vaccination, the diagnosis itself could not be corroborated from the existing record, and Petitioner had not been experiencing symptoms “consistent with active sarcoidosis” in that entire timeframe. *Id.* at 8; *see also Id.* at 5–6. In addition, Dr. Merrill pointed out that support for the alleged sarcoidosis-AIHA association came from mostly case reports, some of which were thirty to forty-years old. *Id.* at 6–8.

B. Respondent’s Expert – Dr. You-Wen He, Ph.D.

Dr. He, an academic physician and immunologist, authored one expert report for Respondent. Report, dated Feb. 7, 2024, filed as Ex. A (ECF No. 40-1) (“He Rep.”).

Dr. He is a Professor of Integrative Immunobiology in the Department of Integrative Immunobiology at Duke University School of Medicine. *See Curriculum Vitae*, dated Feb. 14, 2024, filed as Ex. B (ECF No. 41-22) (“He CV”) at 1. He received his medical degree from the Fourth Military Medical University in China and received his Ph.D. from the Miami School of Medicine.

5); F. Shlamovitz & S. Johar, *A Case of Evan’s Syndrome following Influenza Vaccine*, 44 J. Emergency Med. E149 (2013), filed as Ex. 31 (ECF No. 58-6).

Id. Dr. He went on to complete a senior fellowship in the Department of Immunology at the University of Washington and completed his residency at Qindu Hospital in China. *Id.* Dr. He has been conducting research in immunology since he graduated from medical school in 1986. He Rep. at 1. Over the past 27 years, he has been invited to lecture nationally and internationally on the topic of host immune responses to microbial infections and tumors. *Id.* Dr. He has also served as a co-Principal Investigator for four clinical trials focusing on cancer immunotherapy using personalized cancer vaccines. *Id.* In addition, he has been published extensively and has served as an ad hoc reviewer for more than 30 scientific journals. *Id.*; He CV at 7–16.

Like Dr. Merrill, Dr. He included in his report an overview of Petitioner’s relevant medical history. He Report at 2–3. He accepted the AIHA diagnosis (although he did not purport to have the specific expertise in hematology necessary to comment on it). *Id.* at 4. Dr. He noted AIHA is believed to be antibody-mediated, and although it is more often than not deemed idiopathic in origin, he accepted its association with “viral infections, autoimmune disorders, lymphoproliferative disorders, immunodeficiency states, and pregnancy”—but denied vaccination could also be so linked. *Id.* at 4, 6.

In support, Dr. He noted that the Institute of Medicine (the “IOM”) had made no mention of AIHA as a possible vaccine-associated adverse event, despite listing many others. He Report at 4; *Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality* (K. Stratton, et al., eds., 2012), filed as Ex. A, Tab 2 (ECF No. 40-3) (“2012 IOM Rep.”). A more recent review article linked vaccination to 12 of 46 possible adverse events—but again made no mention of AIHA. *See* M. Dudley, et al., *The State of Vaccine Safety Science: Systematic Reviews of the Evidence*, 20 *Lancet Infect Dis* e80 (2020), filed as Ex. A, Tab 3 (ECF No. 40-4) (“Dudley”). Given how commonly the flu vaccine was administered, this absence of even passive surveillance supporting evidence was a telling factor weighing against an association. He Report at 4. And the existence of VAERS reports of AIHA after vaccination was weak and unreliable proof of causation, since VAERS reports did not involve confirmed instances of the putative vaccine-caused event, and also provided no comparison to background rates of the event’s occurrence (which would be required to determine if the risk was heightened in the context of vaccination). *Id.* at 8.

Dr. Merrill had attempted to justify the lack of evidence corroborating an AIHA-flu vaccine association by proposing that there was “underreporting” of AIHA as a possible vaccine injury, but Dr. He maintained that this was erroneous. He Report at 12. The general incidence of AIHA was already quite low, while millions of individuals received the flu vaccine every year—meaning “any increased risk of AIHA upon influenza vaccination will be highly likely presented with sufficient epidemiologic evidence”—if such a relationship existed. *Id.* But articles relying merely on surveillance data, like Dudley, observed no such connection.

Dr. He then reviewed in a point-by-point manner some of Dr. Merrill’s contentions. *See generally* He Report at 6–13. Dr. He accepted as a general matter Dr. Merrill’s explanations for

how autoimmune mechanisms might propagate disease, but denied that they had been shown specifically to bear on the context of alleged flu vaccine-caused AIHA. *Id.* at 6–7. The same was true for evidence relating to drug-induced AIHA; while some drugs had been credibly linked to AIHA, no comparable evidence existed for the flu vaccine. *Id.* at 8.

In addition, Dr. He differentiated between the general scientific reliability of the mechanisms by which autoimmune diseases might work and their applicability in the context of this case. He Report at 9–12. For example, Dr. He allowed that molecular mimicry (the concept that “shared antigenic epitope similarity between infectious pathogens or vaccines and human proteins renders cross-reactivities by host adaptive immunity”) had a certain degree of validity (although he characterized it as an “old theory”). *Id.* at 9. But he noted that more recent scientific and medical thinking called it into question as an all-purpose explanation for autoimmunity, noting that amino acid sequential similarity is very common in nature, but occurs without a high incidence of autoimmune disease. *Id.* at 9.⁸ Rather, autoimmune reactions were more likely the product of “the strength/extent of the immune activation induced by the overall immunological encounters,” and not the mere possibility of peptide mimicry. *Id.* at 10. The same was true for other putative mechanisms—and in any event, AIHA has not been shown to develop via any of them. *Id.*

Vaccination also could not be deemed completely congruent in impact, immunologically-speaking, with a wild infection, even if vaccines are intended to stimulate the immune system (for the purpose of building immune memory to a particular foreign pathogen). He Report at 10–12. Instead, Dr. He emphasized that “[i]mmune activation in response to infections and vaccinations are fundamentally different,” with the former far stronger. *Id.* at 10. The “depth of an immune response induced by the virus infection” would inherently exceed a vaccination response. *Id.* at 11. And the pathways by which vaccines are “seen” by the immune system (intramuscular injection) was also relevant, since wild viral infections would invade the body via the “respiratory mucosa,” replicating and causing harm by that function alone. *Id.* This made it far less likely that the kind of aberrant immune response seen in autoimmune processes would occur after vaccination.

Dr. Merrill had proposed that there was in this case no alternative explanation for Petitioner’s AIHA, but Dr. He identified one from Mr. Johnson’s medical history: sarcoidosis. He Report at 13. Dr. He purported that there was “extensive evidence” to support a sarcoidosis/AIHA association, and that evidence included both case reports and more analytic articles. *See, e.g.,* R. Mayock et al., *Manifestations of Sarcoidosis*, 35 Am. J. Med. 67, 80 (1963), filed as Ex. A, Tab 20 (ECF No. 41-10) (studying 145 patients with sarcoidosis and finding that 31 patients had hemoglobin values below 11 gm. per cent, 3 patients with hemolytic anemia); P. Brito-Zerón et al., *Coexistence of Immune-Mediated Diseases in Sarcoidosis. Frequency and Clinical*

⁸ Dr. He offered several items of literature for this contention—but they are articles with which I am very familiar in adjudicating Vaccine Act claims, and therefore I do not include a summary or reference of them.

Significance in 1737 Patients, 88 Joint Bone Spine 1 (2021), filed as Ex. A, Tab 30 (ECF No. 41-20) (reporting that the frequency of IMDs in patients with sarcoidosis was approximately 2-fold higher than the frequency observed in the general population). This preexisting comorbidity was also more consistent with his sudden onset than vaccination. A one-day onset was “too soon to activate host innate and adaptive immune responses” due to the vaccine, whereas a preexisting condition could more logically fit the facts. He Report at 13.

III. Procedural History

The matter was initiated in September 2021, but not activated out of “pre-assignment review” until the summer of 2022, while records pertinent to the claim were obtained and filed. Respondent’s Rule 4(c) Report opposing compensation was filed in January 2023 (ECF No. 29), and the matter was reassigned to me from a different special master later that winter. After some delay, Petitioner filed Dr. Merrill’s first expert report in the fall of 2023, and expert opinions were obtained by both sides, with completion of the process in August 2024. I initially proposed to the parties that the matter be resolved via hearing (ECF No. 47), but after issuance of a prehearing order and some compliance with it, the parties expressed the desire to adjudicate the claim on the basis of the written record. *See* Scheduling Order, dated Mar. 12, 2025 (setting Ruling on Record schedule). The parties filed briefs in support of their respective positions, and the matter is now ripe for resolution.

IV. Parties’ Arguments

Petitioner

Petitioner contends that his AIHA was likely caused by his receipt of the flu vaccine on October 28, 2020. Br. at 1. In his briefing, Petitioner addresses all three prongs of the test set by the Federal Circuit in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) for causation claims.

Petitioner first maintains that his expert, Dr. Merrill, has offered a biologically plausible explanation for how the flu vaccine can trigger AIHA. Br. at 10. According to Dr. Merrill, warm AIHA “results from the production of IgG autoantibodies that bind to red blood cell surface antigens and mediate extravascular hemolysis via macrophage Fc receptor recognition, typically in the spleen.” *Id.* (referencing First Merrill Rep. at 3–4). It occurs at body temperature, which not only aligns with Petitioner’s case, as confirmed by his laboratory profile, but further distinguishes the condition from cold agglutinin diseases. *Id.* Moreover, Dr. Merrill’s proposed explanation—“dysregulated immune activation through mechanisms such as molecular mimicry, bystander activation, and epitope spreading—is not only recognized in the medical and scientific literature, but “real-world epidemiologic data” as well. *Id.* at 10, 11; *see also* B. Fattizzo & W. Barcellini,

Autoimmune Hemolytic Anemia: Causes and Consequences, 18 Ex. Rev. Clinical Immunology 731, 731–32 (2022), filed as Ex. 19 (ECF No. 38-2) (describing pathogenesis of AIHA as multifactorial, and thus, implicating both endogenous immune dysregulation and exogenous triggers such as vaccines, infections, and drugs); Vadala at 296–97 (linking various autoimmune disease, including hematologic ones, to vaccination, with a focus on immune priming in genetically susceptible individuals); Jacobs at 2–3 (documenting over 100 reports of post-influenza vaccine AIHA in the VAERS database).

In addition, Petitioner argues that Respondent’s expert, Dr. He, “is a laboratory-based immunologist with no clinical training or board certification in hematology, autoimmune cytopenias, or vaccine-related injury.” Br. at 12. Thus, his opinion “lacks both methodological reliability and clinical foundation, and would not survive scrutiny under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), were this a federal evidentiary proceeding. *Id.*

As for the second, “did cause” *Althen* prong, Petitioner notes that he has preponderantly established a logical sequence of cause and effect showing that the flu vaccine did cause his AIHA. Br. at 13. Dr. Merrill concluded that the flu vaccine was the proximate cause of Petitioner’s AIHA due to Petitioner’s rapid onset of symptoms, classic serologic and hematologic markers, and the absence of any plausible alternative explanation. *Id.* Specifically, Petitioner emphasizes the documented treater support concluding that the flu vaccine was the most probable precipitating factor, as well as his positive direct antiglobulin test, elevated LDH, undetectable haptoglobin, and compensatory reticulocytosis. *Id.* at 14. Moreover, Petitioner underwent a comprehensive infectious and autoimmune workup that ruled out several potential infectious triggers. *Id.*; see also Ex. 2 at 466, 467. Accordingly, Petitioner argues that he has provided a “clear, medically grounded, and case-specific explanation for how the flu vaccine led to [his] injury.” Br. at 15.

Finally, Petitioner contends that he has satisfied his burden under *Althen* prong three, as the temporal relationship between his receipt of the flu vaccine and his subsequent development of AIHA is “direct, biologically supported, and unbroken by competing causes.” Br. at 16. Petitioner notes that he developed symptoms (i.e., fatigue, chills, tingling in hands, and shortness of breath) within 48 hours of receiving the flu vaccine on October 28, 2020, and by day five, he was hospitalized with a laboratory-confirmed diagnosis of warm AIHA. *Id.* at 15; Ex. 2 at 541. Dr. Merrill further argues that such a timeframe is medically appropriate based on immunologic principles and aligns with the established literature on vaccine-triggered autoimmune disorders. Br. at 15. Additionally, the record evidence does not indicate any plausible alternative explanation for Petitioner’s injury. *Id.* at 16.

In his reply, Petitioner reiterates the arguments set forth in his initial brief and maintains that Respondent’s opposition relies on an “unduly narrow reading of the Vaccine Act, improperly elevating Petitioner’s burden of proof.” Reply at 2–4.

Respondent

Respondent accepts Petitioner’s diagnosis of warm AIHA, adding that it “can arise spontaneously (primary idiopathic warm AIHA) or is associated with conditions or medications that predispose to the production of autoantibodies (secondary warm AIHA).” Opp. at 13. But the flu vaccine is not also so associated with AIHA.

Respondent first maintains that Dr. Merrill’s opinions pertaining to *Althen* prong one are not reliable. Opp. at 14. Dr. Merrill failed to provide “any one preponderant causal mechanism to establish AIHA caused by [the] flu vaccine”, but instead discussed only general concepts of autoimmunity and mechanisms for autoantibody production in systemic autoimmune diseases. *Id.*; see also Vadala; J. Suurmond & B. Diamond, *Autoantibodies in Systemic Autoimmune Diseases: Specificity and Pathogenicity*, 125 J. Clinical Investigation 2194 (2015), filed as Ex. 20 (ECF No. 38-3); Y. Pacheco et al., *Bystander Activation and Autoimmunity*, 103 J. Autoimmunity 1 (2019), filed as Ex. 23 (ECF No. 38-6). Moreover, Dr. He had noted that “there is a complete lack of clinical evidence to support any causal link between [the flu] vaccination and AIHA,” as evidenced by the 2012 IOM report which did not even identify AIHA as a possibly-recognized adverse event. Opp. at 15; He Rep. at 4.

In addition, Dr. He emphasizes that a vast number of flu vaccines are administered each year, and “the lack of clinical reports to suggest a relation between [the flu] vaccine and AIHA indicates that [flu] vaccine is highly unlikely to cause AIHA.” Opp. at 15. Of note, Dr. Merrill references several studies that identify various drug associations with AIHA, yet no such confirmation has been shown regarding the flu vaccine specifically. *Id.* at 16; see also G. Garratty, *Drug-Induced Immune Hemolytic Anemia*, Hematology 73, 74 (2009), filed as Ex. 21 (ECF No. 38-4); Barcellini at 1. To justify this lack of causal evidence, Dr. Merrill argues that the “pathogenesis of autoimmune cytopenia as well as autoimmunity in general remain poorly defined,” yet several articles (such as the Dudley vaccine safety review) indeed find associations between *other* autoimmune cytopenias and vaccines. Opp. at 16; Dudley at e83; see also C. Gidengil et al., *Safety of Vaccines Used for Routine Immunization in the United States: An Update*, 244 Comparative Effectiveness Rev. 19 (2021), filed as Ex. A, Tab 18 (ECF No. 41-8) (noting moderate evidence to support an increased risk of ITP following MMR vaccine). Here, by contrast, no similar evidence exists.

Application of Dr. Merrill’s proposed causal mechanisms of molecular mimicry, bystander activation, and epitope spreading in the context of flu vaccine and AIHA were incompletely established and have little direct support, as acknowledged by both experts herein. Opp. at 16–18. Moreover, and as argued by Dr. He, “it is not appropriate for [P]etitioner to transplant the mechanism by which some infections can cause AIHA onto [the] flu vaccine.” *Id.* at 20 (citing He Rep. at 10). Not only does the wild flu virus have the capacity to activate more immune pathways

than the flu vaccine, but none of the referenced literature herein establishes an association between wild-type influenza virus and AIHA in the first place. *Id.* Yet AIHA has been associated with other wild infections—the human immune deficiency virus, Epstein-Barr virus, cytomegalovirus, haptotropic virus, and COVID-19. *Id.*; *see also* C. Brugnara & R. Brodsky, *Warm Autoimmune Hemolytic Anemia (AIHA) in Adults*, in UpToDate (R. Means, Jr. & J. Tirnauer, eds., 2023), filed as Ex. A, Tab 1 at 5 (ECF No. 40-2) (“Brugnara & Brodsky”). Thus, Respondent argues that Petitioner has failed to present a reliable and persuasive medical theory demonstrating that the flu vaccine can cause AIHA, and therefore, his claim fails under *Althen* prong one. Opp. at 22.

Respondent further argues that the second, “did cause” *Althen* prong has not been met. He notes that Petitioner relies on his rapid, post-vaccination onset of symptoms and that the diagnosis was confirmed by hemolysis markers and the absence of a plausible alternative explanation. *Id.* at 22. But there is no record evidence that specifically connects Petitioner’s symptoms (i.e., fatigue, hand tingling, nausea, and chills) to an autoimmune response likely triggered by his receipt of the flu vaccine. *Id.* Moreover, there are multiple instances in the record where Petitioner’s treaters opined that the etiology of Petitioner’s anemia is uncertain. *Id.* at 23; *see also* Ex. 2 at 470, 477 (documenting internist Dr. Peterson’s observations that Petitioner had “warm autoimmune hemolytic anemia of unknown trigger”). Dr. He also emphasizes Petitioner’s “long disease history” of sarcoidosis prior to his receipt of the vaccine at issue, as well as the extensive evidence supporting a causal association between sarcoidosis and AIHA. Opp. at 23 (referencing He Rep. at 13). Accordingly, Respondent argues that Petitioner has failed to satisfy his burden under *Althen* prong two.

Lastly, Respondent briefly argues that Petitioner has failed to produce reliable evidence of a temporal relationship between the flu vaccine and his AIHA. He notes Petitioner’s reported onset of symptoms as occurring on the same day as his vaccination, and therefore “too soon to activate host innate and adaptive immune responses to cause autoimmune disease.” Opp. at 24 (citing He Rep. at 13). In addition, not only does literature filed by Petitioner not support such a rapid onset of AIHA, but Dr. Merrill’s embrace of an onset within two days of vaccination is outside what he describes as the typical range of “3 to 10 days post-exposure for cytopenic conditions.” *Id.* (citing Br. at 15).

V. Applicable Legal Standards

A. Petitioner’s Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; §

11(c)(1)(C)(ii)(I); *see also Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).⁹ There is no Table claim for the injury of hemolytic anemia/AIHA after receipt of any covered vaccine.

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(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 proximate temporal relationship between vaccination and injury.”

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical

⁹ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus 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.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (May 6, 2015) (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Cerrone v. Sec’y of Health & Hum. Servs.*, 146 F.4th 1113, 1121 (Fed. Cir. 2025) (claimant’s contention that *Althen* prong one requires only a showing of plausibility “understates the burden [a petitioner] bears under the first factor in the *Althen* formulation”); *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff’d*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical 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). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec’y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Legal Standards Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir.

1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law”), *aff’d*, *Rickett v. Sec’y of Health & Hum. Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec’y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff’d*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less

deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). See *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the factors for analyzing the reliability of testimony are:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are

employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App’x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner’s case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision”) (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App’x 875, 884 (Fed. Cir.

2013) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

E. Determination of Claim on Basis of Record

The parties have agreed to my resolving this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

I. Hemolytic Anemia and Program's Treatment of it as a Possible Vaccine Injury

It is not disputed that Mr. Johnson was properly diagnosed with warm AIHA. *See Opp.* at 13. But some discussion of its nature, and how prior Program cases have addressed it as an alleged vaccine-associated adverse event, would still be beneficial in explaining my determination. AIHA is understood to be a rare autoimmune disease oftentimes characterized by autoantibody-mediated destruction of self-red blood cells. Brugnara and Brodsky at 2, 3 (“almost always IgG, although IgA and warm-acting IgM have [also] been reported” as driving AIHA). Warm AIHA, the diagnosis herein, occurs where the destructive autoantibodies are active at body temperature. *Id.* It is also understood to either arise spontaneously or in the setting of a condition or medication that predisposes an individual to the production of an autoantibody. *Id.* at 3.

As noted above, there is no Table claim for AIHA. At most, a *different* hematologic injury—ITP—is a Table injury, but only after receipt of the MMR vaccine. 42 U.S.C.A. 300aa-14(a)(V)(A). But reasoned decisions exist finding that ITP can be caused by other vaccines as well. *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-113V, 20017 WL 772534 (Fed. Cl. Spec. Mstr. Jan. 6, 2017) (petitioner presented sufficient evidence to conclude the HPV can cause ITP); *Walls v. Sec'y of Health & Hum. Servs.*, No. 16-557V, 2020 WL 13801342, at *16 (Fed. Cl. Spec. Mstr. June 23, 2020) (petitioner preponderantly established that vaccines such as DTaP, Hib, Hep B, and

PCV can cause ITP). Nevertheless, although ITP is also likely autoimmune-mediated, it involves destruction of *platelets* rather than erythrocytes, and thus is distinguishable as an injury despite some of the overlap.

I am aware of some prior cases in which hemolytic anemia has been claimed as a vaccine injury, and some have been successfully settled. But there are few relevant *reasoned* decisions in which claims of purported vaccine-caused anemia have resulted in a favorable entitlement decision. *See, e.g., Berenji v. Sec’y of Health & Hum. Servs.*, No. 14-699V, 2019 WL 4640228 (Fed. Cl. Spec. Mstr. Aug. 30, 2019).

In *Berenji*, a petitioner alleged that receipt of several covered vaccines aggravated an asymptomatic case of Evan’s syndrome (a chronic autoimmune disorder characterized by concurrent AIHA and ITP), with several secondary conditions occurring as a result. *Berenji*, 2019 WL 4640228, at *1. The special master allowed for the possibility that a vaccine could *plausibly*¹⁰ worsen preexisting Evans syndrome (perhaps by causing the failure of regulatory immune factors to function), but ultimately found it had not been demonstrated the vaccines at issue *did* cause this to occur (since the illness at issue was known to be difficult to treat (and hence likely to persist independently of vaccination), and the petitioner’s course was not shown to differ materially from what a non-vaccinated patient with Evans syndrome would experience. *Id.* at *15, 21. Accordingly (although in part because the case involved a claim of significant aggravation),¹¹ *Berenji* provides little guidance herein, and is not particularly supportive of causation. But the claim that AIHA could be vaccine-caused is not one that the Program has clearly embraced or rejected, making it more than reasonable for evaluation herein (and in future cases as well).

II. *Petitioner Has Not Carried His Althen Burden of Proof*

I address the *Althen* prongs in order of their importance to my decision rather than in the order in which they are delineated in that decision.

Prong Three

The most glaring deficiency to Petitioner’s causation showing is the fact that his purported onset—the same day as vaccination—has not been shown to be a medically acceptable causal timeframe. Not only did Petitioner report to treaters on November 2, 2020, that his onset had begun five days before (October 28th), but blood testing performed at this later time yielded abnormal results, corroborating the conclusion that Petitioner’s AIHA likely was already occurring. Ex. 1 at 2–6, 10. Even if it had been preponderantly demonstrated that the flu vaccine can cause AIHA, it

¹⁰ As noted above, *plausibility* is not the relevant evidentiary standard for resolution of any of the causation prongs.

¹¹ Petitioner has not in this case alleged his AIHA began pre-vaccination but was worsened by it, and the record would not support either finding.

is not likely that any autoimmune disease process could begin so quickly—and this is so even in the context of a person with considerable comorbidities like Petitioner. This is simply too fast for an autoimmune process to be triggered by vaccination – resulting in the production of the autoantibodies responsible for attacking blood cells, *and* then later resulting in outward clinical symptoms.¹² Rather, an autoimmune process is usually thought to involve the adaptive immune response (in which the immune system generates antibodies in reaction to a foreign antigen), but such a process is never thought to occur in so short a timeframe, and can often take a week or more. *See Curry v. Sec’y of Health & Hum. Servs.*, No. 22-279V, 2025 WL 1693655, at *21 (Fed. Cl. Spec. Mstr. Apr. 28, 2025) (“[a] s is well understood in the Program, [], the adaptive immune response *lags* the innate, initial response, and takes time to unfold and cause the production of purportedly cross-reactive antibodies.” It is not instantaneous—and certainly requires more than a few days.”).

Dr. Merrill’s opinion did not render such a rapid onset timeframe more persuasive or medically/scientifically likely. He also did not establish, even through case report instances involving other vaccines, sufficient evidence in which AIHA occurred post-vaccination in a comparably-fast timeframe. *See, e.g., H. Tsuchiya et al., A Case of Coombs-Negative Autoimmune Hemolytic Anemia, Possibly Caused by Influenza Vaccination*, 28 *Acta Paediatr. Jpn.* 78 (1986), filed as Ex. 26 (ECF No. 58-1) at 2 (discussing case report of a 9-year-old boy who was administered flu vaccines (25 days and 5 days) prior to AIHA onset); A. Seltsam et al., *Vaccination-Associated Immune Hemolytic Anemia in Two Children*, 40 *Transfusion* 907, 907–08 (2000), filed as Ex. 27 (ECF No. 58-2) (case reports of two children who developed AIHA approximately four days and 2 weeks post vaccination). And he did not sufficiently flesh out any other pathogenic mechanism in which onset of symptoms (triggered *first* by RBC destruction) could happen so fast after instigation by some foreign factor.

Prong One

It also has not been preponderantly demonstrated that the flu vaccine can likely cause AIHA at all—regardless of the timeframe in which it might reasonably occur under the proposed causation theory. Even if AIHA can be associated with some pharmaceutical interventions, it has not been established by the evidence filed in this case that *vaccines* are also thought to possess such an association. At most, Dr. Merrill referenced passive surveillance reports of anemia occurring temporally after receipt of a vaccine - a kind of evidence that is not generally given much weight in Program cases when evaluating causation. *Hiatt v. Sec’y of Health & Hum. Servs.*, No. 19-1363V, 2025 WL 3230494, at *19 (Fed. Cl. Spec. Mstr. Oct. 24, 2025), *mot. for review den’d*, No. 19-1363, 2026 WL 730718 (Fed. Cl. Feb. 5, 2026). The possibility (as Dr. Merrill speculated) that AIHA is underreported as a vaccine-associated adverse event (or even as a disease at all) is

¹² Even the Table claim for ITP (an analogous blood cell-impacting autoimmune condition) attributable to the MMR vaccine requires an onset of no sooner than *seven* days post-vaccination. 42 C.F.R. § 100.3(a)(V)(A).

not an excuse for an absence of preponderant evidence supporting causation. Similarly, Dr. Merrill invoked the fact that much about AIHA's pathogenesis remains unknown to explain his inability to offer more evidence specific to the flu vaccine and how it might cause this injury (Second Merrill Rep. at 4)—an unpersuasive contention that amounts to requesting that the preponderant standard be lowered, simply because vaccine causation specific to this injury has not been a widely-embraced research topic. *Caves v. Sec'y of Dep't of Health & Hum. Servs.*, 100 Fed. Cl. 119 (2011), *aff'd sub nom. Caves v. Sec'y of Health & Hum. Servs.*, 463 F. App'x 932 (Fed. Cir. 2012) (“[t]he standard of proof does not operate as a sliding scale that varies depending upon the quantity and quality of the scientific evidence that is available”). That standard demands a preponderant showing – not merely evidence supporting the *plausibility* of causation.

In response, Dr. He noted a number of bases for concluding (at least given the record filed in this case) that it is not likely the flu vaccine can cause AIHA. Although he acknowledged its autoimmune nature, Dr. He persuasively observed that as a general matter there was little evidence that AIHA could be vaccine-associated (adding that VAERS data is not particularly helpful in assessing causation). He also noted that contentions about underreporting of AIHA as a vaccine injury flew in the face of the fact that the flu vaccine is highly-administered (thus calling into question why there are not more reports of a putative association, if one existed). And he recounted the limits to theories that all autoimmune processes likely occur via molecular mimicry, or that antigenic similarity between a foreign antigen and self-protein or tissue structure is alone enough to render cross-reactivity due to mimicry likely. He Rep. at 9–12.

Overall, Dr. Merrill's causation theory was thin, constructed of the kinds of arguments seen all too often in Program cases and yet rejected. It is certainly not beyond the realm of possibility that the autoimmune attack at the heart of AIHA *could* be vaccine-associated, but the evidence necessary to find that contention preponderantly established has not been offered *in this case*.

Prong Two

Resolution of this *Althen* prong presents the closest case. The instances of treater acceptance of a vaccine association both direct and indirect (to the extent treaters agreed Petitioner should not receive certain vaccines in the future after his alleged reaction) *do* support the contention the flu vaccine caused Petitioner's injury (even if those treater suppositions provide little explanation for the perceived association, beyond the temporal relationship—and even where some treaters disclaim an opinion as to causation). On the other hand, Dr. He compellingly demonstrated a basis for a possible sarcoidosis-AIHA relationship (although in doing so he ironically relied on the kind of case report evidence frequently deemed of low probative value), but Dr. Merrill accurately noted that this possible alternative cause was not fully corroborated by the record—let alone shown to be an active concern within even a few years of the vaccination at issue.

Regardless, I have not found (on the basis of the evidence before me) that the flu vaccine likely “can cause” AIHA, or that Petitioner’s injury began in a medically-acceptable timeframe. These findings—which did not present close calls at all—are a sufficient basis for denying entitlement, since all three *Althen* prongs must be met by a petitioner. *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. App. 976, 980 (Fed. Cir. 2014).

CONCLUSION

Because Petitioner did not carry his preponderant burden of showing causation, I am compelled to deny compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.¹³

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

¹³ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.