

# In the United States Court of Federal Claims

No. 16-1465V

Filed Under Seal: October 29, 2020

Reissued: December 7, 2020\*

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GERALD TEMES,	)	
	)	
Petitioner,	)	
	)	National Childhood Vaccine Injury Act,
v.	)	42 U.S.C. § 300aa–1 to –34;
	)	Influenza Vaccine; Pneumococcal
SECRETARY OF HEALTH AND	)	Vaccine; Cryoglobulinemia; Vasculitis.
HUMAN SERVICES,	)	
	)	
Respondent.	)	
_____	)	

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## **MEMORANDUM OPINION AND ORDER**

GRIGGSBY, Judge

### **I. INTRODUCTION**

Petitioner, Dr. Gerald Temes, seeks review of the May 12, 2020, Decision of the special master denying his claim for compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. § 300aa–1 to –34. For the reasons set forth below, the Court

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\* This Memorandum Opinion and Order was originally filed under seal on October 29, 2020. ECF No. 65. The parties were given an opportunity to advise the Court of their views with respect to what information, if any, should be redacted from the Memorandum Opinion and Order. On December 1, 2020, petitioner filed a joint status report on behalf of the parties stating that the parties had no redactions to the Memorandum Opinion and Order. ECF No. 67. And so, the Court is reissuing its Memorandum Opinion and Order, dated October 29, 2020, as the public opinion.

**DENIES** petitioner’s motion for review of the special master’s May 12, 2020, Decision and **SUSTAINS** the decision of the special master.

## **II. FACTUAL AND PROCEDURAL BACKGROUND<sup>1</sup>**

### **A. Factual Background**

Dr. Temes is a retired thoracic surgeon who has been diagnosed with Type II cryoglobulinemia—a blood disorder that can lead to vasculitis.<sup>2</sup> Pet’r Pet. at 1. In this Vaccine Act matter, Dr. Temes alleges that he developed cryoglobulinemia as a result of receiving the influenza (“flu”) and pneumococcal (“Prevnar 13”) vaccines on October 19, 2015. *Id.*; *see also* Pet’r Mot. for Rev. at 1. On May 12, 2020, the special master denied Dr. Temes’ claim for compensation under the Vaccine Act. *See generally* May 12, 2020, Decision.

#### **1. Dr. Temes’ Medical History**

Dr. Temes’ medical history is discussed in detail in the special master’s May 12, 2020, Decision and is summarized here. May 12, 2020, Decision at 2-7.

Dr. Temes received the flu and Prevnar 13 vaccines at issue on October 19, 2015. Pet’r Ex. 8. During a subsequent consultation with Dr. Tuna Ozyurekoglu, a hand specialist, on October 26, 2015, Dr. Temes reported experiencing symptoms of purple discoloration and numbness in his hands, which improved in the clinic upon warming. Pet’r Ex. 3 at 6-7.

During an appointment with his primary care physician, Matthew Rogers, M.D., on that same day, Dr. Temes complained of a persistent high fever that started three days earlier, as well as hand pain, myalgias in his legs, and dysuria. Pet’r Ex. 1 at 16, 21. At the time, Dr. Rogers expressed concern that Dr. Temes was experiencing cryoglobulinemia and ordered Dr. Temes to undergo further laboratory testing. *Id.* at 20-21.

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<sup>1</sup> The facts recounted in this Memorandum Opinion and Order are taken from the petitioner’s petition (“Pet’r Pet.”); petitioner’s motion for review (“Pet’r Mot. for Rev.”) and the memorandum in support thereof (“Pet’r Mem.”); petitioner’s exhibits (“Pet’r Ex.”); the Secretary’s exhibits (“Resp’t Ex.”) and the special master’s May 12, 2020, Decision (“May 12, 2020, Decision”). Except where otherwise noted, the facts recited herein are undisputed.

<sup>2</sup> Cryoglobulinemia is a condition in which certain immunoglobulins found in the blood precipitate under cool conditions. May 12, 2020, Decision at 1 n.3; *Dorland’s Illustrated Medical Dictionary* 438, 908 (33d ed. 2020).

On October 30, 2015, Dr. Temes presented to John Huber, M.D., for a consultation. Pet'r Ex. 16 at 273. Dr. Huber reviewed Dr. Temes' laboratory results and noted a slightly elevated rheumatoid factor, depressed complement levels, and the absence of cold agglutinins. *Id.* Dr. Temes' cryoglobulin test results were still pending at that time. *Id.* at 277. A physical examination revealed signs of ischemia in Dr. Temes' fingers and toes. *Id.* at 276. Dr. Huber concluded that Dr. Temes was likely experiencing mixed cryoglobulinemia as the result of receiving the flu vaccine. *Id.* at 277. And so, Dr. Huber prescribed Dr. Temes prednisone and directed him to follow-up after receiving the results of his cryoglobulin test. *Id.*

After consulting with a dermatologist, Jeffrey Callen, M.D.—who noted that Dr. Temes' cryoglobulinemia “is presumed to be due to a[ flu] vaccination[.]”—Dr. Temes underwent additional laboratory testing on November 17, 2015. Pet'r Ex. 2 at 9-10; *see also* Pet'r Ex. 1 at 183. Dr. Temes subsequently presented for a follow-up appointment on November 24, 2015, with Dr. Huber, who noted that Dr. Temes' rheumatoid factor was significantly elevated compared to his prior test results. Pet'r Ex. 16 at 225. Although Dr. Temes reported improving pain in his fingers and toes, a physical examination revealed worsening ischemia. *Id.* at 227. And so, Dr. Huber ordered Dr. Temes to begin Rituxan treatments, the first of which Dr. Temes received on December 1, 2015. *Id.* at 207, 230.

Dr. Temes complained of necrosis in certain fingers and severe pain in his right foot at a follow-up appointment with Dr. Huber on January 5, 2016. *Id.* at 161. Dr. Huber noted, however, an overall improvement in Dr. Temes' condition and recommended two additional Rituxan treatments and a continued taper of Dr. Temes' prednisone dosage from 20 to 10 milligrams per day. *Id.* at 164, 166-67. At his next appointment with Dr. Huber on January 19, 2016, Dr. Temes exhibited dramatic improvement and showed almost no signs of ischemic changes in his hands or feet. *Id.* at 145. And so, Dr. Huber advised Dr. Temes to continue his Rituxan treatments and to further taper his prednisone to five milligrams per day. *Id.* at 151.

Throughout the remainder of 2016 and early 2017, Dr. Temes attended numerous follow-up appointments with various medical providers and he reported considerable improvement of his symptoms. *See generally* May 12, 2020, Decision at 5-6. Despite never achieving complete remission, Dr. Temes was able to return to many of the activities that he had enjoyed prior to the onset of his cryoglobulinemia, including playing golf. *See, e.g.,* Pet'r Ex. 16 at 84.

Dr. Temes' condition began to deteriorate again in May 2017, when he experienced increased discomfort in his hands and feet, as well as pain precipitated by cold temperatures. Pet'r Ex. 51 at 10. Dr. Huber recommended restarting Rituxan treatments, which Dr. Temes began on May 18, 2017. *Id.* On May 30, 2017, Dr. Temes attended a follow-up with Dr. Huber and complained of a rash on his bilateral feet. *Id.* A biopsy confirmed that Dr. Temes was suffering from cutaneous vasculitis. *Id.*

On June 28, 2017, John Lust, M.D., an expert in the study of cryoglobulinemia at the Mayo Clinic, reviewed Dr. Temes' medical history and outside laboratory results and concluded that they evidenced a diagnosis of leukocytoclastic vasculitis. Pet'r Ex. 19 at 14, 17. Testing conducted during Dr. Temes' consultation with Dr. Lust "showed a trace [amount] of cryoprecipitate and immunofixation[, which] demonstrated a Type II cryoglobulinemia (monoclonal IgM kappa plus polyclonal IgG)." Pet'r Ex. 50. In his notes from that visit, Dr. Lust also wrote that Dr. Temes' "clinical diagnosis" was cryoglobulinemia that developed "in response to [a flu] vaccination." Pet'r Ex. 19 at 14. Dr. Lust recommended that Dr. Temes continue with the two additional Rituxan treatments four weeks apart. *Id.* But, Dr. Temes suffered a severe reaction to his Rituxan treatment on July 6, 2017. Pet'r Ex. 51 at 11. And so, he began treatment with Cytoxan on July 11, 2017. *Id.*

Dr. Temes continued to follow-up with Dr. Huber throughout the remainder of 2017 and 2018, and his condition remained stable with some slight fluctuations. *See* May 12, 2020, Decision at 7. At a follow-up appointment on April 13, 2018, Dr. Huber wrote that Dr. Temes' symptoms were "clinically . . . more consistent with a Type II cryoglobulinemia that we suspect was induced by his [flu] vaccine." Pet'r Ex. 51 at 12. Dr. Temes' Cytoxan treatment was discontinued on November 5, 2019. Pet'r Ex. 59 at 13. But, in February of 2020, Dr. Temes' condition worsened, and his physicians discussed restarting Cytoxan. *Id.* at 2, 13.

## **2. Proceedings Before The Special Master**

Dr. Temes commenced this Vaccine Act case before the Office of Special Masters on November 7, 2016. Pet. at 1. In support of his claim, Dr. Temes submitted fifty-seven exhibits and two affidavits. *See* Pet'r Exs. 1-59. The special master held an entitlement hearing on September 10, 2019. *See generally* Tr. Thereafter, the parties filed post-hearing briefs. *See* Pet'r Post-Hr'g Br.; Resp't Post-Hr'g Resp. Br.

During the entitlement hearing, Dr. Temes testified that he was in overall good health before the vaccinations, and that he developed a high fever, muscle pain and aches, and discoloration in one of his fingertips, within a week of his vaccinations. *See generally* Tr. 14:24-15:1; Tr. 15:8-15:16. Dr. Temes also testified that he experienced a resurgence of his symptoms in May 2017, and that he consulted with Dr. Lust at the Mayo Clinic, who expressed the opinion that the vaccinations that Dr. Temes received may have played a role in the development of his condition. Tr. 29:19-31:8.

Joseph Bellanti, M.D., an immunologist, provided two expert reports and testimony in support of Dr. Temes' claim.<sup>3</sup> *See generally* Pet'r Exs. 20, 52; Tr. 51:8-104:12. Dr. Bellanti attributed Dr. Temes' symptoms, which began within a week of vaccination, to an inflammatory response and he concluded that Dr. Temes suffered from cryoglobulinemia. *See* Tr. 57:13-58:9. But, Dr. Bellanti also acknowledged that many cases of cryoglobulinemia are "idiopathic," or without a known etiology. Tr. 86:15-86:17; 89:14-89:20.

With regards to Dr. Temes' theory of causation, Dr. Bellanti's expert reports and testimony generally relied upon the concept of epigenetics, which he described as the study of environmental influence on gene expression. *See* Tr. at 65:6-66:8. Dr. Bellanti opined that the vaccines Dr. Temes received triggered the expression of certain genes responsible for producing cryoglobulins. Tr. 66:23-66:25. He also acknowledged, however, that other environmental factors, such as changes in nutrition and certain viral infections, could provoke similar changes in gene expression. Tr. 67:5-67:7.

Dr. Bellanti's causation theory also "assumed that an aberrant autoimmune response could cause B cells to produce cryoglobulins essential to the development of cryoglobulinemia." May 12, 2020, Decision at 11; Tr. at 81:5-82:22; Pet'r Post-Hr'g Br. at 5. To support this aspect of his expert opinion, Dr. Bellanti cited to the *Catsoulis* article—a study involving the effects of hyper-immunizing rabbits with a pneumococcal vaccine. *See* Pet'r Ex. 22; E. A. Catsoulis *et al.*, *Cryoglobulinaemia in Rabbits Hyperimmunized with a Polyvalent Pneumococcal Vaccine*, 9 *Immunology* 327, 327-31 (1965) ("*Catsoulis*"). This study found that administering the

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<sup>3</sup> Dr. Bellanti serves as a professor emeritus in pediatrics and microbiology-immunology at the Georgetown University School of Medicine. Pet'r Ex. 55 at 1.

pneumococcal vaccine to rabbits every three days induced cryoglobulinemia within three to four months. *Catsoulis* at 327. The study also found that when the rabbits were no longer vaccinated, they recovered to baseline within five weeks. *Id.* at 330. When researchers re-initiated vaccination, the rabbits suffered a recurrence of cryoglobulinemia, usually after three to five weeks. *Id.* at 327. And so, the *Catsoulis* study concluded that intense pneumococcal immunization can stimulate the production of cryoglobulins. *Id.* at 330.

In addition, Dr. Bellanti proposed that molecular mimicry or bystander activation could explain how vaccine-induced cryoglobulinemia, which is an acute condition, could persist after a single vaccination. Tr. 101:12-101:17. In this regard, Dr. Bellanti relied upon several case reports identifying instances of vasculitis, cold contact urticaria, and cryoglobulinemia following vaccination. See Tr. at 74:16-78:12.<sup>4</sup> First, the *Tavadia* case report describes four cases of leucocytoclastic vasculitis following receipt of the flu vaccine. See Pet'r Ex. 23; S. Tavadia *et al.*, *Leukocytoclastic Vasculitis and Influenza Vaccination*, 28 *Clinical and Experimental Dermatology* 154, 154-56 (2003) ("*Tavadia*"). Second, Dr. Bellanti relied upon the *Iyngkaran* case report, which describes a patient who experienced the onset of cutaneous vasculitis and exacerbation of pre-existing rheumatoid arthritis two weeks after receiving the flu vaccine. See Pet'r Ex. 24; P. Iyngkaran *et al.*, *Rheumatoid Vasculitis Following Influenza Vaccination*, 42 *Rheumatology* 907, 907-09 (2003) ("*Iyngkaran*"). Third, Dr. Bellanti cited to the *Raison-Peyron*

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<sup>4</sup> Dr. Temes submitted the following medical literature in support of his claim: (1) E. A. Catsoulis *et al.*, *Cryoglobulinemia in Rabbits Hyperimmunized with a Polyvalent Pneumococcal Vaccine*, 9 *Immunology* 327, 327-331 (1965); (2) S. Eid & J. Callen, *Type II Cryoglobulinemia Following Influenza and Pneumococcal Vaccine Administration*, 5(11) *JAAD Case Rep.* 960, 961-62 (2019); (3) Patrizia Felicetti *et al.*, *Spontaneous Reports of Vasculitis as an Adverse Event Following Immunization: A Descriptive Analysis Across Three International Databases*, *Vaccine* (2016); (4) B. Fox & A. Peterson, *Leukocytoclastic Vasculitis After Pneumococcal Vaccination*, 26 *AJIC* 365, 365-66 (1998); (5) P. Iyngkaran *et al.*, *Rheumatoid Vasculitis Following Influenza Vaccination*, 42 *Rheumatology* 907, 907-909 (2003); (6) Po-Yu Liu *et al.*, *Cutaneous Vasculitis Following Influenza Vaccination*, 49 *Internal Medicine* 2187, 2187-88 (2010); (7) Anne Lohse *et al.*, *Vascular Purpura and Cryoglobulinemia after Influenza Vaccination*, 66(6) *Rev. Rheumatology* 359, 359-62 (1999); (8) Seena Monjazebe *et al.*, *A Case of Leukocytoclastic Vasculitis Following Influenza Vaccination*, 2 *JAAD Case Rep.* 340, 340-42 (2016); (9) Maria Inês Fernandes Pimentel *et al.*, *Henoch-Schönlein Purpura Following Influenza A H1N1 Vaccination*, 44(4) *Revista da Sociedade Brasileira de Medicina Tropical* 531 (2011); (10) Nadia Raison-Peyron *et al.*, *Cold Contact Urticaria Following Vaccination: Four Cases*, 96 *Acta Dermato-Venereologica* 852, 852-53 (2016); (11) S. Tavadia *et al.*, *Leukocytoclastic Vasculitis and Influenza Vaccination*, 28 *Clinical and Experimental Dermatology* 154, 154-56 (2003); (12) Ronni Wolf *et al.*, *Neutrophilic Dermatitis of the Hands After Influenza Vaccination*, 48 *Int'l J. of Dermatology* 66, 66-68 (2009).

case report, which documents the development of cold contact urticaria following vaccination. *See* Pet'r Ex. 25; Nadia Raison-Peyron *et al.*, *Cold Contact Urticaria Following Vaccination: Four Cases*, 96 *Acta Dermato-Venereologica* 852, 852-53 (2016) ("*Raison-Peyron*"). Lastly, Dr. Bellanti relied upon the *Lohse* case report, which involves a 68-year-old man who developed Type II/mixed cryoglobulinemia two weeks after receiving the flu vaccine. *See* Pet'r Ex. 26; Anne Lohse *et al.*, *Vascular Purpura and Cryoglobulinemia after Influenza Vaccination*, 66(6) *Rev. Rhum.* 359, 359-62 (1999) ("*Lohse*").

The Secretary relied upon two expert reports and testimony from Harry Schroeder, Jr., M.D., Ph.D. Resp't Exs. A, G; Tr. 105:14-168:16. During the entitlement hearing, Dr. Schroeder testified that Dr. Temes' cryoglobulinemia was most likely unrelated to the vaccines that he received. Tr. at 110:21-111:2. In this regard, Dr. Schroeder criticized Dr. Bellanti's causation theory regarding epigenetics, and he noted the absence of reliable scientific evidence to suggest that the flu virus or flu vaccine could directly result in B cell mutations, which occurs with cryoglobulinemia. Tr. 113:6-113:13; Tr. 116:12-116:18.

Dr. Schroeder also testified that he rejected the probative value of the medical literature offered by Dr. Temes. *See* Tr. 128:25-130:15. Specifically, Dr. Schroeder observed that the *Lohse* case study authors avoided reaching a conclusion regarding vaccine causality. Tr. at 126:20-126:25 (citing *Lohse* at 359 (finding that a relationship between vaccination and cryoglobulinemia could not be confirmed)). Dr. Schroeder also found the *Catsoulis* study to be unpersuasive, because the effects of the hyperimmunization conducted in *Catsoulis* could not be induced by the administration of a single high-dose flu vaccine, like the single dose received by Dr. Temes. Tr. 111:12-111:23; 112:21-113:5. And so, Dr. Schroeder opined that the effects of hyperimmunization observed in *Catsoulis*—the production of cryoglobulins—could not have resulted from Dr. Temes' single-dose of the flu vaccination. Tr. 122:1-122:7.

With regards to the *Tavadia* and *Iyngkaran* case reports, Dr. Schroeder also opined that these reports were not relevant, because they focused on diseases other than cryoglobulinemia. Tr. 129:2-129:21. In addition, Dr. Schroeder observed that the other medical literature offered by Dr. Temes to show that vaccines can cause vasculitis did not involve patients first suffering from cryoglobulinemia—like Dr. Temes. Tr. 163:10-165:15 (citing Pet'r Ex. 56; S. Monjazebe *et al.*, *A Case of Leukocytoclastic Vasculitis Following Influenza Vaccination*, 2 *JAAD Case*

Reports 340, 340-42 (2016) (“*Monjaze*”); Pet’r Ex. 57; B. Fox & A. Peterson, *Leukocytoclastic Vasculitis After Pneumococcal Vaccination*, 26(3) AJIC 365, 365-66 (1998) (“*Fox*”). And so, Dr. Schroeder concluded that the articles submitted by Dr. Temes did not support his contention that the flu and/or Prevnar 13 vaccines can cause cryoglobulinemia.

Lastly, Dr. Schroeder testified that the onset of Dr. Temes’ cryoglobulinemia, with clinical evidence appearing within a week of vaccination, was too soon to establish a causal relationship between the vaccinations that Dr. Temes received and his cryoglobulinemia. Tr. 122:24-123:7; 156:10-156:14. In this regard, Dr. Schroeder opined that it would take approximately two to three weeks for an adequate concentration of immunoglobulins to build up in the body before symptoms of cryoglobulinemia would manifest. Tr. 123:1-123:3. And so, he concluded that the onset of symptoms following Dr. Temes’ vaccinations did not occur within a medically acceptable time frame.<sup>5</sup> Tr. 123:4-123:7.

### **3. The May 12, 2020, Decision**

On May 12, 2020, the special master issued a decision denying Dr. Temes’ Vaccine Act claim. *See generally* May 12, 2020, Decision.

In his May 12, 2020, Decision, the special master first addressed the characteristics of cryoglobulinemia. *See* May 12, 2020, Decision at 23-24. In this regard, he observed that “cryoglobulinemia is a condition in which particular serum antibodies called ‘cryoglobulins’ reversibly precipitate in the blood when cooled below 37 degrees Celsius (98.8 degrees Fahrenheit).” *Id.* at 23 (citing J. Damoiseaux & J. Tervaert, *Diagnostic and Treatment of Cryoglobulinemia: It Takes Two to Tango*, 47 *Clinic. Rev. Allerg. Immunol.* 299, 299 (2014) (“*Damoiseaux*”). The special master also observed that “Type II, or ‘mixed’ [cryoglobulinemia] is thought to be caused by systemic autoimmune or infectious disease, . . . features monoclonal IgM, polyclonal IgG, and rheumatoid factor activity[]” and is “particularly associated with a hepatitis C infection.” *Id.* (citing *Damoiseaux* at 303).

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<sup>5</sup> The special master observes in the May 12, 2020, Decision that there are several points on which Dr. Bellanti and Dr. Schroeder agree—namely that: (1) Dr. Temes’ condition was properly diagnosed as Type II mixed cryoglobulinemia; (2) several of Dr. Temes’ treating physicians expressed the opinion that his condition was related to the vaccinations that he received in October 2015; and (3) Dr. Temes later experienced leukocytoclastic vasculitis secondary to his cryoglobulinemia. May 12, 2020, Decision at 15; Tr. 128:10-128:18; 147:18-147:23; 152:7-152:10.

The special master then determined, as an initial matter, that Dr. Temes had not offered a scientifically-reliable causation theory under *Althen* Prong One, because there was sparse evidentiary support that the flu and/or Prevnar 13 vaccines can cause cryoglobulinemia.<sup>6</sup> *See id.* at 25-28. Specifically, the special master found Dr. Bellanti “over-relie[d] on assumptions about the interplay of vaccination with genetic susceptibility to cryoglobulinemia that the evidence does not support.” *Id.* at 25. In this regard, the special master observed that, while Dr. Bellanti proposed that vaccines could trigger a malfunction in the expression of genes responsible for cryoglobulin production, he did not: (1) “identify the genes responsible for cryoglobulin production[;]” (2) “discuss which vaccine components could trigger or silence gene expression[;]” or (3) “offer persuasive evidence showing that any vaccines . . . have this capacity.” *Id.* In addition, the special master found that “[n]one of the literature offered in this case otherwise acknowledged epigenetics as a potential mechanism through which an individual may develop cryoglobulinemia, regardless of [the] trigger.” *Id.* And so, the special master found Dr. Temes’ arguments related to epigenetics to be unpersuasive. *See id.*

The special master also rejected Dr. Temes’ theory that an immunocompromised state resulting from epigenetic changes could allow a vaccination to initiate the abnormal production of cryoglobulins. *See id.* at 25-26. In this regard, the special master observed that Dr. Temes relied upon the *Catsoulis* study to support his theory that the Prevnar 13 vaccine can initiate the production of cryoglobulins. *Id.* at 25. But, the special master determined that the *Catsoulis* study had limited probative value, because the study only suggests that the Prevnar 13 vaccine can cause cryoglobulin production after hyperimmunization over a prolonged time period. *Id.* at 25-26. Specifically, the special master found that the hyperimmunization that occurred in *Catsoulis* was “not comparable to a single-instance receipt of the [Prevnar 13] vaccine” which occurred in Dr. Temes’ case. *Id.* In addition, the special master determined that Dr. Temes’ proposition that the flu vaccine could similarly induce cryoglobulin production lacked evidentiary support, because it “was not supported with more than conclusory statements . . . and a single high dose flu vaccine is unlikely to produce results similar to those seen in *Catsoulis*, which required roughly *thirty to forty* immunizations to induce cryoglobulinemia.” *Id.* (emphasis

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<sup>6</sup> The special master also observed that Dr. Temes erroneously argued for an evidentiary standard of mere plausibility in evaluating whether he can satisfy *Althen* Prong One. May 12, 2020, Decision at 25.

in original); *Catsoulis* at 327. And so, the special master rejected Dr. Temes' arguments that the flu and/or Prevnar 13 vaccines can instigate the production of cryoglobulins necessary for the development of cryoglobulinemia. *See* May 12, 2020, Decision at 26.

The special master also determined that none of the case reports referenced by Dr. Temes confirmed a causal relationship between the flu vaccine and the subsequent development of leukocytoclastic vasculitis. *Id.* Specifically, the special master observed that, apart from the *Lohse* study, "none of the cited case reports observing [a] temporal association between leukocytoclastic vasculitis and vaccination mentioned cryoglobulinemia as occurring first." *Id.* at 26-27. The special master acknowledged that the *Lohse* study does "suggest[] that cryoglobulinemia and . . . leukocytoclastic vasculitis may develop simultaneously[.]" *Id.* at 27. But, he concluded that *Lohse* study "does not describe how an initial onset of cryoglobulinemia can produce leukocytoclastic vasculitis years later, as occurred in Dr. Temes'[] case." *Id.*

The special master similarly found Dr. Temes' arguments that molecular mimicry or bystander activation could explain why he developed chronic cryoglobulinemia after a single dose of the flu and/or Prevnar 13 vaccines to be scientifically unreliable. *See id.* at 27-28. First, the special master found that, "beyond conclusory statements by Dr. Bellanti, no reliable literature was offered to suggest that the relevant vaccines can trigger such a process in causing persistent cryoglobulinemia." *Id.* at 27. Second, the special master found that Dr. Bellanti's characterizations of bystander activation to explain the persistence of a vaccine-caused cryoglobulinemia "were no better supported, and in fact were inconsistent." *Id.* In this regard, the special master observed that "Dr. Bellanti did not substantiate his contention [regarding bystander activation] with either independent literature or his own personal experience and research to show that cryoglobulinemia is known to become chronic in this manner." *Id.* at 28.

Lastly, the special master determined that, based upon Dr. Schroeder's expert testimony, "[o]nly ongoing exposure to an antagonizing antigen will perpetuate IgM production [resulting in persistent cryoglobulinemia.]" *Id.* In this regard, the special master found that Dr. Temes "did not offer any evidence to suggest that the antigenic components of the flu and/or [Prevnar 13] vaccines remained present and active in the body for a sufficiently prolonged period to produce the same chronic effects." *Id.* Given this, the special master concluded that, "[Dr. Temes'] theories were ultimately too conclusory and incomplete to be deemed preponderantly reliable."

*Id.* And so, the special master also concluded that “[t]he lack of credible and persuasive evidence on the issue of causation leads [him] to conclude that [Dr. Temes] has not satisfied the first *Althen* prong.” *Id.*

Regarding *Althen* Prong Two—which requires that Dr. Temes establish that the flu and/or Prevnar 13 vaccines did in fact cause his injury—the special master found that the conclusions of Dr. Temes’ treating physicians, alone, were not enough to satisfy the burden of proof under this prong. *Id.* at 28-29. In this regard, the special master determined that the medical records did contain some favorable evidence for Dr. Temes, mainly in the form of statements made by several of his treating physicians that his cryoglobulinemia was vaccine induced. *Id.* But, the special master observed that he was “not bound by [these] treater opinions, especially when other evidence rebuts or contradicts the grounds for such views.” *Id.* at 29 (citing *Snyder ex rel. Snyder v. Sec’y of Health and Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009)).

The special master also determined that “none of the literature filed in this matter supported a causal relationship between vaccination and the subsequent development of cryoglobulinemia.” *Id.* Specifically, the special master observed that “Dr. Bellanti [failed to] substantiate his opinions with reference to his own experience researching or studying the condition or its relationship to vaccination.” *Id.* The special master also observed that Dr. Callen’s case report, which focused on Dr. Temes’ clinical course, “conceded that ‘the mechanisms of vasculitis and cryoglobulinemia induced by the [flu] and [Prevnar 13] vaccination remain unknown’ and ‘it is not clear why cryoglobulins are produced as a response to a viral antigen triggered in response to a vaccination.’” *Id.* (emphasis in original) (quoting Pet’r Ex. 58; S. Eid & J. Callen, *Type II Mixed Cryoglobulinemia Following Influenza and Pneumococcal Vaccine Administration*, 5(11) *JAAD Case Reports* 960, 961-62 (2019)). And so, the special master concluded that, while “the treater views in this case do aid [Dr. Temes’] showing, they ultimately relied too much on the obvious temporal relationship between vaccination and injury to carry [Dr. Temes’] ‘did cause’ burden.” *Id.*

The special master also determined that the evidence about Dr. Temes’ subsequent development of vasculitis did not support the conclusion that his injuries were likely vaccine-caused, because “the symptoms leading to that diagnosis did not manifest until a significant time

after onset of his cryoglobulinemia in 2015.” *Id.* (emphasis in original). Given this, the special master concluded that Dr. Temes’ vasculitis “so significantly post-dated vaccination that it is difficult to associate the October 2015 vaccines with it[.]” *Id.* at 30.

Lastly, regarding the onset of Dr. Temes’ cryoglobulinemia symptoms, the special master determined that Dr. Temes failed establish a medically acceptable onset timeframe under his causation theory. *Id.* Notably, the special master found that Dr. Temes’ showing with respect to this prong “presents a similarly ‘mixed bag’ of evidence that in the end cannot satisfy this element of his burden, largely due to his inability to persuasively establish the first prong [of *Althen*].” *Id.* In this regard, the special master recognized that the evidentiary record “establishes an obviously close temporal association (approximately five to seven days) between the date of Dr. Temes’[] vaccinations and initial symptoms onset.” *Id.* But, he observed that Dr. Schroeder testified that “it takes approximately five to seven days from the time of vaccination for B cells to *begin* the production of plasma and memory cells” and “then takes up to three to four weeks *more* for the body to produce enough IgM antibody to induce cryoglobulinemia.” *Id.* (emphasis in original) (citing Tr. at 117:5-117:7).

In addition, the special master observed that “the process of causing [the] appearance of the cryoglobulins took several weeks (and only after repeated vaccination)[.]” in the *Catsoulis* study. *Id.* (citing *Catsoulis* at 328). Given this, the special master found that Dr. Schroeder’s testimony and the *Catsoulis* article “cut[] against such a short turn-around from vaccination to manifestation of the clinical symptoms [Dr. Temes] first reported[.]” *Id.* And so, the special master concluded that Dr. Temes’ onset of cryoglobulinemia did not occur within a medically acceptable timeframe under his proposed causation theory.<sup>7</sup> *Id.*

Because the special master determined that Dr. Temes did not successfully establish that either the flu and/or Prevnar 13 vaccines “could cause cryoglobulinemia, and/or [did] so in a timeframe of one week,” he concluded that the record evidence did not preponderate in a favorable ruling. *Id.* at 31. And so, the special master denied entitlement in this case. *Id.*

Dr. Temes, alleging error, seeks review of the special master’s decision.

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<sup>7</sup> The special master also rejected the argument that Dr. Temes would have experienced a faster response because he had developed immunologic memory from the flu vaccines that he received throughout his life—a concept known as “re-challenge.” May 12, 2020, Decision at 30-31.

## **B. Procedural Background**

On June 11, 2020, Dr. Temes filed a motion for review of the special master's May 12, 2020, Decision. *See generally* Pet'r Mot. for Rev. On July 13, 2020, the Secretary filed a response to Dr. Temes' motion for review. *See generally* Resp't Resp.

The motion for review having been fully briefed, the Court resolves the pending motion.

## **III. STANDARDS FOR DECISION**

### **A. Vaccine Act Claims**

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, 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).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id.* (citation omitted); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (“We uphold the special master's findings of fact unless they are arbitrary or capricious.”). The special master's discretionary rulings are reviewed for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In addition, a special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are “supported by substantial evidence.” *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to afford greater weight to

contemporaneous medical records or later given testimony is “uniquely within the purview of the special master”); *see also Hibbard v. Sec’y of Dep’t of Health & Human Servs.*, 698 F.3d 1355, 1363 (Fed. Cir. 2012) (citation omitted) (stating that there is no reversible error so long as the special master considers relevant evidence, draws plausible inferences from said evidence, and articulates a rational basis for his decision.). This “level of deference is especially apt in a case in which the medical evidence of causation is in dispute.” *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). And so, the Court will not substitute its judgment for that of the special master, “if the special master has considered all relevant factors, and has made no clear error of judgment.” *Loneragan v. Sec’y of Dep’t of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

Under the Vaccine Act, the Court must award compensation if a petitioner proves, by a preponderance of the evidence, all the elements set forth in 42 U.S.C. § 300aa–11(c)(1), unless there is a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (the “Table”), or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii); *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) the petitioner suffered a “Table Injury” that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) petitioner’s injury was actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii), 300aa–14(a); *see also Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In addition, in Table and non-Table cases, a petitioner bears “a preponderance of the evidence” burden of proof. 42 U.S.C. § 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, 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 (brackets existing) (citations omitted); *see also Snowbank Enters., Inc. v. United States*, 6 Cl. Ct. 476, 486

(1984) (holding that mere conjecture or speculation is insufficient under a preponderance standard).

In *Althen*, the Federal Circuit addressed the three elements to prove causation-in-fact. *Althen*, 418 F.3d at 1278. The Federal Circuit has also held that all three elements “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Specifically, to establish a *prima facie* case when proceeding on a causation-in-fact theory, a petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface*, 165 F.3d at 1352. In addition, a petitioner must prove 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. While the Vaccine Act does not require medical or scientific certainty, any theory posited must be “sound and reliable.” *Boatman v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen by Knudsen v. Sec’y of Dep’t of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

The Federal Circuit has also recognized the probative value of the opinions of treating physicians contained in contemporaneous medical records. *Capizzano*, 440 F.3d at 1326. Such opinions and medical records are favored in Vaccine Act matters, because “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.’” *Id.* (quoting *Althen*, 418 F.3d at 1280) (brackets existing). But, these opinions are not “binding on the special master or court.” 42 U.S.C. § 300aa–13(b)(1); *see also Snyder ex rel. Snyder*, 88 Fed. Cl. at 745 n.67 (citing *Andreu ex rel. Andreu*, 569 F.3d at 1375) (“[T]here 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.”). Rather, “the special master or court shall consider the entire record and the course of the injury” when “evaluating the weight to be afforded to any such” opinion. 42 U.S.C. § 300aa–13(b)(1).

Lastly, if a petitioner establishes a *prima facie* case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also* *Shalala v. Whitecotton*, 514 U.S. 268, 270-71 (1995). But, regardless of whether the burden of proof shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case. *See* *Stone v. Sec’y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a *prima facie* showing has been made that the vaccine was a substantial factor in causing the injury in question.”); *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case[-]in-chief.”).

#### IV. LEGAL ANALYSIS

In his motion for review, Dr. Temes raises three objections to the special master’s May 12, 2020, Decision. First, Dr. Temes argues that the special master impermissibly raised the burden of proof under *Althen* Prong One, by requiring confirmation or certainty of the validity of his theory of causation in the medical literature. Pet’r Mot. for Rev. at 10-17. Second, Dr. Temes argues that the special master impermissibly raised the burden of proof under *Althen* Prong Two, by requiring direct evidence and scientific confirmation of how the flu and/or Prevnar 13 vaccines caused his cryoglobulinemia. *Id.* at 17-19. Lastly, Dr. Temes argues that the special master erred in his analysis of *Althen* Prong Three, by finding that the timing of Dr. Temes’ onset of cryoglobulinemia was not medically acceptable. *Id.* at 19-20.

The Secretary counters that the special master reasonably concluded, after examining the evidence, that Dr. Temes failed to establish by preponderant evidence that either the flu or Prevnar 13 vaccines administered on October 19, 2015, can or did cause Dr. Temes to develop cryoglobulinemia. Resp’t Resp. at 1, 9-19. The Secretary further argues that Dr. Temes has not shown that the special master erred, or that the special master’s factual findings and legal conclusions were arbitrary, capricious, an abuse of discretion or contrary to law. *Id.* at 1-2, 5-6, 17. And so, the Secretary requests that the Court deny Dr. Temes’ motion for review and sustain the decision of the special master. *Id.* at 2, 19.

For the reasons discussed below, the evidentiary record before the Court shows that the special master did not abuse his discretion, or act contrary to law, in reaching the decision to deny Dr. Temes' Vaccine Act claim. And so, the Court **DENIES** Dr. Temes' motion for review of the special master's May 12, 2020, Decision and **SUSTAINS** the decision of the special master.

**A. The Special Master Reasonably Concluded That Dr. Temes Did Not Satisfy *Althen* Prong One**

As an initial matter, the record evidence demonstrates that the special master applied the correct legal standard to analyze Dr. Temes' claim under *Althen* Prong One. In the May 12, 2020, Decision, the special master stated that the preponderant standard under the Vaccine Act does not mandate medical certainty. May 12, 2020, Decision at 25. But, he also observed that the preponderant standard does not permit recovery based upon the reasonable-sounding nature of a particular theory. *Id.* It is well-established that the Vaccine Act does not require medical or scientific certainty to establish causation, but a theory posited must be, nonetheless, "sound and reliable." *Boatman v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). In this case, the record evidence shows that the special master conducted his analysis of *Althen* Prong One consistent with this standard. And so, the Court concludes that the special master did not err in applying the law in this case. May 12, 2020, Decision at 25.

The record evidence also shows that the special master reasonably considered and weighed the opinions of Dr. Bellanti—and the scientific evidence—in determining that Dr. Temes failed to meet his burden of proof under *Althen* Prong One. The Court will not disturb the special master's findings regarding the probative value of this evidence in this case, so long as those findings are "supported by substantial evidence." *Doe*, 601 F.3d at 1355.

**1. The Special Master Reasonably Weighed The Expert Opinions And Evidence Regarding Epigenetics**

First, the substantial evidence in the record supports the special master's determination that Dr. Bellanti's expert opinions regarding epigenetics were not adequately supported to meet the requirements under *Althen* Prong One. In the May 12, 2020, Decision, the special master found that Dr. Bellanti made certain assumptions about the interplay between a vaccination and

changes in the genes responsible for cryoglobulin production (*i.e.* epigenetics) “that the evidence does not support.” May 12, 2020, Decision at 25. Specifically, the special master observed that Dr. Bellanti failed to: (1) “identify the genes responsible for cryoglobulin production[;]” (2) “discuss which vaccine components could trigger or silence gene expression[;]” or (3) “offer persuasive evidence showing that any vaccines, the specific [vaccines] at issue, or even the wild virus or bacterial antigens underlying those vaccines have [the] capacity[.]” to cause cryoglobulinemia. *Id.* The special master also observed that Dr. Bellanti did not provide any medical literature to support his views related to epigenetics. *Id.* And so, the special master found Dr. Bellanti’s opinions related to the interplay of epigenetics and vaccination to be unpersuasive. *Id.* at 25, 28.

The special master’s decision to afford limited weight to Dr. Bellanti’s opinions regarding epigenetics is supported by the substantial evidence. As the special master correctly observes in the May 12, 2020, Decision, Dr. Bellanti failed to address which vaccine was capable of stimulating genetic changes in this case; which vaccine components were responsible for stimulating genetic changes; or which gene or genes were the target of these changes, during the proceedings before the special master. *See generally* Pet’r Exs. 20, 52; Tr. 51:8-104:12. In fact, as the special master also correctly observes, Dr. Bellanti failed to provide *any* evidentiary support for the epigenetics portion of his causation theory. *See* May 12, 2020, Decision at 25; *see also id.* A careful reading of the articles that Dr. Bellanti submitted with his expert reports also reveals that none of these articles address epigenetics in relation to vaccines. *See generally* *Catsoulis; Fox; Iyngkaran; Lohse; Monjazebe; Raison-Peyron; Tavadia.* Given this evidence, the special master’s determination that Dr. Bellanti’s opinions regarding epigenetics were not adequately supported is substantiated by the substantial evidence in this case.

## **2. The Special Master Reasonably Weighed The Evidence Regarding Molecular Mimicry And Bystander Activation**

The substantial evidence also supports the special master’s determinations about the probative value of Dr. Bellanti’s opinions regarding molecular mimicry and bystander activation.

In the May 12, 2020, Decision, the special master found that Dr. Bellanti’s testimony regarding how a single dose of the flu and/or Prevnar 13 vaccines could result in chronic cryoglobulinemia to be “scientifically unreliable.” May 12, 2020, Decision at 27. Specifically,

with regards to Dr. Bellanti's opinions related to molecular mimicry, the special master found that Dr. Bellanti did not support his views "beyond conclusory statements." *Id.* The special master also observed that Dr. Bellanti failed to provide any "reliable literature" to demonstrate that the flu and/or Prevnar 13 vaccines "can trigger [molecular mimicry to] caus[e] persistent cryoglobulinemia." *Id.* With regards to Dr. Bellanti's opinions on bystander activation, the special master similarly found that "Dr. Bellanti did not substantiate his contention with either independent literature or his own personal experience and research to show that cryoglobulinemia is known to become chronic in this manner." *Id.* at 28. And so, the special master concluded that Dr. Bellanti's opinions related to molecular mimicry and bystander activation did not meet the preponderant standard under *Althen Prong One*.

Again, the special master's conclusions regarding the probative value of this evidence are supported by the substantial evidence. The record evidence shows that Dr. Bellanti did not provide any support—by way of medical literature or otherwise—for his opinion that either molecular mimicry or bystander activation played a role in Dr. Temes' case. *See generally* Pet'r Exs. 20, 52; Tr. 51:8-104:12. Notably, Dr. Bellanti responded to a question from the special master about how Dr. Temes' cryoglobulinemia became chronic, by simply stating that "all I can say is that I believe these bystander effects are the cause of perpetuating[ Dr. Temes' condition]." Tr. 101:19-101:20. Given this evidence, the special master reasonably concluded that Dr. Bellanti's opinions regarding molecular mimicry and bystander activation should be afforded limited weight.

### **3. The Special Master Reasonably Weighed The Evidence Regarding Hyperimmunization**

The special master's findings regarding the probative value of the *Catsoulis* article and the issue of hyperimmunization were also reasonable in light of the record evidence in this case. In the May 12, 2020, Decision, the special master found that Dr. Temes failed to provide evidence that a single dose of the Prevnar 13 vaccine or flu vaccine could trigger cryoglobulinemia. May 12, 2020, Decision at 26. In making this finding, the special master observed that Dr. Temes received just a single dose of the Prevnar 13 and flu vaccines before the onset of his symptoms. *Id.* Given this, the special master concluded that the "probative value" of the *Catsoulis* article was limited, because the study in that article involved hyperimmunized

rabbits that experienced cryoglobulinemia after approximately three to four months of repeatedly receiving the pneumococcal vaccine. *Id.* at 25-26.

The special master's conclusion that the *Catsoulis* article has limited probative value in this case is supported by the substantial evidence. As the special master correctly observes in the May 12, 2020, Decision, the *Catsoulis* article is distinguishable from this case, because the rabbits in *Catsoulis* were vaccinated with the pneumococcal vaccine every three days until they developed cryoglobulinemia—which usually occurred after approximately three to four months of repeated vaccinations. *Catsoulis* at 327. In contrast, it is undisputed that Dr. Temes received a single dose of the Prevnar 13 and flu vaccines prior to the onset of his symptoms. *See* Pet'r Ex. 8. Given this, the special master's determinations regarding the probative value of the *Catsoulis* article and the issue of hyperimmunization were reasonable.

#### **4. The Special Master Reasonably Considered Petitioner's Case Reports**

Dr. Temes' argument that the special master failed to adequately consider the case reports that he submitted in this case is also unavailing. In his motion for review, Dr. Temes argues that the special master erred, because "Dr. Bellanti's theory of causation was certainly supported by case reports." Pet'r Mot. for Rev. at 13. As Dr. Temes correctly observes in his motion for review, Dr. Bellanti submitted numerous case reports documenting either cryoglobulinemia or forms of vasculitis following the administration of the flu or pneumococcal vaccines. *See, e.g., Catsoulis; Tavadia; Iyngkaran; Monjazeab* (documenting cases of vasculitis following flu vaccination); *Fox* (documenting a case of leukocytoclastic vasculitis following pneumococcal vaccination); *Raison-Peyron* (documenting cases of cold contact urticaria following flu vaccination); *Lohse* (documenting a case of vascular purpura and cryoglobulinemia following flu vaccination); *Callen* (a case report documenting Dr. Temes' clinical course). But, the record evidence also makes clear that the special master adequately considered these case reports and reasonably determined that the reports were not probative evidence to show causation in this case. May 12, 2020, Decision at 26.

Notably, the special master correctly observes in the May 12, 2020, Decision that none of the case reports that document leukocytoclastic vasculitis, or other forms of vasculitis, espouse a causal connection between such diseases and the flu vaccine. *Id.* at 26; *see, e.g., Lohse* at 359 (noting that "in none of the reported cases [discussed in the article] was proof of a causal link

with the [flu] vaccine obtained.”); *Monjaze* at 341 (“The temporal nature of these cases of vasculitis following vaccination suggests an immunopathogenic link that has yet to be explained.”). The special master also correctly observes in his decision that, with the exception of the *Lohse* case report, none of the submitted case reports involve an individual who developed vasculitis after first suffering from cryoglobulinemia—which is what occurred to Dr. Temes in this case. May 12, 2020, Decision at 26-27. In fact, the record evidence makes clear that Dr. Temes did not show how these case reports—which mostly do not involve patients that are similar to him in either demographic characteristics or symptom development—are analogous to his own experience during the proceedings before the special master. And so, the special master reasonably concluded that the case reports were insufficient to meet Dr. Temes’ burden under *Althen* Prong One. *Id.* at 26-27.

##### **5. The Special Master Reasonably Weighed The Opinions Of Petitioner’s Treating Physician Opinions**

Lastly, the special master’s determinations regarding the probative value of the opinions of Dr. Temes’ treating physicians were also reasonable and supported by the substantial evidence in this case. Dr. Temes argues in his motion for review that the special master erred, because the opinions of his treating physicians support a finding that he met his burden under the *Althen* Prong One. Pet’r Mot. for Rev. at 17. But, again, the record evidence shows that the special master appropriately weighed this evidence and reasonably concluded that the treating physician evidence was not sufficient to meet Dr. Temes’ burden of proof.

Specifically, in the May 12, 2020, Decision, the special master acknowledges that the medical records “contain some favorable evidence” by way of “statements made by several of Dr. Temes’[] treating physicians in which they expressed the opinion that his cryoglobulinemia was the result of the vaccinations he received.” May 12, 2020, Decision at 28-29. The record evidence also shows that all of Dr. Temes’ treating physicians concluded that Dr. Temes was likely experiencing mixed cryoglobulinemia as the result of receiving the flu vaccine. *See* Pet’r Ex. 1 at 20-21; Pet’r Ex. 2 at 2, 9; Pet’r Ex. 16 at 277; Pet’r Ex. 50 at 1. While there is no dispute that Dr. Temes’ treating physicians agree that he is experiencing cryoglobulinemia as a result of the flu vaccine, the special master decided to afford limited weight to these opinions, because the opinions “relied too much on the obvious temporal relationship between vaccination and injury[.]” May 12, 2020, Decision at 29.

The special master’s decision to afford limited weight to the views of Dr. Temes’ treating physicians is supported by the substantial evidence. A careful review of the medical records shows that the opinions of Dr. Temes’ treating physicians are based in large part upon the temporal association between the date of his vaccinations and the onset of symptoms—approximately five to seven days later. For example, one of Dr. Temes’ treating physicians, Dr. Callen, observes in his medical notes that Dr. Temes developed symptoms of cryoglobulinemia “[five] days after his flu shot.” Pet’r Ex. 2 at 9. The record evidence also shows that none of Dr. Temes’ treating physicians espoused a causation theory to explain how the flu vaccine caused Dr. Temes’ symptoms. *See, e.g., id.*; Pet’r Ex. 16 at 277; Pet’r Ex. 19 at 14, 17. In fact, Dr. Callen acknowledges in his case report documenting Dr. Temes’ clinical course that “a causal link with the [flu] vaccination cannot be proved by our observation[.]” *Callen* at 962; *see also* Pet’r Ex. 16 at 16 (Dr. Huber noting that “[i]t was suspected that [Dr. Temes] had developed a cryoglobulinemia induced by the [flu] vaccine[.]” without providing a basis for that opinion, aside from the timeline of Dr. Temes’ symptom development and subsequent laboratory testing).

As the special master also correctly observes in the May 12, 2020, Decision, there is other evidence in the record that contradicts the opinions of Dr. Temes’ treating physicians. Specifically, none of the medical literature submitted in this case supports finding a causal relationship between the flu and/or Prevnar 13 vaccines and cryoglobulinemia. *See generally Catsoulis; Fox; Iyngkaran; Lohse; Monjazez; Raison-Peyron; Tavadia.* In addition, as discussed above, Dr. Bellanti did not substantiate his theory of causation with other scientific evidence during the proceedings before the special master. May 12, 2020, Decision at 25-28. Given this, the special master reasonably decided to afford limited weight to the opinions of Dr. Temes’ treating physicians. *See Snyder ex rel. Snyder*, 88 Fed. Cl. at 745 n.67.

Because the evidentiary record makes clear that the special master appropriately considered and weighed the expert opinions and reports of Dr. Bellanti—as well as the other evidence submitted by both parties—in analyzing this case under *Althen* Prong One, Dr. Temes has not shown that the special master erred by concluding that Dr. Temes failed to satisfy *Althen* Prong One.

**B. The Special Master Reasonably Concluded That Dr. Temes Did Not Satisfy *Althen* Prong Two**

The record evidence also makes clear that the special master reasonably determined that Dr. Temes failed to satisfy *Althen* Prong Two. In his motion for review, Dr. Temes argues that the special master incorrectly focused his *Althen* Prong Two analysis on evidence that Dr. Temes submitted under *Althen* Prong One. Pet'r Mot. for Rev. at 17. In this regard, Dr. Temes correctly observes that the special master began his *Althen* Prong Two analysis by considering the evidentiary concerns with Dr. Temes' arguments regarding the theory of causation in this case. May 12, 2020, Decision at 29 (noting that "none of the literature filed in this matter supported a causal relationship between vaccination and the subsequent development of cryoglobulinemia."). But, the special master did not err in doing so, as Dr. Temes suggests.

The Federal Circuit has long held that there is "no reason why evidence used to satisfy one of the *Althen* . . . prongs cannot overlap to satisfy another prong." *Capizzano*, 440 F.3d at 1326. And so, in this case, the special master appropriately considered the lack of evidentiary support for Dr. Temes' theory of causation to analyze whether there was sufficient evidence to establish a logical sequence of a cause and effect showing that the vaccines at issue were the reason for the Dr. Temes' injury. May 12, 2020, Decision at 28-29.

Dr. Temes also argues without persuasion that the special master erred in finding that the treating physician evidence in this case failed to satisfy *Althen* Prong Two. Pet'r Mot. for Rev. at 22. As the special master correctly states in the May 12, 2020, Decision, special masters are not bound by the opinions of treating physicians when there is conflicting evidence in the record. *Snyder ex rel. Snyder*, 88 Fed. Cl. at 745 n.67 (citing *Andreu ex rel. Andreu*, 569 F.3d at 1375) (stating that "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 discussed above, the special master found the views of the treating physicians in this case to be in stark contrast with the submitted medical literature, which does not establish a definitive causal relationship between the flu vaccine and cryoglobulinemia. May 12, 2020, Decision at 29. And so, the special master reasonably concluded that the views of Dr. Temes' treating physicians were not sufficient to meet petitioner's burden under *Althen* Prong Two. *Id.* at 30.

**C. The Special Master Reasonably Concluded That Petitioner Failed To Establish A Medically Acceptable Timeframe**

As a final matter, the record evidence also shows that the special master reasonably concluded that Dr. Temes had not established a medically acceptable timeframe for the onset of his symptoms. In his motion for review, Dr. Temes argues that the special master erred, because the “record clearly shows that all treaters and Dr. Bellanti support the temporal association between the October 19, 2015[,] vaccinations and the onset of Dr. Temes’ cryoglobulinemia as being medically appropriate.” Pet’r Mot. for Rev. at 19-20. But, as the special master observes in the May 12, 2020, Decision, Dr. Temes failed to establish what a medically acceptable onset timeframe would be based upon his causation theory in this case. *See* May 12, 2020, Decision at 30. In fact, Dr. Temes did not put forward *any* evidence to show that the onset of his symptoms—five to seven days after receiving the vaccinations—was medically acceptable, during the proceedings before the special master. *See generally* Pet’r Exs. 20, 52.

Rather, the evidence regarding the expected onset of cryoglobulinemia symptoms contradicts Dr. Temes’ theory in this case. Notably, the Secretary’s expert, Dr. Schroeder, testified that it takes up to three to four weeks after receiving a vaccination for the body to produce enough IgM antibody to induce cryoglobulinemia. Tr. 116:19-117:17. Dr. Temes did not rebut this testimony during the proceedings before the special master. *See* Pet’r Ex. 52 at 3 (failing to provide a detailed discussion of what an appropriate temporal relationship would be under petitioner’s theory beyond noting that the onset that occurred in this case was appropriate). Given this, the special master reasonably concluded that Dr. Temes failed to satisfy his burden to establish a medically acceptable timeframe for the onset of his symptoms in this case.

**V. CONCLUSION**

In sum, the evidentiary record in this Vaccine Act case shows that the special master did not abuse his discretion, or act contrary to law, in finding that petitioner failed to establish that the flu and/or Prevnar 13 vaccines can cause, or did in fact cause, his cryoglobulinemia. While petitioner understandably disagrees with the special master’s May 12, 2020, Decision, petitioner’s objection to the decision is, at bottom, a disagreement about the probative value of the evidence submitted in this case. Because the record evidence shows that the special master

considered relevant evidence—and that the special master’s determinations regarding the probative value of that evidence are supported by substantial evidence—the Court will not substitute its judgment for that of the special master.

And so, for the forgoing reasons, the Court:

1. **DENIES** petitioner’s motion for review of the special master’s May 12, 2020, Decision; and
2. **SUSTAINS** the decision of the special master.

The Clerk shall enter judgment accordingly.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential or sensitive personally-identifiable information that should be protected from disclosure. And so, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **December 1, 2020**, a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction.

**IT IS SO ORDERED.**

s/Lydia Kay Griggsby \_\_\_\_\_  
LYDIA KAY GRIGGSBY  
Judge