In the United States Court of Federal Claims

No. 17-623V
Filed Under Seal: January 27, 2025[1]
Reissued Publicly: February 12, 2025

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DONALD R. IZARD *
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Petitioner, *
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v. *
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SECRETARY OF HEALTH AND *
HUMAN SERVICES, *
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Respondent. *
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Stacey Amanda Subryan-Gerber, Tiveron Law, PLLC, Amherst, NY, for Petitioner.
Irene Angelica Firippis, U.S. Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

DAMICH, Senior Judge.

Petitioner Donald R. Izard seeks review of Special Master Dorsey's November 13, 2024, Entitlement Decision ("Decision" or "Dec."), which denied entitlement to compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "Act"), as amended. Petitioner brought this action alleging that the influenza ("flu") vaccine he received on October 14, 2015, caused him to develop chronic inflammatory demyelinating polyneuropathy ("CIDP"), and systemic lupus erythematosus (SLE). The Special Master dismissed the petition because Petitioner did not establish by preponderant evidence that the influenza ("flu") vaccine caused him to develop CIDP, SLE, or any other injury. Here, Petitioner alleges the Special Master erred in (1) determining the correct diagnosis, (2) determining the onset timing of the symptoms, and (3) evaluating the causation evidence. For the reasons below, this Court **DENIES** Petitioner's Motion for Review.

[1] This Opinion was issued under seal on November 12, 2024. The parties were directed to propose redactions by February 10, 2025. No proposed redactions were received. The Court hereby publicly releases the Opinion and Order in full.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

I. Factual Summary

The Court notes that the Motion for Review ("MFR"), filed December 12, 2024, consists of approximately one and one-half pages and does not contain a single citation to the Decision. *See* ECF No. 162. The Court, therefore, adopts and incorporates the facts and procedural history in their entirety as set forth in the Decision.[2]

To summarize, Petitioner was sixty-six years old when he received a flu vaccine (Fluzone) on October 14, 2015. He had a past medical history of depression and anxiety, prostate cancer (in remission), hypertension, mixed hyperlipidemia, bladder calculus, and iron deficiency anemia. More than three months post-vaccination, January 2016, Petitioner presented to his primary care provider ("PCP"), Sukhwinder Kodial, M.D., for depression, panic anxiety syndrome, hypertension, and anemia. The report noted that he had tingling in his hands and feet with stress, no nocturnal symptoms, no weakness in his upper extremities and lower extremities and that his neurological examination was normal, including his sensory examination and his balance and gait.

From January 2016 through May 2016, Petitioner's examinations were normal. Then during his May 2016 visit with Dr. Kodial, Petitioner reported a two-month balance disorder but denied numbness in his hands and feet, headache, weakness, and vision problems. Thereafter, Dr. Kodial referred Petitioner to neurologist Bennett Myers, M.D. at DENT Neurologic Institute ("DENT"), for tingling in his hands and feet and imbalance. At a June 2016 appointment, Dr. Myers noted that past medical history was significant for onset of paresthesias in the feet in January 2016, and in the hands in April 2016, with associated imbalance. On physical examination, Dr. Myers noted that Petitioner had normal strength. Dr. Myers then opined that Petitioner's history and examination were strongly suggestive of a polyneuropathy. He also noted that Petitioner responded well to prednisone.

On July 5, 2016, Petitioner presented to Dr. Kodial for an annual examination. Dr. Kodial noted that Petitioner's neuropathy was stable on prednisone. On July 20, 2016, Petitioner returned to DENT for a follow-up examination. Petitioner was to continue daily prednisone and Dr. Myers noted that Petitioner should be treated as presumed CIDP until he saw a rheumatologist.

On December 5, 2016, Petitioner presented to rheumatologist Harbrinder Sandhu, M.D. who diagnosed Petitioner with SLE and peripheral neuropathy. In 2017, Dr. Myers diagnosed Petitioner with CIDP and he was uncertain with regard to a diagnosis of SLE even though some factors were present.

From 2017 through 2018, Petitioner saw several specialists for different aliments.

Then in the spring and summer of 2018, Petitioner presented to neurologist Nicholas Silvestri, M.D. He diagnosed Petitioner with SLE and autoimmune anemia and peripheral neuropathy with a history of CIDP. In October 2018, Petitioner saw rheumatologist Dr. Amar

[2] A complete recitation of the facts and procedural history can be found at Dec. at 3-4, 7-19.

Oza, M.D. who also diagnosed Petitioner with SLE. From the end of 2018 through 2019 Petitioner became weaker and was hospitalized for a broken hip. To date, he continues with follow up appointments with Dr. Silvestri.

Petitioner submitted reports by his experts: Marcel Kinsbourne, M.D. (neurology), Vera S. Byers, M.D., Ph.D. (immunology), Rebecca Shepherd, M.D. (rheumatology), and Joseph Bellanti, M.D. (immunology). Respondent submitted reports by its experts: Vinay Chaudhry, M.D. (neurology), Diane Kamen, M.D. (rheumatology), Ross Kedl, Ph.D. (immunology), and Harold Moses, Jr., M.D. (neurology).

On June 26, 2023, the parties filed a joint status report, indicating that they preferred to proceed with a ruling on the record instead of the entitlement hearing scheduled for July 2023. Petitioner filed his motion for a ruling on the record on September 18, 2023. Respondent filed his response on November 16, 2023, and Petitioner filed a reply on December 18, 2023. The Special Master filed her opinion and order on November 13, 2014, denying entitlement. This review followed.

II. Standard of Review

This Court may only set aside a special master's findings of fact or conclusions of law if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B); RCFC, App. B, Vaccine Rule 36(b)(7); RCFC, App. B, Vaccine Rule 27(b). Findings of fact receive deferential review under an "arbitrary and capricious" standard; legal conclusions are reviewed *de novo* under the "not in accordance with law" standard; and discretionary rulings are reviewed for "abuse of discretion." *Boatmon v. HHS*, 941 F.3d 1351, 1358 (Fed. Cir. 2019); *Munn v. HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). This standard of review is "uniquely deferential for what is essentially a judicial process," and the Federal Circuit has warned against "second guess[ing] the Special Master[s'] fact-intensive conclusions." *Hodges v. HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993).

III. Causation Standard in Vaccine Act Cases

Petitioner does not allege, nor does the record support, that he suffered an injury covered by the Vaccine Injury Table. *See* 42 C.F.R. § 100.3. Accordingly, to prove actual causation, petitioner must establish: (1) a reputable, persuasive, sound, and reliable scientific or medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect demonstrating that the vaccination was the reason for the injury; and (3) a showing of a medically acceptable temporal relationship between the vaccination and injury. *See, e.g., Boatmon*, 941 F.3d at 1354-55; *Broekelschen v. HHS*, 618 F.3d 1339, 1350 (Fed. Cir. 2010); *Moberly v. HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010); *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Petitioner must prove each of the three *Althen* prongs by a preponderance of the evidence. *Boatmon*, 941 F.3d at 1355; *see also Dobrydnev v. HHS*, 566 F. App'x 976, 980 (Fed. Cir. 2014) ("Because petitioners must meet their burden under all three *Althen* factors to prevail, a failure to do so on any one of these factors is dispositive.").

The Vaccine Act prohibits special masters from concluding that a vaccine-related injury has occurred based solely upon the claims of petitioner. 42 U.S.C. § 300aa-13(a)(1). Rather, petitioner must provide independent evidence of vaccine causation. *See, e.g.*, *Cucuras v. HHS*, 933 F.2d 1525, 1528 (Fed. Cir. 1993); *Lett v. HHS*, 39 Fed. Cl. 259, 260 (1997); *Reusser v. HHS*, 28 Fed. Cl. 516, 523 (1993); *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992). A special master may not accept an expert's opinion based on the expert's *ipse dixit*, as the opinion of an expert is "no better than the soundness of the reasons supporting it." *Perreira v. HHS*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994); *see also Sword v. United States*, 44 Fed. Cl. 183, 188 (1999) ("Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions."). Special masters are "entitled – indeed, expected – to make determinations as to the reliability of evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326. The focus is evidentiary reliability, which is based on scientific validity. *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 590 n.9 (1993). In evaluating the reliability of an expert's opinions, a special master "'may conclude that there is simply too great an analytical gap between the data and the opinion proffered.'" *Cedillo*, 617 F.3d at 1339 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

IV. Discussion

Petitioner contends that the Special Master erred in (1) determining the correct diagnosis, (2) determining the onset timing of the symptoms, and (3) evaluating the causation evidence. However, in his MFR, Petitioner only provides these bare allegations. Petitioner does not offer any objection as to how the Special Master weighed the evidence nor does the Petitioner argue that the Special Master was arbitrary or capricious or abused her discretion in her determinations. Even so, the Court is tasked with reviewing the Special Master's factual determinations to determine whether her findings are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law keeping in mind that the Court may not second guess the Special Master's fact-intensive conclusions.

A. The Court holds that the Special Master neither erred nor abused her discretion when she found that Petitioner has SLE with neuropathy and/or CIDP as the presenting symptom.

The Special Master concluded that Petitioner's correct diagnosis was systemic lupus erythematosus (SLE) with neuropathy/CIDP as a presenting symptom, rather than a separate condition of CIDP. This conclusion, according to Petitioner, is contrary to the expert opinions provided by Dr. Silvestri and Dr. Shephard. MFR at 1. In particular, Petitioner argues that Dr. Shephard noted that SLE is known to occur in conjunction with peripheral neuropathies, including CIDP. *Id*. at 1-2. Petitioner argues that his medical treaters and experts assert that he has SLE that was triggered by the flu vaccine and has presented as CIDP. MFR at 2. This evidence supports Petitioner's claim that he developed CIDP as a result of the flu vaccine, independent of his SLE diagnosis. *Id*. Petitioner attaches Exhibit A and Exhibit B to its MFR, alleging that they confirm "petitioner's symptoms meet the criteria for both CIDP and SLE diagnoses." MFR at 1-2. The Court turns to the Decision for review.

In this case, the Special Master noted that "Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the *Althen* analysis." Dec. at 47 (citing *Broekelschen v. Sec'y of Health & Hum. Servs.,* 618 F.3d 1339, 1346 (Fed. Cir. 2010))." Dec. at 47. She further noted that because "each prong of the *Althen* test is decided relative to the injury[,]" it is sometimes necessary to determine the facts that relate to the claimed injury where the diagnosis is not clear. *Id*. Since the parties disputed the diagnosis, the Special Master was tasked with first resolving that issue.

In her discussion, the Special Master first noted that the parties stipulated that Petitioner suffers from SLE. *Id*. Second, the Special Master noted that the parties' experts also agreed Petitioner suffers from SLE. *Id*. In particular the Special Master noted:

> Petitioner's expert Dr. Shepherd opined that Petitioner met the diagnostic criteria for SLE based on the SLICC.[3] Pet. Ex. 20 at 6. Petitioner's expert Dr. Bellanti opined Petitioner was first diagnosed with "CIDP that [] was subsequently diagnose[d] as SLE." Pet. Ex. 27 at 4, 6. Respondent's experts Dr. Moses and Dr. Kamen opined Petitioner met the SLICC criteria for SLE and was correctly diagnosed with SLE.

Id.

The Special Master continued by reviewing the record and considered the opinions of all of Petitioner's treating physicians. For instance, the Special Master noted that in December 2016, rheumatologist Dr. Sandhu diagnosed Petitioner with SLE using the SLICC criteria,

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[3] Systemic Lupus International Collaborating Clinics ("SLICC"). Pet. Ex. 20, Tab 3 at 1.

> Under the SLICC classification criteria, one is appropriately diagnosed with SLE if they satisfy "[four] of the clinical and immunologic criteria," including one of each category. *Id*. at 5. The criteria do not need to present concurrently. *Id*.; see also Pet. Ex. 20, Tab 5 at 5-6. The SLICC clinical criteria include inflammatory conditions from different connective tissue systems, including, but not limited to, skin (e.g., rashes, ulcers, nonscarring alopecia), 20 joints (e.g., synovitis), pulmonary (e.g., pleurisy, pleural effusion), cardiac (pericarditis), neurologic (e.g., peripheral neuropathy), and hematology (hemolytic anemia). Pet. Ex. 20, Tab 3 at 6 tbl.3. Immunologic criteria include, for example, elevated ANA, elevated anti-double-stranded DNA ("dsDNA") antibodies, 21 and the presence of anti-Smith antibodies. *Id*. Peripheral neuropathy is specifically noted as meeting the criteria for a neurological inflammatory condition. *Id*.
>
> As acknowledged in the SLICC criteria, peripheral neuropathies, including CIDP, are associated with SLE. Pet. Ex. 20, Tab 3 at 6 tbl.3; see also Pet. Ex. 20, Tab 1 at 3.

Dec. at 6 (footnotes omitted).

documenting positive serologies and peripheral neuropathy. *Id*. The Special Master further noted that Dr. Sandhu determined that Petitioner's "peripheral neuropathy [was] a presenting symptom." *Id*. (citing Pet. Ex. 11 at 12.). Further reviewing the record, the Special Master noted that in "October 2018, rheumatologist Dr. Oza also assessed Petitioner with SLE, opining that it likely explained both his neurologic and hematologic disease (AIHA)." Dr. Oza acknowledged and the Special Master did not ignore that the Petitioner "lacked the classical clinical features of SLE." *Id*. However, Dr. Oza opined that petitioner's neurologic symptoms and pulmonary findings satisfied both the American College of Rheumatology ("ACR") and Systemic Lupus International Collaborating Clinics ("SLICC") diagnostic criteria. *Id*. Thus, after reviewing these medical records, the Special Master concluded that Petitioner's "rheumatologists consistently diagnosed him with SLE, with peripheral neuropathy as a presenting symptom." *Id*.

The Special Master did not ignore the opinion of Petitioner's treating neurologist Bennett Myers, M.D., and Dr. Myers's February 2017 assessment that petitioner had CIDP, not SLE. *Id*. at 48 (citing Ex. 4 at 3). The Special Master properly weighed the persuasiveness of Dr. Myers's opinion by considering that he is not a rheumatologist, *id.*, and the Special Master was within her discretion to reject it. *See* 42 U.S.C. § 300aa-13(b)(1) (while a special master must consider any diagnosis contained in the medical records, "[a]ny such diagnosis . . . shall not be binding on the special master"); *see also Perreira*, 33 F.3d at 1377 n.6 ("An expert opinion is no better than the soundness of the reasons supporting it"). Indeed, the Special Master provided ample support from Vaccine Act case law confirming her discretion to reject Dr. Myers's opinion. Dec. at 48 (citing *Pafford*, 451 F.3d at 1359; *Koehn v. HHS*, No. 11-355V, 2013 WL 3214877, at *32 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250, at *64 (Fed. Cl. Spec. Mstr. Mar. 12, 2010)).

The Special Master also considered all expert opinions and medical literature in concluding that both parties' experts agreed that SLE can present "with peripheral neuropathy and/or CIDP." Dec. at 48. The Special Master noted that Dr. Kinsbourne and Dr. Byers opined polyneuropathies are occasionally associated with SLE and SLE can present as a neuropathy and/or CIDP, which is supported in the literature. *Id.* (citing Ex. 14 at 5-6; Ex. 23-c; Ex. 20, Tab 2). Further, the Special Master considered Dr. Shepherd's opinion that "up to 30% of SLE patients have peripheral neuropathy confirmed by EMG/NCS" and the case reports cited by Dr. Shepherd that demonstrate peripheral neuropathy/CIDP is a manifestation of SLE. *Id*. (citing Ex. 20, Tabs 1, 2, and 6).[4]

The Special Master noted that Dr. Bellanti and Dr. Kamen each cited literature that showed neuropathy can be a presenting symptom or neurological manifestation of SLE. *Id.* She explained that "[n]one of Petitioner's experts preponderantly explain why they believe Petitioner had a distinct case of peripheral neuropathy/CIDP separate from his SLE," and that petitioner's immunologist, Dr. Bellanti, specifically "opined Petitioner's 'CIDP . . . was subsequently diagnose[d] as SLE.'" *Id*. at 49 (citing Ex. 27 at 6).

[4] Exhibit B is a duplicate of Exhibit 20, Dr. Shepherd's expert report which was reviewed and discussed by the Special Master contrary to Petitioner's contentions that it was not discussed. Additionally, Exhibit A, is a copy of Exhibit 52, which the Special Master also reviewed and discussed. *See* Dec. at 16 (citing Exhibit 52 and noting petitioner's follow-up appointments with Dr. Silvestri in 2022 and 2023).

Thus, there is no evidence that the Special Master committed a legal error in her analysis or that she abused her discretion in finding that petitioner did not have two distinct conditions, SLE and peripheral neuropathy/CIDP but instead, had one condition—SLE. The Special Master's factual findings were extensively reasoned and supported by the medical records, expert opinions, and medical literature, and as such are not arbitrary or capricious.

B. The Court holds that the Special Master did not err as a matter of law in finding the onset of Petitioner's symptoms was in January 2016.

Petitioner's second objection asserts that the Special Master erred in finding that a three-month onset is "too long" and "is not supported by the evidence" because the Special Master failed to consider Petitioner's "expert's credible testimony and the medical literature supporting the proposed mechanisms of causation." MFR at 2. Once again, Petitioner makes this allegation without any support, citing neither medical records nor expert opinion, and he fails to explain how the Special Master erred in her findings. Thus, the Court once again turns to the Decision to review the Special Master's determination and conclusion.

The Court first notes that in making her determination regarding onset, the Special Master reviewed and discussed the opinions of Petitioner's experts Dr. Kinsbourne and Dr. Bellanti. Dec. at 56. She noted that Dr. Kinsbourne relied on Petitioner's affidavit when opining that Petitioner's onset was approximately one month after his October 14, 2015, vaccination. *Id*. She further explained that Dr. Bellanti also relied on Petitioner's affidavit when opining that Petitioner first showed symptoms of CIDP in mid-November 2015, within forty-two days of vaccination. *Id*.

The Special Master then proceeded to review Respondent's experts, Dr. Chaudhry, Dr. Moses, and Dr. Kamen. In her Decision, the Special Master noted that Dr. Chaudhry relied on Petitioner's most contemporaneous records to opine that Petitioner's neurologic symptoms began in January 2016. *Id*. Reviewing Dr. Chaudhry's report, the Special Master noted that Dr. Chaudhry was "not persuaded by petitioner's affidavit that onset was in November 2015 because this date is inconsistent with contemporaneous medical records" and that Petitioner's affidavit was executed in April 2017, one-and-one-half years after vaccination. *Id*. The Special Master also noted that Dr. Moses also concluded that Petitioner's neuropathy symptoms began three months post-vaccination and agreed that Petitioner's symptoms were not temporally linked to his flu vaccine. *Id*. And finally, the Special Master noted that Dr. Kamen's expert report indicated that the affidavits conflicted with Petitioner's medical records and opined that if Petitioner's symptoms began in January 2016, "an onset of over two months post-vaccination is inconsistent with the vaccination being linked to petitioner's development of SLE." *Id*.

The Special Master did not only review the expert reports in making her onset determination. Indeed, she also reviewed the medical records to determine Petitioner's first neurological symptoms. *Id*. at 57. The Special Master noted that Petitioner's first neurological abnormality was documented on January 26, 2016, when he reported tingling in his hands and feet. *Id*. (citing Ex. 3 at 25-26). She further noted that when Petitioner presented to a neurologist

in June 2016, he complained that tingling in his feet began in January 2016. *Id.* (citing Ex. 4 at 14).

The Special Master also reviewed the affidavits submitted by Petitioner, Petitioner's wife, and Petitioner's family friend. In her Decision, the Special Master noted that the affidavits discuss that Petitioner fell on Thanksgiving 2015 but "none of petitioner's contemporaneous medical records document any fall or neuropathic symptoms before January 2016" and "[t]he affidavits were executed later in time, in April 2017 and June 2018, years after vaccination." *Id*.

After review of all the evidence, the Special Master found that:

> Because Petitioner's affidavits are inconsistent with and contradicted by the contemporaneous medical records, the undersigned find it reasonable to give greater weight to the contemporaneous medical records. *See Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); *Doe/70 v. Sec'y of Health & Hum. Servs*., 95 Fed. Cl. 598, 608 (2010); *Stevens v. Sec'y of Health & Hum. Servs*., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); *Vergara*, 2014 WL 2795491, at *4 ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.").

Thus, the Special Master properly weighed the affidavits against Petitioner's contemporaneous medical records to conclude that Petitioner's onset occurred no earlier than January 2016. Indeed, the Decision shows that the Special Master appropriately examined the testimony and weighed the evidence consistent with applicable law her conclusion. There is no error.

C. The Court holds that the Special Master did not err when she determined that Petitioner had failed to preponderantly demonstrate that the flu vaccine can cause SLE.

The Special Master concluded that Petitioner failed to provide preponderant evidence of a sound and reliable theory by which the flu vaccine can cause SLE. However, Petitioner argues that his "experts opined that the flu vaccine caused him to develop CIDP and/or SLE via mechanisms like molecular mimicry" and that "Dr. Shephard confirmed that Petitioner's symptoms meet the criteria for both CIDP and SLE diagnoses and noted that SLE is known to occur in conjunction with peripheral neuropathies, including CIDP." MTD at 2. This evidence, according to Petitioner, "provides a sound and reliable theory for how the flu vaccine could have caused Petitioner's condition." *Id*.

Althen prong one provides guidance for finding causation. And in this case, as the Special Master correctly pointed out in her Decision:

> Under *Althen* prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. *Andreu*, 569 F.3d at 1375; *Pafford*, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. *Boatmon*, 941 F.3d at 1359; *see also Knudsen*, 35 F.3d at 548; *Veryzer v. Sec'y of Health & Hum. Servs.,* 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. *See Broekelschen*, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); *Perreira v. Sec'y of Health & Hum. Servs*., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing *Fehrs v. United States*, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Dec. at 49.

In this case, the Special Master found that Petitioner did not provide preponderant evidence of a sound and reliable theory by which the flu vaccine can cause SLE. Therefore, the Special Master found that Petitioner failed to satisfy the first *Althen* prong. In support, of this determination, the Special Master first noted that only one of Petitioner's experts, Dr. Bellanti, discussed *Althen* prong one as it relates to SLE. Dec. at 49. She further noted that Dr. Kinsbourne addressed *Althen* prong one only relative to CIDP, but not CIDP as a presenting symptom of SLE, and Dr. Byers and Dr. Shepherd did not address *Althen* prong one at all. *Id*.

Turning to Dr. Bellanti's report and opinion, the Special Master noted that Dr. Bellanti opined:

> The flu vaccine "can trigger . . . SLE" in genetically predisposed individuals and proposed four mechanisms by which vaccination can cause an autoimmune disease: molecular mimicry, polyclonal activation, "tissue damage caused by the infecting agent (or vaccine)," and bystander activation.

Id. (citing Pet. Ex. 27 at 4, 8-10). Thereafter, the Special Master discussed the deficiencies of Dr. Bellanti's opinion, explaining that:

> Most of his discussion related to molecular mimicry generally and how it relates to GBS,[5] arguing the mechanism is also applicable to CIDP. However, Dr. Bellanti did not describe how the flu vaccination can cause

[5] Guillain-Barré syndrome.

> SLE via molecular mimicry. Nor did he provide any literature or other evidence supporting a relationship between molecular mimicry and SLE. For his other proposed mechanisms, Dr. Bellanti failed to provide a supportive framework beyond simply asserting the theories generally.
>
> Simply asserting a causal theory without context or a supportive factual framework based on medical literature, research, or other evidence is insufficient. Further, the causal theory must be specific to Petitioner's case. *Moberly*, 592 F.3d at 1322. Merely identifying a mechanism for a disease process without additional evidence specific to Petitioner's case is insufficient to preponderantly show causation. *See Monzon v. Sec'y of Health & Hum. Servs*., No. 17-1055V, 2021 WL 2711289, at *29 (Fed. Cl. Spec. Mstr. June 2, 2021); *Baron v. Sec'y of Health & Hum. Servs*., No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019); *Duncan v. Sec'y of Health & Hum. Servs.*, No. 16-1367V, 2020 WL 6738228, at *11 (Fed. Cl. Spec. Mstr. Oct. 19, 2020), aff'd, 153 Fed. Cl. 642 (2021); *Boatmon*, 941 F.3d at 1360; *LaLonde v. Sec'y of Health & Hum. Servs*., 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing Moberly, 592 F.3d at 1322); *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013).
>
> Further, although molecular mimicry is an accepted scientific mechanism, generally opining that molecular mimicry is a causal theory, without more, is insufficient. *See, e.g., Loyd ex rel. C.L. v. Sec'y of Health & Hum. Servs*., No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021) ("[T]hough molecular mimicry is a generally accepted scientific concept, and is frequently invoked in Program cases, the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard. Rather, it must be shown that the mechanism likely does link the vaccine in question to the relevant injury." (internal citations omitted)).

Dec. 49-50.

It is clear from the Decision that the Special Master reviewed Dr. Bellanti's opinions to find that he failed to provide a supportive framework beyond simply asserting the theories generally. Simply asserting a causal theory without context or a supportive factual framework based on medical literature, research, or other evidence is insufficient. Citing numerous cases, the Special Master appropriately weighed the evidence and concluded that petitioner failed to meet his burden because "[m]erely identifying a mechanism for a disease process without additional evidence specific to petitioner's case is insufficient to preponderantly show causation." *Id*. at 50.

The Special Master also discussed the case where CIDP was alleged as a vaccine related injury post flu vaccination in Vaccine Program cases and in some of these, Petitioners have prevailed on *Althen* prong one. See, e.g., *Nieves v. Sec'y of Health & Hum. Servs*., No. 18-

1602V, 2023 WL 3580148, at *36 (Fed. Cl. May 22, 2023). However, she distinguished those cases due to Petitioner's diagnosis of SLE. In particular she found:

> The cases set forth above do not address SLE associated CIDP, or CIDP as the presenting symptom of SLE. The literature herein states that "CIDP is a peripheral nervous system manifestation of SLE" that "can occur before, after, or simultaneously with the onset of SLE." Pet. Ex. 20, Tab 2 at 9. "Neuropsychiatric manifestations in SLE should be first evaluated and treated as in patients without SLE, and secondarily attributed to SLE and treated accordingly." Pet. Ex. 20, Tab 4 at 1. Therefore, the undersigned evaluates the causal theory here in the context of the umbrella diagnosis of SLE, and not as CIDP standing alone, or separate from the underlying illness at issue.

Dec. at 51.

The Special Master also discussed how petitioner's experts failed to provide foundational "evidence, studies, or medical literature demonstrating how the flu vaccine can cause SLE." *Id*. The Special Master noted that Dr. Bellanti's literature pertaining to SLE "either did not discuss or did not report an association with the flu vaccine." *Id*. Citing multiple cases, the Special Master concluded that the literature was not persuasive in part because Dr. Bellanti failed to explain how the literature or data from other vaccines could be extrapolated to the flu vaccine. The Special Master explained that petitioner's theories "are unsupported by medical or scientific facts, research, or any other reliable evidence. Moreover, these theories are speculative and/or conclusory in nature." *Id*.

In sum, the Court holds that the Special Master's determination that Petitioner had not proven his theory under *Althen* prong one by preponderant evidence was based upon extensive factual findings that took account of all relevant evidence, and was thoroughly reasoned, explained, and amply supported by the record. Petitioner has not demonstrated any error. Petitioner's only quarrel is with how the Special Master weighed the evidence and as this Court has noted, the Court of Federal Claims "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence of the credibility of the witnesses – these are all matters within the purview of the fact finder." *Argueta v. HHS*, 102 Fed. Cl. 272, 275 (Fed. Cl. 2011) (citing *Porter*, 663 F.3d at 1249, 1254).

V. CONCLUSION

The Special Master applied the correct legal standard and weighed the evidence properly within her discretion. Accordingly, the Court **DENIES** Petitioner's Motion for Review and **SUSTAINS** the Special Master's Decision. The Clerk of the Court shall enter judgment for Respondent accordingly.

IT IS SO ORDERED.

s/Edward J. Damich
EDWARD J. DAMICH
Senior Judge