

In the United States Court of Federal Claims

No. 20-596V

(Filed Under Seal: September 16, 2025)

(Public Filing: October 6, 2025)

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JAMES HARVEY, M.D.,)
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<i>Petitioner,</i>)
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v.)
)
SECRETARY OF HEALTH AND)
HUMAN SERVICES,)
)
<i>Respondent.</i>)
)
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Jessica Wallace, Siri & Glimstad, LLP, Aventura, FL, for Petitioner.

Ryan D. Pyles, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With him on the briefs were Yaakov M. Roth, Acting Assistant Attorney General, C. Salvatore D'Alessio, Director, Heather L. Pearlman, Deputy Director, and Voris E. Johnson Jr., Assistant Director.

OPINION AND ORDER

SOLOMSON, Chief Judge.

Petitioner, Dr. James Harvey, filed a claim for compensation against Respondent, the Secretary of Health and Human Services, pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et seq. (the "Vaccine Act"). ECF No. 1. He alleges that an influenza vaccination (the "Flu Vaccine") caused him to suffer leukocytoclastic vasculitis ("IgAV"), and, in turn, a neuropathy.¹ *Id.* On March 18, 2025,

* This decision was initially issued under seal on September 16, 2025, in accordance with Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims, to permit Petitioner time

Special Master Moran denied Dr. Harvey's petition for vaccine compensation. ECF No. 126. The Special Master concluded that Dr. Harvey did not meet his burden to prove, by a preponderance of evidence, that the Flu Vaccine was the cause-in-fact of Dr. Harvey's injury. *Id.* at 29. Dr. Harvey now petitions this Court for review of the Special Master's decision. ECF No. 128. For the reasons explained below, this Court concludes that the Special Master's decision in this case was not arbitrary or capricious. Accordingly, the Special Master's decision is **AFFIRMED**.

I. FACTUAL BACKGROUND²

Dr. Harvey received the Flu Vaccine on October 6, 2017. ECF No. 126 at 3. At the time, he was 76 years old, a retired medical practitioner, and had relevant pre-existing conditions, including severe asthma and diabetes. *Id.* at 2-3. Within several hours of receiving the Flu Vaccine, Dr. Harvey developed a rash all over his legs and "began to feel down." *Id.* at 3.

On October 12, 2017 – six days after receiving the Flu Vaccine – Dr. Harvey saw a dermatologist, Dr. Kari Boucher, to whom Dr. Harvey described the rash symptoms he had experienced over the preceding five days. Dr. Boucher diagnosed Dr. Harvey with IgAV, and prescribed both "a topical cream and prednisone." ECF No. 126 at 3. On October 17, 2017, as the pain and rash persisted, Dr. Harvey sought an opinion from a second dermatologist, Dr. Amy C. Musiek. *Id.* at 4. Dr. Harvey again reported that he received the Flu Vaccine on October 6, 2017, and developed a rash the following day. *Id.* Dr. Musiek performed a punch biopsy, which confirmed that Dr. Harvey had IgAV. *Id.*

On October 18, 2017, Dr. Harvey was hospitalized for a planned bronchial thermoplasty – a procedure used to treat severe asthma. ECF No. 126 at 3-4. During his hospitalization, an internist "memorialized that Dr. Harvey stated his [IgAV] was triggered [secondary to]" the Flu Vaccine. *Id.* at 4 (second alteration in original).

to propose redactions. Petitioner indicted that he requests no redactions. This public version also reflects several typographical corrections.

¹ IgAV symptoms often include, but are not limited to, severe rashes on the legs, and itchiness. For additional information about IgAV, see the Special Master's summary of the condition. ECF No. 126 at 3-4.

² Because the material facts are undisputed, this Court's fact summary facts is largely drawn from the Special Master's decision. ECF No. 126.

Dr. Harvey consulted over the phone with an internist at the Cleveland Clinic, Dr. Stephen Hayden, on October 26, 2017. ECF No. 126 at 5. Dr. Hayden documented that a recent punch biopsy showed Dr. Harvey had IgAV. *Id.* On October 31, 2017, during Dr. Harvey's first in-person visit with Dr. Hayden, Dr. Hayden memorialized his impressions, including that Dr. Harvey suffered from IgAV. *Id.*

Dr. Harvey's "rash . . . subsided after a few weeks."³ ECF No. 126 at 4-5.

Thereafter, on November 1, 2017, an endocrinologist at the Cleveland Clinic, Dr. Susan William, first diagnosed Dr. Harvey with a neuropathy. ECF No. 126 at 5. Over the ensuing few months, Dr. Harvey met with Dr. Hayden and communicated with him via a patient portal on several occasions. *See Id.* at 5-6. These communications centered around Dr. Harvey's neuropathy, including resulting neuromuscular issues. *Id.* During this period, Dr. Harvey made no reference to his IgAV or the Flu Vaccine. *Id.*

On February 8, 2018, after Dr. Hayden suggested that Dr. Harvey see a neurologist due to his ongoing neuropathy – more than four months after the Flu Vaccine, and long after his IgAV symptoms had dissipated – Dr. Harvey *for the first time*, "raised the possibility of an adverse reaction to the [Flu Vaccine]." ECF No. 126 at 6. Via the patient portal, Dr. Harvey asked Dr. Hayden if it would "be a good idea [] to see somebody [who

³ To demonstrate entitlement to compensation pursuant to the Vaccine Act, a petitioner must meet a "severity" requirement. 42 U.S.C. § 300aa-11(c)(1)(D) (providing, in relevant part, that a petitioner must show he or she "suffered the residual effects or complications of [an alleged vaccine-induced] illness . . . for more than 6 months after the administration of the vaccine"). In this case, however, based on Dr. Harvey's own account, his IgAV-related symptoms did not last six months and subsided *within* six months of his receipt of the Flu Vaccine. Thus, in an attempt to meet the severity requirement, Dr. Harvey maintains that the IgAV, *in turn*, caused a neuropathy whose symptoms lingered well beyond the six-month period. ECF No. 126 at 5 n.6. Relatedly, although Dr. Harvey's medical record – as summarized in the Special Master's decision, discussed *infra* – contains an ample discussion supporting the possibility of the Flu Vaccine's having *directly* caused Dr. Harvey's neuropathy, the Special Master found that Dr. Harvey did not "assert that theory," and thus the Special Master "[did] not address that question." *Id.* at 24 n.18. This Court similarly does not reach the issue because Dr. Harvey has waived it – both before the Special Master and now before this Court. Indeed, Dr. Harvey maintains only that the vaccine caused IgAV, which, in turn, caused a neuropathy. Furthermore, because this Court affirms the Special Master's reasonable conclusion that Dr. Harvey did not prove, by preponderant evidence, that the Flu Vaccine caused IgAV, we do not need to reach his neuropathy claim, in any event.

is an] expert in vaccines,” noting that Dr. Harvey found it difficult to attribute his then-current problems related to his *neuropathy* to other life events. *Id.* A few days later, on February 13, 2018, Dr. Harvey also questioned if the Flu Vaccine caused his IgAV. *Id.* at 7. Dr. Hayden, in his notes to a neurologist Dr. Harvey saw shortly thereafter, memorialized that Dr. Harvey “questions flu vaccine [sic].” *Id.*

Dr. Ilia Itin – a neurologist Dr. Harvey visited on February 20, 2018 – documented how Dr. Harvey “broke out in a rash following [his Flu Vaccine],” and “was diagnosed with IgAV.” ECF No. 126 at 7. Dr. Itin further documented events and symptoms related to Dr. Harvey’s neuropathy. *Id.*

On March 29, 2018, Dr. Timothy Harris Lucas, from the University of Pennsylvania, memorialized a complaint from Dr. Harvey that he “had a rocky year with . . . reactions to vaccines.” ECF No. 126 at 8. It is unclear from the record, however, if Dr. Harvey, in his complaint to Dr. Lucas, was referring to his neuropathy – from which he still suffered at the time – or also his IgAV, which had long since improved. As with Dr. Hayden’s note to Dr. Harvey’s neurologist, however, Dr. Lucas was memorializing Dr. Harvey’s reports regarding reactions to the Flu Vaccine, *not* Dr. Lucas’s own independent conclusions.

On July 7, 2018, Dr. Harvey again communicated with Dr. Hayden via the patient portal, this time inquiring if Dr. Harvey should get a shingles vaccine. ECF No. 126 at 9. Dr. Hayden responded that he does not “think [Dr. Harvey] should get [an] egg-based flu vaccine *if* that is what caused the previous reaction.” *Id.* (emphasis added). When prescribing Tamiflu to Dr. Harvey, on another occasion, Dr. Hayden similarly noted that Dr. Harvey is “unable to have influenza vaccine because of [a] prior severe reaction[.]” *Id.* It is unclear, however, if Dr. Hayden’s reference to a “prior severe reaction,” was to Dr. Harvey’s IgAV, neuropathy, or both.

On October 5, 2018, Dr. Harvey emailed Dr. Hayden. ECF No. 126 at 9. Dr. Harvey indicated that he remained “dissatisfied” with his understanding of the “neuromuscular symptoms” temporally related to his Flu Vaccine, and asked if “anybody could address his concern.” *Id.* Dr. Harvey continued to press this concern with Dr. Hayden on multiple occasions thereafter. *Id.* at 10. On February 25, 2019, in response to yet another inquiry on the same subject, Dr. Hayden responded that “he did not know how to prove

whether the [Flu Vaccine] caused the problem. *Id.*⁴

Given that Dr. Harvey continued to experience neuromuscular symptoms despite various treatments, Dr. Harvey, on April 15, 2019, saw two specialists in neuromuscular disorders: Dr. Monica Scarsella and Dr. Rebecca Kuenzler.

Reviewing Dr. Harvey's medical history, Dr. Scarsella concluded that the "[t]ime course of [Dr. Harvey's] symptoms fits in correlation with a post-vaccine polyneuropathy." ECF No. 126 at 12. As to whether the Flu Vaccine could have caused IgAV, which *in turn* caused a neuropathy, Dr. Scarsella opined that "[t]here are rare reports of [IgAV] occurring after vaccination. Additionally, polyneuropathy can occur in correlation with IgAV, although this is also rare." *Id.* Put simply, Dr. Scarsella believed that Dr. Harvey's neuropathy was a *direct* result of the Flu Vaccine, because the alternative theory – which Dr. Harvey now presses – would assume a double rarity, something which Dr. Scarsella would not do.

That same day, Dr. Kuenzler expressed her opinion that the "time course [of Dr. Harvey's symptoms was] most compatible with post-vaccine autoimmune response causing [IgAV] *and* neuropathy." ECF No. 126 at 12. (alteration in original) (emphasis added). Thus, Dr. Kuenzler was the *first* doctor to opine, independently, that Dr. Harvey's IgAV was causally connected to the Flu Vaccine.

The next day, on April 16, 2019, Dr. Harvey saw a specialist in rheumatology, Dr. Alexandra Villa Forte. ECF No. 126 at 12. Like Dr. Kuenzler, Dr. Forte opined that Dr. Harvey's IgAV was causally connected to the Flu Vaccine. First, in connection with Dr. Harvey's ongoing neuropathy, she opined that "[a]lthough polyneuropathy can be seen in association with IgA[V,] it is extremely rare[,] and it is much more likely that [Dr. Harvey] had the neuropathy as a [direct] reaction to the flu vaccine and not as part of a systemic vasculitic syndrome." *Id.* As to Dr. Harvey's IgAV, she observed that "[t]he rash has not recurred and he has no other symptoms or signs to suggest chronic or relapsing IgA[V] – making it even more suggestive of a vaccine induced reaction." *Id.*⁵

⁴ Here, Dr. Hayden's reference to "the problem" is clearly to Dr. Harvey's neuropathy-related issues (and *not* IgAV).

⁵ Although Drs. Kuenzler and Forte support Dr. Harvey's claim that the Flu Vaccine may have caused his IgAV, they reject the idea that IgAV caused Dr. Harvey's neuropathy. The problem

After deciding to file a vaccine compensation claim pursuant to the Vaccine Act in this Court (but before doing so), Dr. Harvey saw an immunologist, Dr. David Lang, on September 19, 2020. ECF No. 126 at 14. Dr. Lang documented the purpose of the visit: “to evaluate an adverse reaction to an influenza vaccination in October 2017.” *Id.* Dr. Lang noted that while “he did not have the benefit of reviewing all the outside records,” he had some of the records, and he interviewed Dr. Harvey. *Id.* Dr. Lang concluded that the “[h]istory furnished today of cutaneous reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitic process.” *Id.* Put simply, Dr. Lang believed that it was unlikely the Flu Vaccine caused IgAV, given the short period between when Dr. Harvey received the Flu Vaccine and the onset of IgAV-related symptoms. Thus, Dr. Lang disagreed with Dr. Kuenzler and Dr. Forte’s conclusion that the Flu Vaccine caused Dr. Harvey’s IgAV, and, instead, agreed with Dr. Scarsella’s opinion — that such a cause-and-effect was unlikely.

II. PROCEDURAL HISTORY

On May 13, 2020, Dr. Harvey filed a petition for compensation pursuant to the Vaccine Act. ECF No. 1. Dr. Harvey asserts that the Flu Vaccine caused him to suffer from IgAV — and, as a consequence of the IgAV, from a neuropathy — and that he is therefore entitled to compensation pursuant to the Vaccine Act. *Id.*; see ECF No. 126 at 5 n.6.

On May 16, 2020, this case was assigned to Chief Special Master Corcoran. That same day, Dr. Harvey filed his medical records. ECF Nos. 7-9. On July 6, 2020, this case was reassigned to Special Master Moran. ECF No. 15. Dr. Harvey retained Dr. M. Eric Gershwin and Dr. Enrique Aradillas to present expert testimony. ECF No. 126 at 15. The government, in turn, presented testimony from Dr. Jonathan Miner and Dr. Daniel Feinberg. *Id.*

After the case was briefed by both parties, on March 18, 2025, the Special Master concluded that “[w]hen called upon in this litigation to establish with preponderant

for Dr. Harvey, however, is that he can only recover here — due to the severity requirement, discussed *supra* — if he can prove that the neuropathy resulted from the IgAV. But, again, that is a hypothesis both of these doctors reject. And while both doctors *arguably* support the idea that Dr. Harvey’s neuropathy resulted directly from the vaccine — although not via the IgAV — Dr. Harvey never argued before the Special Master or this Court that the Flu Vaccine directly caused Dr. Harvey’s neuropathy. See *supra* note 3.

evidence that the [Flu Vaccine] was the cause-in-fact for his [IgAV], Dr. Harvey did not meet his burden. Therefore, his claim for compensation is denied.” ECF No. 126 at 29.

On April 17, 2025, Dr. Harvey filed a motion for review of the Special Master’s decision, ECF No. 128, and, with it, a memorandum in support of his motion, ECF No. 129. Dr. Harvey asks this Court to set aside the Special Master’s findings of fact that are arbitrary and capricious, and conclusions of law that “are not in accordance with the law,”⁶ and to “remand the case back to the Special Master with instructions to enter a finding” that Dr. Harvey is entitled to compensation” *Id.* at 17. On May 15, 2025, Respondent filed its response to Dr. Harvey’s motion for review, requesting that this Court affirm the Special Master’s decision. ECF No. 131 at 20.

III. JURISDICTION

Pursuant to the Vaccine Act, this Court has jurisdiction to review a special master’s decision upon the filing of a petition from either party within thirty days of that decision. 42 U.S.C. § 300aa-12(e)(1). On review, this Court may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2). No party disputes this Court’s jurisdiction.

IV. STANDARD OF REVIEW

“Under the Vaccine Act, the Court of Federal Claims reviews the Special Master’s decision to determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.’” *Markovich v. Sec’y of Health & Hum. Servs.*, 477 F.3d 1353,

⁶ Dr. Harvey, in his brief, solely challenges the Special Master’s factual findings as arbitrary and capricious, but does not argue that the Special Master misapplied the relevant law. See ECF No. 129.

1355–56 (Fed. Cir. 2007) (quoting 42 U.S.C. § 300aa-12(e)(2)(B)). “Fact findings are reviewed [by this Court] under the arbitrary and capricious standard.” *Munn v. Sec’y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). “‘Arbitrary and capricious’ is a highly deferential standard of review: ‘[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.’” *Rodriguez v. Sec’y of Health & Hum. Servs.*, 632 F.3d 1381, 1384 (Fed. Cir. 2011) (quoting *Hines on Behalf of Sevier v. Sec’y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Our appellate court, the United States Court of Appeals for the Federal Circuit, has thus explained that “the statute contemplates that fact finding will be done by the special master.” *Munn*, 970 F.2d at 870. Indeed, Congress tasked the special masters with the “unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims.” *Hodges v. Sec’y of Dep’t of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

Therefore, on a petition for review, “[t]his court does not ‘reweigh the factual evidence, or [] assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.’” *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010) (quoting *Munn*, 970 F.2d at 871). “Rather, as long as a special master’s finding of fact is ‘based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.’” *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (quoting *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

Put simply, “[t]he statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master[’]s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process.” *Hodges*, 9 F.3d at 961. “That level of deference is *especially apt* in a case in which the *medical evidence of causation* is in dispute.” *Id.* (emphasis added).

While a special master’s overall conclusion is reviewed under the deferential standard of review, a special master’s conclusions of law are reviewed *de novo*. *Rodriguez*, 632 F.3d at 1384 (citing *Markovich*, 477 F.3d at 1356); *see also Munn*, 970 F.2d at 870 n.10 (explaining that, unlike factual findings which are reviewed “under the arbitrary and capricious standard[,]” legal questions are reviewed “under the ‘not accordance with the

law' standard" (quoting 42 U.S.C. § 300aa-12(e)(2)(B)).

In sum, a special master's decision "is entitled to deference," *Morse v. Sec'y of Health & Hum. Servs.*, 93 Fed. Cl. 780, 783 (2010), but this Court will find that a special master has abused his or her discretion if the special master's decision: "(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) follows from a record that contains no evidence on which the [special master] could rationally base [his] decision." *Wirtshafter v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 665, 671 (2021) (quoting *Ninestar Tech. Co. v. Int'l Trade Comm'n*, 667 F.3d 1373, 1379 (Fed. Cir. 2012)).⁷

V. DISCUSSION

A. Burden of Proof for Non-Table Claims

Pursuant to the Vaccine Act, a petitioner seeking compensation for an injury due to a vaccine must assert that he or she: (a) received a vaccine specified in 42 U.S.C. § 300aa-14 (the "Vaccine Injury Table" or "Table"); and (b) suffered either (1) an injury falling within the Table in "association" with the vaccine, and which manifested within the time period set forth in the Table (a "Table claim"), or (2) an injury not within the Table, but which was "caused" by the vaccine (a "non-Table claim"), or (3) an injury falling within the Table, that did not manifest within the time period set forth in the Table, and which was "caused" by the vaccine (also a "non-Table claim"). *Id.* § 300aa-11(c)(1) (emphasis added). To be awarded compensation, a petitioner must prove entitlement by a preponderance of the evidence. *Id.* § 300aa-13(a)(1).

The salient difference between Table and non-Table claims is the quantum of evidence required to prove causation. While the Vaccine Act "provides . . . a statutorily-prescribed presumption of causation" for a Table claim, a petitioner must "prove[] causation in fact" for a non-Table claim. *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (noting that, given the "causal" language in § 300aa-11(c)(1) for non-Table claims, "the petitioner in an off-table case has the burden to prove the vaccination in question 'caused' the illness, disability, injury, or condition" pursuant to 42 U.S.C.

⁷ *See also Spahn v. Sec'y of Health & Hum. Servs.*, 138 Fed. Cl. 252, 257 (2018) ("This Court will find an abuse of discretion only where the special master's decision is clearly unreasonable, based upon an erroneous conclusion of law, rests on erroneous fact finding, or based on a record without evidence to support the special master's decision.").

§ 300aa-13(a)(1)).

In this case, Dr. Harvey asserts only a non-Table claim. Thus, Dr. Harvey was required to “prove ‘actual causation’ or ‘causation in fact’ by a preponderance of the evidence.” *Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (citing cases). The Federal Circuit has succinctly articulated the burden to prove causation-in-fact:

Concisely stated, [a petitioner’s] burden is to show by preponderant evidence that the vaccination brought about [petitioner’s] injury by providing: (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. These elements are often referred to as the “*Althen* Prongs” or the “*Althen* Test.”

B. The Special Master’s *Althen* Prong 2 Analysis and Conclusion Were Not Arbitrary or Capricious

The Special Master concluded that Dr. Harvey failed to prove causation-in-fact because he did not prove all three *Althen* Prongs by the preponderance of the evidence. ECF No. 126 at 27. Thus, the Special Master denied Dr. Harvey’s compensation claim pursuant to the Vaccine Act. *Id.* This Court first addresses the Special Master’s *Althen* Prong 2 analysis because it is ultimately dispositive of this case.

Althen Prong 2 requires a petitioner asserting a non-Table claim “to show by preponderant evidence . . . a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. As discussed further below, this Court finds that the Special Master’s decision regarding *Althen* Prong 2 was not arbitrary, capricious, or otherwise contrary to law. Accordingly, and on that basis alone, this Court must uphold the Special Master’s decision. *See, e.g., Greene v. Sec’y of Health & Hum. Servs.*, 841 F. App’x 195, 201–03 (Fed. Cir. 2020) (discussing *Althen* Prong 3, “while noting that, in any event, the special master’s finding as to [*Althen* Prong 2] independently supports affirmance” of the special master’s denial of compensation

(internal citation omitted)).⁸

In evaluating whether a petitioner has met *Althen* Prong 2, the Federal Circuit has instructed special masters to consider carefully the views of treating physicians. “[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether ‘a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” *Capizzano*, 440 F.3d at 1326 (discussing *Althen* Prong 2) (alteration in original); see also *Simanski v. Dep't of Health & Hum. Servs.*, 601 F. App'x 982, 987–88 (Fed. Cir. 2015) (“[M]edical records from treating physicians . . . can be ‘quite probative’ or ‘favored’ when considering issues relating to claims under the Vaccine Act.” (citing *Capizzano*, 440 F.3d at 1326)).

As a threshold matter, the Special Master correctly noted the Federal Circuit’s preferred focus on treating physicians’ medical records when analyzing *Althen* Prong 2. ECF No. 126 at 20. Ultimately, the Special Master concluded that “when considered as a whole, the collection of statements from treating doctors do not persuasively show that the [F]lu [V]accine caused Dr. Harvey’s [IgAV],” and therefore were insufficient “to meet Dr. Harvey’s burden to show with preponderant evidence” a logical sequence of cause and effect, demonstrating “that the flu vaccine was the cause . . . of his [IgAV].” *Id.* at 26.

In reaching that conclusion, the Special Master observed that the “bulk of [Dr. Harvey’s] argument” regarding *Althen* Prong 2 involved “a chronology of some of his medical appointments.” ECF No. 126 at 20. The Special Master aptly pointed out that while that “presentation is not necessarily wrong . . . [i]t is just incomplete[,]” and that a “stronger argument with respect to [this prong] might draw upon statements from

⁸ In other words, even if a petitioner satisfies *Althen* Prongs 1 and 3, by proving “that a vaccine *can* cause the injury at issue” (satisfying *Althen* Prong 1), and that “the injury was temporally proximate to the vaccination” (satisfying *Althen* Prong 3), a petitioner must also show a “logical sequence of cause and effect” connecting *his injury* to the vaccination. *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1327 (Fed. Cir. 2006) (discussing *Althen* 418 F.3d at 1278). Simply put, “[t]he second prong of the *Althen* Test is not without meaning.” *Id.* For example, “[a] claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury.” *Id.* The Special Master in this case — citing *Capizzano* and other instructive cases — correctly noted that Dr. Harvey must satisfy *Althen* Prong 2 irrespective of whether he met his burden of proof as to the other *Althen* Prongs. ECF No. 126 at 21.

treating doctors.” *Id.* at 20-21. The Special Master thus took it upon himself to create a comprehensive chart of potentially relevant opinions from various treating physicians. *Id.* at 21-24.

Based on that chart, and after canvassing the entire medical record, the Special Master made several important findings. First, the Special Master emphasized the peculiar nature of Dr. Harvey’s claim – namely, that the Flu Vaccine directly caused IgAV, but *not* the neuropathy, and that the neuropathy was a mere sequela to IgAV. ECF No. 126 at 24. “Thus, [physician] statements that the [Flu Vaccine] caused Dr. Harvey to suffer a neuropathy [were] off target,” given that was not even Dr. Harvey’s claim. *Id.* (footnote omitted). Second, the Special Master highlighted another “aspect to the chronology of medical appointments”: “often, the association between the Flu Vaccine and [IgAV] was reported by Dr. Harvey,” but not by “independent opinions offered spontaneously by his treating physicians.” *Id.* The Special Master cited Dr. Harvey’s many communications with Dr. Hayden to demonstrate this pattern. *Id.* at 24-25.

The Special Master then noted that Dr. Harvey, in his briefs, “relies most heavily,” on the statement from Dr. Kuenzler to meet Dr. Harvey’s burden under *Althen* Prong 2. ECF No. 126 at 25. In particular, Dr. Harvey relies on Dr. Kuenzler’s statement that the “time course [of Dr. Harvey’s symptoms was] most compatible with post-vaccine autoimmune response causing [IgAV] and neuropathy.” *Id.* at 12.⁹ While acknowledging that Dr. Kuenzler’s statement provides “some support” that the Flu Vaccine caused Dr. Harvey’s IgAV, the Special Master pointed to Dr. Lang’s contrasting opinion. *Id.* While visiting with Dr. Harvey, Dr. Lang noted that the “[h]istory furnished today of

⁹ The Special Master’s decision is particularly confusing on this issue because he mistakenly attributes a quote from Dr. Scarsella’s medical records (that is unhelpful for Dr. Harvey) to Dr. Kuenzler. ECF No. 126 at 25. While Dr. Kuenzler supports Dr. Harvey’s view that the Flu Vaccine caused his IgAV, Dr. Scarsella rejected that conclusion. *Id.* at 12. Neither Dr. Harvey, in his motion for review, nor the government, caught the mistaken quote in the Special Master’s decision. *See* ECF No. 129 at 10-11; ECF No. 131 at 19. This error is immaterial, however, because the Special Master correctly recognized that Dr. Kuenzler’s view supported Dr. Harvey’s claim. In contrast, there is no indication that the Special Master believed that Dr. Scarsella supported Dr. Harvey. Indeed, while Dr. Scarsella concluded that the Flu Vaccine *directly* caused Dr. Harvey’s neuropathy, ECF No. 126 at 12, Dr. Scarsella rejected Dr. Harvey’s claim that the Flu Vaccine caused the IgAV, which, in turn, caused the neuropathy. *Id.* At the end of the day, then, the Special Master’s misquote was harmless.

cutaneous reaction beginning as early as 8 hours after administration of influenza vaccination would be unusual for a vasculitis process.” *Id.*

Weighing these conflicting physician statements, the Special Master gave more weight to that of Dr. Lang, reasoning that he “is an immunologist” and, as such, “his opinion regarding the time of an adverse reaction to a vaccine is more credible than the opinion of someone, like Dr. Kuenzler, who appears not to specialize in immunology.” ECF No 126 at 25-26.¹⁰ A special master may – and oftentimes must – weigh conflicting treating physicians’ testimony; it is not error to conclude that one opinion is more persuasive than another. *See, e.g., Hibbard v. Sec’y of Health & Hum. Servs.*, 698 F.3d 1355, 1368 (Fed. Cir. 2012) (upholding special master’s *Althen* Prong 2 analysis where the special master weighed an “array of different opinions among [] examining and treating physicians as to the cause” of the alleged vaccine-induced illness – where some physicians connected it to the vaccine and some did not – and ultimately determined that the petitioner did not meet his burden).

In arguing that the Special Master’s analysis of *Althen* Prong 2 was arbitrary and capricious, ECF No. 129 at 10-12, Dr. Harvey’s position boils down to a simple assertion: the Special Master erroneously determined that Dr. Lang’s opinion was more credible than Dr. Kuenzler’s. According to Dr. Harvey, “the special master left out critical facts and statements from Dr. Lang[],” which, taken together, effectively weakens Dr. Lang’s overall conclusion. *Id.* at 11. In particular, Dr. Harvey notes that Dr. Lang made his assessment without the benefit of having reviewed Dr. Harvey’s medical records from two physicians he visited soon after taking the Flu Vaccine – Dr. Boucher and Dr. Musiek – and that Dr. Lang admitted as much in his report. *Id.* at 11-12. Both Drs. Boucher and Musiek diagnosed Dr. Harvey with IgAV, documenting his complaints about the occurrence of severe rashes mere hours after taking the Flu Vaccine.

Nevertheless, Dr. Harvey’s argument is unpersuasive. Dr. Lang acknowledges, as

¹⁰ As discussed *supra*, two additional doctors expressed an opinion regarding whether the Flu Vaccine likely caused Dr. Harvey’s IgAV: Dr. Scarsella and Dr. Forte. ECF No. 126 at 25-26. Dr. Forte’s opinion supported the existence of such a causal relationship, while Dr. Scarsella’s undermined it. *Id.* The Special Master, however, did not discuss either of those opinions in his *Althen* Prong 2 analysis. *See* ECF No. 126 at 20-26. But, given that those opinions merely add an additional treating physician’s support for each side, and because neither Dr. Scarsella nor Dr. Forte is a neurologist, *see id.* at 12, such omission does not meaningfully alter the Special Master’s analysis.

a given, that Dr. Harvey suffered from IgAV soon after receiving the Flu Vaccine — that fact is not contested now before this Court or previously before the Special Master. But Dr. Lang simply opines that the Flu Vaccine was unlikely to have been the cause of Dr. Harvey’s IgAV given the tight timeline between the Flu Vaccine and the onset of IgAV symptoms. Furthermore, Drs. Boucher and Musiek did not themselves express an opinion on whether the Flu Vaccine *caused* Dr. Harvey’s IgAV. Accordingly, this Court cannot conclude that, had Dr. Lang reviewed the medical records from Dr. Harvey’s visits with Drs. Boucher and Musiek, Dr. Lang might have reached a different causal explanation. Regardless, the Special Master’s determination on this record is well within his discretion. In sum, Dr. Harvey’s single grievance with respect to the Special Master’s *Althen* Prong 2 analysis lacks merit.

More generally, however, this Court concludes that the Special Master correctly: (1) articulated Dr. Harvey’s burden with respect to *Althen* Prong 2; (2) summarized the pertinent facts and evidence; (3) arrived at conclusions of fact supported by the record; and (4) weighed conflicting treating physician testimony, while expressing a reasoned basis for the weight ultimately given to each. On that basis, the Special Master reasonably held that Dr. Harvey did not meet his “burden to show with preponderant evidence that the flu vaccine was the cause-in-fact of his [IgAV].” ECF No. 126 at 26. Because the Special Master “considered the relevant evidence of record, [drew] plausible inferences and articulated a rational basis for [his] decision,” *Hines*, 940 F.2d at 1528, this Court cannot find that the Special Master’s determination, with respect to *Althen* Prong 2, is “arbitrary, capricious an abuse of discretion, or otherwise not in accordance with the law.” *Markovich*, 477 F.3d at 1355-56 (quoting 42 U.S.C. § 300aa-12(e)(2)(B)).¹¹

C. The Special Master Did Not Articulate a Reasoned Basis for Concluding that Petitioner Failed to Meet *Althen* Prongs 1 and 3

Although this Court affirms the Special Master’s overall denial of compensation due to his well-reasoned decision regarding *Althen* Prong 2, we nevertheless address Dr. Harvey’s critique of the Special Master’s conclusions regarding the other two *Althen* Prongs. *Althen* Prong 1 requires a petitioner “to show by preponderant evidence . . . a medical theory causally connecting the vaccination and the injury,” while Prong 3, in

¹¹ This Court further notes, in support for the Special Master’s determination, that Dr. Harvey only first raised the potential of his Flu Vaccine *causally* contributing to his IgAV well after his IgAV-related symptoms had fully disappeared.

turn, requires “a showing of a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. In that regard, Prongs 1 and 3 are somewhat related, as a petitioner must demonstrate not only a “proximate temporal relationship” between the vaccine and the injury, but also that the injury occurred in a medically acceptable timeframe given the medical theory being offered. See *Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).¹²

In contrast with the Special Master’s thorough *Althen* Prong 2 analysis, the Special Master provided only a brief explanation in support of his conclusion that Dr. Harvey failed to prove *Althen* Prongs 1 and 3 by preponderant evidence. ECF No. 126 at 18, 20.

With respect to *Althen* Prong 1, the Special Master – after documenting and swiftly dismissing an insufficient theory put forward by Dr. Harvey in connection with “abnormal immunological activation” – catalogued several other theories Dr. Harvey posited. ECF No. 126 at 17-18. Specifically, the Special Master noted that Dr. Harvey suggested that the Flu Vaccine caused “cytokines,” issues with the “complement system,” or an “immune complex deposition.” *Id.* Then – absent any analysis as to what those theories entail – the Special Master concluded that Dr. Harvey and his experts did not explain “why [they] are sound and reliable,” and “failed to connect [those] theories to what is known about [IgAV].” *Id.* at 17-18. While acknowledging that “[p]ersuasive evidence shows [IgAV] is due, in part,” to defective IgA, the Special Master concluded that “Dr. Harvey [had] not reliably linked cytokines, complement, and/or immune complexes to defective IgA.” *Id.* at 18.

With respect to *Althen* Prong 3, the Special Master first emphasized how “any theory Dr. Harvey could propose[,] is limited by the sequence of events in that the [IgAV] appeared within 24 hours of the [Flu Vaccine],” as Dr. Harvey admitted in his briefs.

¹² As an illustration, even if symptoms of an injury occur within mere hours of a vaccine, a petitioner will not meet his burden under *Althen* Prong 3 if the medical theory posits that the vaccine caused an ailment for which the medically acceptable timeframe for post-exposure symptoms is a few days. *Bazan*, 539 F.3d at 1352. Thus, in practice, *Althen* Prong 3 “can be broken down into two steps.” *Goodwin v. Sec’y of Health & Hum. Servs.*, 2024 WL 4758470, *2 (Fed. Cl. Oct. 10, 2024). First, a petitioner must “establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the [disorder] was caused by the vaccination.” *Id.* Second, the petitioner must “show that the onset of [the disorder] occurred during this causation period.” *Id.* (alterations in original) (quoting *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011)).

ECF No. 126 at 18. Thereafter, the Special Master sided with the government's expert, and concluded that there was a "reliable basis for finding that the medically appropriate interval" for IgAV-related symptoms, was "at least three days after exposure to the triggering infection or agent." *Id.* at 18-19. As for Dr. Harvey's opposing theory, the Special Master addressed it with merely *a single sentence*: "By way of contrast, Dr. Gershwin's opinion that the flu vaccine can cause [IgAV] to occur within one day[,] lacks reliability, is poorly explained, and is not persuasively supported by any medical or scientific articles." *Id.* at 19.

Dr. Harvey contends that the Special Master's conclusions as to *Althen* Prongs 1 and 3 were arbitrary and capricious. ECF No. 129 at 6, 12. Dr. Harvey argues that, *inter alia*, the Special Master did not sufficiently articulate relevant facts, evaluate the evidence proffered, or provide a reasoned basis for his conclusions. *Id.* at 6-17.¹³ With respect to *Althen* Prong 1, specifically, Dr. Harvey argues that the Special Master "did not provide any substantive discussion regarding [Dr. Harvey's] medical theory and medical literature." *Id.* at 9-10. Dr. Harvey primarily relies on this Court's decision in *Goodwin* in which the Court held that a special master's "conclusory statements alone are insufficient" to uphold a special master's finding and that, instead, a "finding must be supported by a reasoned explanation." *Goodwin*, 2024 WL 4758470, at *3.¹⁴

In *Goodwin*, the sole issue before the Court was the special master's analysis under *Althen* Prong 3. *Goodwin*, 2024 WL 4758470, at *1. Judge Somers highlighted several problems with the special master's analysis of the petitioner's proffered evidence, including: (1) only two sentences of the fact section "arguably" related to *Althen* Prong 3; (2) in dismissing an expert opinion, the special master, "in [] conclusory fashion" – and without identifying a single flaw – determined that the expert "had not persuasively" supported his opinion; and (3) when analyzing a case study proffered by the petitioner's expert, the special master asked a "critical question" relating to the study's reliability, but "in what seem[d] to be a trend," the Special Master did not answer that question, and instead simply dismissed the study as unreliable. *Id.* at *3-4. Judge Somers thus concluded that "although the result the special master reached . . . may

¹³ Dr. Harvey only raises this argument in connection with the Special Master's *Althen* Prong 1 analysis. ECF No. 129 at 9-10.

¹⁴ Nor is it "adequate [for a special master] to summarize and reject arguments without explaining why. . . ." *Goodwin*, 2024 WL 4758470, at *3 (quoting *In re Nu Vasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016)).

[have] ultimately be[en] correct, the Court simply [could] not sustain the result based on the reasoning given.” *Id.* at *6. The Court, therefore, remanded the case to the special master to “articulate a basis for his decision that the Court [could] consider under the prescribed standard. . . .” *Id.*

There are remarkable similarities between this case and *Goodwin* with respect to the Special Master’s analysis of *Althen* Prongs 1 and 3. For starters, the Special Master’s fact section is virtually devoid of facts relating to *Althen* Prongs 1 and 3. *See generally* ECF No. 126 at 1-14. Indeed, the Special Master’s fact section contains *no* details as to what Dr. Harvey proffered to satisfy his burden pursuant to *Althen* Prongs 1 and 3. The Special Master dismissed Dr. Harvey’s various medical theories under *Althen* Prong 1 “in conclusory fashion,” *Goodwin* 2024 WL 4758470, at *3. Moreover, “in what seems to be a trend,” *Id.* at *4, the Special Master dismissed Dr. Harvey’s expert’s opinion with respect to *Althen* Prong 3 in a single conclusory sentence, noting that his opinion “lack[ed] reliability, [was] poorly explained, and [was] not persuasively supported by any medical or scientific articles.” ECF No. 126 at 19.

As such, just like in *Goodwin*, this Court is left with many unanswered questions. For example, what are Dr. Harvey’s medical theories (other than that they involve “cytokines,” issues with the “complement system,” or an “immune complex deposition”)? Why are they not reliable? And, why did the Special Master conclude that Dr. Harvey and his experts failed to connect those theories to IgAV? ECF No. 126 at 17-18. While the Special Master notes “Dr. Harvey [had] not reliably linked cytokines, complement, and/or immune complexes to defective IgA[,]” *id.* at 18, the Special Master did not address either Dr. Harvey’s hypotheses regarding how the various mechanisms caused defective IgA, or why those proposed links were not reliable. Similarly, the Special Master’s single conclusory sentence, rejecting Dr. Gershwin’s opinion that the Flu Vaccine can cause IgAV-related symptoms within one day of exposure, “leaves the reviewing Court to ask,” *Goodwin* 2024 WL 4758470, at *3, why the opinion “lacks reliability”? How is Dr. Harvey’s opinion “poorly explained”? What medical and scientific articles, if any, support Dr. Harvey’s opinion? How is his opinion not “persuasively supported” by those articles? ECF No. 126 at 19.

In sum, the Special Master’s conclusory statements regarding the alleged shortcoming of the evidence Dr. Harvey proffered to satisfy his burden pursuant to *Althen* Prongs 1 and 3 “do not give the Court a reasoned basis from which it can review the special master’s determination[s].” *Goodwin* 2024 WL 4758470, at *3. The arbitrary

and capricious standard “requires that the [special master] not only have reached a sound decision, but have *articulated* the *reasons* for that decision.” *Id.* (emphasis added) (quoting *In re Sang Su Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002)). The Special Master has not done so here.

Nevertheless, because this Court upholds the Special Master’s *Althen* Prong 2 analysis, as explained *supra* – and that provides a sufficient, independent basis to affirm the Special Master’s overall conclusion, *Greene*, 841 F. App’x at 201–03 – this Court need not remand this case to the Special Master for further analysis of *Althen* Prongs 1 and 3.

VI. CONCLUSION

Given the Special Master’s analysis and conclusion with respect to *Althen* Prong 2, this Court finds that the Special Master’s overall decision regarding causation-in-fact was not arbitrary, capricious, or otherwise contrary to law. Accordingly, this Court **AFFIRMS** the Special Master’s decision. The Clerk shall enter **JUDGMENT** for the Respondent, dismissing this petition.

IT IS SO ORDERED.

s/Matthew H. Solomson
Matthew H. Solomson
Chief Judge