In the United States Court of Federal Claims

No. 11-631V
(Filed Under Seal: January 28, 2020)
(Reissued for Publication: February 12, 2020)[1]

ROY GREENE,	*	
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Petitioner,	*	
	*	Vaccine Act; Motion for Review; Tetanus-Diphtheria Vaccine; Brachial Neuritis; Causation; Althen Prongs Two and Three; Burden of Proof
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Richard Gage and Kristen L. Blume, Cheyenne, WY, for petitioner.

Robert P. Coleman, III and Brittany A. Ditto, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Chief Judge

Petitioner Roy Greene seeks compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2018), for an alleged vaccine-caused injury. Before the court is petitioner's motion for review of the special master's decision denying compensation.[2] As discussed below, the court denies petitioner's motion.

[1] Vaccine Rule 18(b), included in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information contained in this opinion.

[2] After issuing the decision at issue, the special master was appointed to the position of chief special master. For simplicity, the court uses the title "special master" throughout this decision.

I. BACKGROUND

Petitioner filed a petition for compensation under the Vaccine Act on September 29, 2011, alleging that he developed brachial neuritis as a result of a July 22, 2009 tetanus-diphtheria ("Td") vaccination.[3] He asserted two theories of recovery: first, that he was entitled to compensation pursuant to the Vaccine Injury Table, which provides that brachial neuritis that develops between two and twenty-eight days after receiving a vaccine containing tetanus toxoid is a compensable injury; and second, that he was entitled to compensation because the Td vaccine actually caused his brachial neuritis.

The special master held a fact hearing in March 2015 to determine the onset date of petitioner's symptoms. In a July 31, 2015 decision, the special master remarked that petitioner's symptoms satisfied the then-operative definition of brachial neuritis in the Vaccine Injury Table's "qualifications and aids to interpretation." Under that definition, brachial neuritis is

> dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

42 C.F.R. § 100.3(b)(7)(i) (2014). The special master then found that petitioner's symptoms began no earlier than September 1, 2009—forty-one days after the Td vaccination. Because petitioner's symptoms arose after the time period prescribed in the Vaccine Injury Table, the special master dismissed petitioner's Table claim.

Over the next two years, in an effort to resolve petitioner's remaining claim of actual causation, petitioner filed two expert reports from Thomas W. Wright, M.D., an orthopedist, and the parties engaged in settlement discussions. In September 2016, the special master learned that the settlement discussions had not been successful because respondent rejected as inadequate petitioner's showing that forty-one days was a medically acceptable time frame for the Td vaccine to cause brachial neuritis. Thus, the special master directed petitioner to file a supplemental expert report. In early 2017, petitioner filed an expert report from Marcel Kinsbourne, M.D., a neurologist.

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[3] The court derives much of the background from its previous ruling in this case, see generally Greene v. Sec'y of HHS, 136 Fed. Cl. 445 (2018), and the special master's August 2, 2019 decision after remand, see generally Greene v. Sec'y of HHS, No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019). The remaining information is taken from the docket of the case and the regulation setting forth the Vaccine Injury Table, 42 C.F.R. § 100.3.

In March 2017, respondent filed a motion for a ruling on the record, to which petitioner responded the following month. In a May 26, 2017 decision, the special master found that the record did not support petitioner's claim that the Td vaccine caused his brachial neuritis because petitioner could not establish, more probably than not, that a forty-one-day period between the vaccination and the first symptoms of the injury was medically acceptable.

On June 16, 2017, petitioner filed a motion for reconsideration pursuant to Vaccine Rule 10(e), as well as a supplemental expert report from Dr. Kinsbourne and supporting documentation (including eighteen medical and scientific articles and a letter/report from Vera S. Byers, M.D., Ph.D., an immunologist). In his motion, petitioner argued that he had provided sufficient evidence to establish that a forty-one-day onset period was medically acceptable, but that if the special master continued to deem the existing evidence insufficient, Dr. Kinsbourne's supplemental expert report and supporting documentation would establish the medical acceptability of the onset period.

The special master granted petitioner's motion for reconsideration and then, in a September 26, 2017 "Decision on Reconsideration Denying Entitlement," concluded that "[t]he record [did] not support Petitioner's allegation that his Td vaccine more likely than not caused his brachial neuritis 41 days following the vaccination." Greene v. Sec'y of HHS, No. 11-631V, 2017 WL 5382856, at *7 (Fed. Cl. Spec. Mstr. Sept. 26, 2017). He therefore dismissed petitioner's actual causation claim.

Petitioner filed a motion for review of the special master's decision denying entitlement. Because the special master applied the incorrect legal standard when evaluating the evidence offered by petitioner, the court, in a February 27, 2018 Opinion and Order, granted petitioner's motion, vacated the special master's decision, and remanded the case to the special master to issue a new entitlement decision. On May 17, 2018, the special master issued a remand decision in which he denied respondent's motion for a ruling on the record, determined that respondent should be provided the opportunity to submit an expert report, and indicated that an entitlement hearing would likely be necessary.

Respondent filed an expert report from Eric Lancaster, M.D., Ph.D., a neurologist, on June 14, 2018. On November 13, 2018, petitioner filed an expert report from Lawrence Steinman, M.D., a neurologist and immunologist, and a response to Dr. Lancaster's expert report from Dr. Kinsbourne. On April 9, 2019, respondent filed Dr. Lancaster's response to Dr. Steinman's and Dr. Kinsbourne's submissions. Then, on April 29, 2019, petitioner filed a supplemental expert report from Dr. Kinsbourne. Shortly thereafter, on May 9, 2019, the special master held an entitlement hearing during which he heard testimony from Dr. Kinsbourne, Dr. Steinman, Dr. Lancaster, and petitioner.

The special master issued his entitlement decision on August 2, 2019. After summarizing the case's factual and procedural history, he provided an extensive description of the credentials, reports, and testimony of Dr. Kinsbourne, Dr. Steinman, and Dr. Lancaster, along with the medical and scientific literature relied upon by the experts. He also set forth the legal standards for his review of the experts' opinions, for his review of the medical and scientific literature, and

for petitioner to establish causation. Then, the special master analyzed petitioner's case under the test for causation set forth in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005).

In Althen, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") articulated a three-part test, based on prior precedent, explaining what a petitioner must show to prove causation under the Vaccine Act:

> [Petitioner]'s burden is to show by preponderant evidence that the vaccination brought about [the] 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.

Id. at 1278. The special master noted that he had previously concluded that petitioner had established the first prong of the test, and therefore focused his analysis on the second and third prongs.

With respect to the third prong, the special master concluded that petitioner did not establish, by a preponderance of the evidence, that forty-one days was a medically acceptable length of time between petitioner's Td vaccination and the onset of petitioner's brachial neuritis. Specifically, he concluded that petitioner's direct proof was insufficient and that petitioner's arguments based on circumstantial evidence—evidence concerning risk intervals and evidence pertaining to the similarities between brachial neuritis and Guillain-Barré syndrome ("GBS")—were unpersuasive.[4] He further noted that respondent successfully rebutted the evidence and arguments presented by petitioner, finding that respondent's evidence was persuasive and that the opinions of petitioner's experts were not as persuasive as Dr. Lancaster's opinions. The

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[4] "GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes . . . ." 42 C.F.R. § 100.3(c)(15)(i) (2017).

> The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots.

Id. § 100.3(c)(15)(ii).

latter conclusion was based, in part, on petitioner's experts' purported lack of experience in treating patients with brachial neuritis.

With respect to the second prong (which the special master was not required to address having concluded that petitioner had not satisfied the mandatory third prong), the special master determined that petitioner had not satisfied his burden of establishing that the Td vaccine did cause his brachial neuritis. This conclusion was based, in part, on his assessment that the record lacked any evidence that petitioner was experiencing an autoimmune reaction to the vaccine.

In accordance with his analysis, the special master concluded that petitioner failed to establish that the Td vaccine caused his brachial neuritis and therefore dismissed petitioner's actual causation claim. Petitioner timely filed a motion for review on September 3, 2019, and respondent filed a response on October 3, 2019. The court heard argument on January 23, 2019, and is now prepared to rule.

II. DISCUSSION

A. Standard of Review

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,
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> (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
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> (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 standards set forth in section 12(e)(2)(B) "vary in application as well as degree of deference. . . . Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). Specifically, with respect to the special master's fact findings, the court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." Porter v. Sec'y of HHS, 663 F.3d 1242, 1249 (Fed. Cir. 2011); see also Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) ("[O]n 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."). "Rather, as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, [the court is] compelled to uphold that

finding as not being arbitrary or capricious.'" Porter, 663 F.3d at 1249 (first alteration in the original) (quoting Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

In the instant case, petitioner enumerates, pursuant to Vaccine Rule 24, three objections to the special master's August 2, 2019 decision. First, petitioner contends that the special master required petitioner to establish that a forty-one-day postvaccination onset period for his brachial neuritis was medically reasonable rather than medically acceptable, improperly increasing petitioner's burden of proof.[5] Second, petitioner contends that the special master arbitrarily and capriciously found facts related to his experts' qualifications and theories. Third, petitioner contends that the special master required him to supply preponderant evidence that the Td vaccine was the most likely cause of his brachial neuritis rather than preponderant evidence of a logical sequence of cause and effect between the Td vaccine and his brachial neuritis, again improperly increasing his burden of proof. Petitioner accordingly requests that the court, pursuant to 42 U.S.C. § 300aa-12(e)(2)(E), set aside the special master's findings of fact and conclusions of law, issue its own findings and conclusions, and determine that he is entitled to compensation.

B. Legal Standard

All of petitioner's objections relate to the special master's determination that petitioner had not met his burden of proving that the Td vaccine caused his brachial neuritis. As noted above, to prove causation under the Vaccine Act, a petitioner must

> show by preponderant evidence that the vaccination brought about [his] 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; see also Boatmon v. Sec'y of HHS, 941 F.3d 1351, 1355 (Fed. Cir. 2019) (noting that a petitioner must "prove[] all three Althen prongs by a preponderance of the evidence"). Under the first prong, a petitioner must demonstrate that the vaccine at issue can cause the injury alleged. Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). To make this showing, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). The second prong requires a petitioner to show "that the vaccine was the 'but for' cause of the harm," Pafford, 451 F.3d at 1356, or, in other words, "'that the vaccine actually caused the alleged symptoms in [the] particular case,'" id. (quoting the decision of the special master as recited by the trial court). Establishing the third prong "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y

[5] Petitioner does not challenge the special master's finding that the onset of his brachial neuritis occurred forty-one days after his Td vaccination. See Mot. 4 n.3.

of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008); accord Althen, 418 F.3d at 1281 (describing the requirement as "a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury"). In short, a petitioner is required "to 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 v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999); see also Moberly v. Sec'y of HHS, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) ("The burden of showing something by a 'preponderance of the evidence,' the most common standard in the civil law, simply requires 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." (quoting Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602, 622 (1993))).

Generally, "[t]he determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Thus, causation can be established with circumstantial evidence—in other words, with medical records or medical opinion. Althen, 418 F.3d at 1279-80 (citing 42 U.S.C. § 300aa-13(a)(1)); see also Knudsen, 35 F.3d at 548 (observing that the "'logical sequence of cause and effect' must be supported by a sound and reliable medical or scientific explanation" (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Jay v. Sec'y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993))). A petitioner "need not produce medical literature or epidemiological evidence to establish causation," but "where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." Andreu v. Sec'y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009). But see LaLonde v. Sec'y of HHS, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard. The level of specificity of such support may vary from circumstance to circumstance."). Moreover,

> to say that proof in the form of epidemiological studies or well-established medical experience is not mandatory does not mean that the special masters in Vaccine Act cases are precluded from inquiring into the reliability of testimony from expert witnesses. Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and . . . the special masters have that responsibility in Vaccine Act cases.

Moberly, 592 F.3d at 1325.

C. Petitioner's Objections

In his motion for review, petitioner challenges both the special master's findings of fact (with respect to petitioner's experts' qualifications and theories) and conclusions of law (with respect to the second and third prongs of the Althen test). Because an arbitrary and capricious finding of fact can affect a legal conclusion, the court begins its analysis by addressing petitioner's second enumerated objection to the special master's decision.

1. The Challenged Findings of Fact Were Either Not Arbitrary and Capricious or Not Necessary for the Special Master's Ultimate Conclusions

In his second objection, petitioner contends that the special master omitted and misstated information regarding the qualifications and opinions of Dr. Steinman and Dr. Kinsbourne. Specifically, he asserts that the special master:

- did not mention that Dr. Steinman was an immunologist in addition to a neurologist;

- found that Dr. Steinman and Dr. Kinsbourne "do not possess demonstrated, specific experience studying or treating brachial neuritis and its causes," Greene, 2019 WL 4072110, at *20, even though Dr. Kinsbourne testified that he had treated patients with brachial neuritis while he had a clinical practice (which ended in the early 1990s), Hr'g Tr. 28, May 9, 2019 ("Tr."), and Dr. Steinman testified that he has seen "[a]t least 100" cases of brachial neuritis over the past forty years, id. at 136, recently saw a case of brachial neuritis, id. at 51, 58, 68, and is a neuroimmunologist who has focused his research on the causes and treatments of autoimmune diseases, id. at 39-40;

- failed to comparably criticize Dr. Lancaster, who testified that he had diagnosed and treated "10 to 20" patients with brachial neuritis over the last ten years, that his research focus was "autoantibodies to the nervous system," and that his research projects pertained to "autoimmune encephalitis, . . . [chronic immune demyelinating polyradiculopathy,] and autoimmune neuropathies," id. at 74-75;

- ignored the experience of Dr. Wright despite valuing clinical experience over knowledge derived from research;

- distinguished brachial neuritis and GBS for the purpose of determining a medically acceptable onset period by, in part, observing that the former primarily affects the axons of neurons while the latter primarily affects the myelin sheaths of neurons, despite evidence reflecting that a subtype of GBS results from axonal damage;

- disregarded petitioner's direct proof that brachial neuritis can occur forty-one days after a triggering event in the form of (1) an article—that the special master characterized as an outlier but did not reject as incorrect—describing a man who developed brachial neuritis three months after an injury (the Morishima article), and (2) Dr. Steinman's testimony that he had seen cases of brachial neuritis developing "four, five, six weeks" after the triggering event, id. at 141;

- refused to give three case reports from Japan (the Moriguchi, Morishima, and Naito articles) any weight because of his position that case reports are not entitled to much weight, which is derived from a decision of another special master who discounted case reports for a purpose other than the one for which petitioner offered the case reports in this matter; and

- found that there was "nothing from the pre- or post-vaccination record suggesting that an autoimmune reaction was brewing in a subclinical form," Greene, 2019 WL 4072110, at *21, even though no evidence was produced by the parties indicating that petitioner would have symptoms that suggested such a process.

Respondent does not address most of these contentions head on. Instead, he characterizes petitioner's contentions as a "dissatisfaction with the Special Master's weighing of the evidence, and in particular, his decision to credit Dr. Lancaster's opinion over his own experts." Resp. 11. Specifically, he asserts that the special master was correct to discount the expert reports of Dr. Wright because they contained unsupported, conclusory statements,[6] and to find Dr. Lancaster's opinion, which the doctor derived from clinical experience, more reliable than the opinions of Dr. Steinman and Dr. Kinsbourne. In a single sentence at the conclusion of his discussion of petitioner's second objection to the special master's decision, respondent states: "Petitioner's claim that the Special Master made arbitrary and capricious findings of fact regarding the qualifications of petitioner's experts is impossible to reconcile with the Special Master's discussion of their qualifications, credibility, and theories." Id. at 17.

Respondent is correct that the court is not to reweigh the evidence presented by the parties. Indeed, the law is well settled that a special master's fact finding is entitled to deference so long as the special master's findings are based on evidence that is "not wholly implausible . . . ." Porter, 663 F.3d at 1249 (quoting Cedillo, 617 F.3d at 1338). Thus, for petitioner's contentions that are truly just complaints regarding how the special master valued the evidence—the discounting of Dr. Wright's expert reports, the failure to give greater weight to the existence of a subtype of GBS (not brachial neuritis, the injury suffered by petitioner[7]) that is characterized

[6] Respondent makes the same point regarding the letter/report from Dr. Byers even though petitioner did not address the special master's treatment of Dr. Byers's opinion in his motion.

[7] In his decision, the special master found that "[d]espite some of their common features, GBS is simply not sufficiently comparable to brachial neuritis to apply the same onset timeframe to both." Greene, 2019 WL 4072110, at *18. Indeed, it is axiomatic that diseases and injuries are not fungible and may have different triggers, courses, and treatments, such that it may not be appropriate to infer that a vaccine that causes one disease or injury can also cause a different, but related, disease or injury. Accord id. at *17 ("[N]ot all neurologic injuries with an autoimmune component are the same, even if they have some common features. Ample [Vaccine] Program authority has noted that, while petitioners may reasonably analogize an injury to other autoimmune conditions, they cannot prevail solely by doing so.").

by axonal damage, and the failure to give greater weight to the three case studies—the court concludes that the special master's findings of fact were not arbitrary and capricious.

However, several of petitioner's contentions implicate the accuracy of the special master's findings of fact rather than just the weight he placed on the evidence. First, the special master found the opinions of Dr. Steinman and Dr. Kinsbourne less reliable because they "do not possess demonstrated, specific experience studying or treating brachial neuritis and its causes, even if they may have intermittently encountered it in their professional lives," Greene, 2019 WL 4072110, at *20, but did not similarly criticize the reliability of Dr. Lancaster's opinion even though Dr. Lancaster testified to treating only ten to twenty cases of brachial neuritis and did not profess to studying brachial neuritis and its causes in particular. In other words, although the experts—Dr. Steinman and Dr. Lancaster especially—have seen a similar number of cases of brachial neuritis (adjusted for time) and have studied autoimmune diseases in general rather than brachial neuritis in particular, the special master did not similarly critique the experts on these factors. His failure to do so was arbitrary and capricious.

Moreover, the special master arbitrarily and capriciously misstated and downplayed Dr. Steinman's credentials and experience. He remarked:

> Dr. Steinman claimed to have encountered brachial neuritis at least one hundred times in his career (although he did not specify when he most recently encountered it—or whether his encounters came via his role as professor overseeing the work of medical residents, as opposed to his own treatment of patients). Dr. Steinman has also published extensively in peer-reviewed journals on topics including neuroimmunology and GBS. He has demonstrated expertise in both a wide variety of central nervous system diseases (multiple sclerosis in particular) and immunologic issues, and claimed great familiarity in treating brachial neuritis, although he does not appear to have focused on it over other central nervous system diseases (such as multiple sclerosis).

Id. at *8 (citations omitted). Contrary to the parenthetical in the special master's first sentence, Dr. Steinman testified that he "saw a patient with brachial neuritis" while he "was on duty at Stanford Hospital very recently," and that he "know[s] from [his] own practice, as recently as three weeks ago," that brachial neuritis "has the hallmarks of an autoimmune condition." Tr. 51; see also id. at 68 ('[W]hen I see a patient with brachial neuritis, I like to treat them and make them feel better faster . . . . "). And, although he remarks that Dr. Steinman "has demonstrated expertise in . . . immunologic issues," the special master fails to note that Dr. Steinman is actually an immunologist.

Nevertheless, even though the special master's findings regarding the credentials and experience of Dr. Steinman were arbitrary and capricious, they were unnecessary for his conclusion that petitioner did not establish that the Td vaccine caused his brachial neuritis. Indeed, the special master held that respondent had rebutted petitioner's showing on the third prong of the Althen test on the merits of the evidence presented, and only noted petitioner's experts' purported lack of "experience studying or treating brachial neuritis and its causes" as a separate reason for discounting their opinions.

Second, the special master concluded that "what direct proof exists on [the amount of time brachial neuritis will occur after an instigating trigger] does not preponderate in Petitioner's favor," id. at *17, but did not discuss the Morishima article, which described an onset period of three months, or the testimony of Dr. Steinman, who had seen onset periods of four to six weeks. The court does not find the special master's failure to perform a specific analysis of this evidence to be arbitrary and capricious. There is no requirement that a special master discuss every piece of evidence when making a factual finding. See, e.g., Maza v. Sec'y of HHS, 67 Fed. Cl. 36, 38 (2005) ("The Special Master need not discuss every item of evidence in the record so long as her decision makes clear that she considered the petitioners' arguments."); Snyder v. Sec'y of HHS, 36 Fed. Cl. 461, 466 (1996) ("The special master need not discuss every item of evidence in the record so long as the decision makes clear that the special master fully considered a party's position and arguments on point."), aff'd, 117 F.3d 545 (Fed. Cir. 1997); see also Hazlehurst v. Sec'y of HHS, 604 F.3d 1343, 1352 (Fed. Cir. 2010) (noting that a reviewing court presumes that the fact finder has considered all of the material in the record, regardless of whether it is mentioned in his or her decision). More fundamentally, it is clear that the special master considered the evidence identified by petitioner because he mentioned it elsewhere in his decision. See Greene, 2019 WL 4072110, at *6 (remarking that Dr. Kinsbourne recognized that the three-month onset period in the Morishima article was an outlier), *19 (same), *9 (describing Dr. Steinman's testimony).

Third, the special master observed that there was "nothing from the pre- or post-vaccination record suggesting that an autoimmune reaction was brewing in a subclinical form," id. at *21, but did not indicate how such a reaction would be reflected in the record given that "subclinical" means "[n]ot manifesting characteristic clinical symptoms," Subclinical, The American Heritage College Dictionary (4th ed. 2004). However, even if the court found the special master's observation to be arbitrary and capricious, it is but one of three reasons for the special master's conclusion that "[t]he record provides no objective evidence whatsoever—direct, circumstantial, or otherwise—that Petitioner was experiencing an autoimmune-derived injury attributable to vaccination." Id. According to the special master:

> Mr. Greene had no symptoms at all before he presented to the ER in early September 2009, and then only reported he had been feeling pain for a few days before—consistent with the acutely-presenting nature of brachial neuritis. There is nothing from the pre- or post-vaccination record suggesting that an autoimmune reaction was brewing in a subclinical form. And none of Mr. Greene's treaters implicated the tetanus vaccine as causative of his injuries—nor did they ever propose IVIG treatment to remedy it (something that further undercuts the concept that brachial neuritis is properly deemed congruent with GBS—or that medical science is increasingly viewing immunosuppressive treatments as effective for brachial neuritis).

Id. Because petitioner does not challenge the other two bases of the special master's conclusion, the fact that one basis is problematic is of no import.

In short, the court rejects petitioner's second objection to the special master's decision. Many of petitioner's contentions relate to the weight assigned to certain evidence by the special master, which the court does not review, and the remaining contentions regard findings of fact that are not arbitrary and capricious or are not critical to the special master's ultimate conclusions. The court therefore turns to petitioner's contentions that the special master improperly increased his burden of proof under the second and third prongs of the Althen test.

2. The Special Master Did Not Increase Petitioner's Burden of Proof Under the Third Prong of the Althen Test

The court begins with petitioner's Althen prong three objection: that the special master required him to establish that a forty-one-day onset period was medically reasonable, a subjective determination, rather than medically acceptable, an objective determination. He argues that the evidence in the record reflects that brachial neuritis can develop three months after a triggering event and, therefore, "medically, it must be accepted that [brachial neuritis] can arise 41 days post-triggering event." Mot. 22. Respondent counters that petitioner's objection

> is plainly inaccurate and must be rejected, as it simply ignores the Special Master's accurate two-page recitation of case law describing petitioner's burden of proof, the whole of the Special Master's analysis, and the Special Master's specific finding that "Petitioner Has Not Established that his Brachial Neuritis Began in a Medically-Acceptable Post-Vaccination Timeframe."[8]

Resp. 11 (footnote added).

As an initial matter, the court does not understand "medically acceptable" and "medically reasonable" to be legally distinct concepts for the purpose of analyzing the third prong of the Althen test. A scientist or doctor who finds an onset period to be medically acceptable would not find the onset period to be medically unreasonable, and a scientist or doctor who finds an onset period to be medically reasonable would not find the onset period to be medically unacceptable. Indeed, two of petitioner's experts expressed their opinions on the postvaccination timing of the onset of petitioner's brachial neuritis in terms of medical reasonableness. Dr. Wright concluded that petitioner's forty-one-day onset period was "a reasonable onset window," Pet'r's Ex. 22 at 2;

[8] The "specific finding" recited by respondent is actually a heading in the special master's decision. The court is disinclined to treat a heading as a finding of fact or conclusion of law. Accord Target Stores, Div. of Target Corp. v. United States, 471 F. Supp. 2d 1344, 1347 (C.I.T. 2007) ("[A] section heading within a court order is not authority of any sort."); NSK Ltd. v. United States, 462 F. Supp. 2d 1254, 1256 n.1 (C.I.T. 2006) ("[T]he headings demarcating separate sections within an opinion are dicta and not binding under the doctrine of stare decisis."), aff'd, 510 F.3d 1375 (Fed. Cir. 2007); cf. Tutor Perini Corp. v. Banc of Am. Sec. LLC, 842 F.3d 71, 96 (1st Cir. 2016) ("For though a heading in Tutor Perini's opening brief suggests the judge erred in dismissing the intentional-misrepresentation claim, its appellate papers never explain how this is so. And thus Tutor Perini waived any argument it might have on that claim."). However, as set forth below, the court's conclusion would be the same regardless of whether it considered the heading in its analysis.

accord Pet'r's Ex. 29 at 2 (remarking that "41 days . . . is within a reasonable time . . . to implicate the vaccine"), and Dr. Kinsbourne concluded that "[t]he interval of 41 days falls within the 42-day timeframe that is generally recognized as being medically reasonable," Pet'r's Ex. 38 at 4; accord Pet'r's Ex. 45 at 3 ("The medical literature cited above is evidence that a 42-day risk interval for brachial neuritis is medically reasonable.").[9] Thus, for present purposes, the terms "medically acceptable" and "medically reasonable" are interchangeable. Consequently, the special master could not have increased petitioner's burden of proof by using the term "medically reasonable."

Even if the court determined that "medically acceptable" and "medically reasonable" are legally distinct concepts, it would find no error in the special master's analysis of the third prong of the Althen test. As respondent notes, the special master accurately described petitioner's burden to demonstrate a medically acceptable onset period and the special master's analysis of the evidence regarding the timing issue reflects a proper understanding of that burden. Moreover, the special master clearly indicated that his holding was that petitioner had not shown, by a preponderance of evidence, that a forty-one-day onset period was medically acceptable. See Greene, 2019 WL 4072110, at *21 ("Even if I had found that a forty-one-day timeframe for onset of brachial neuritis was medically acceptable, the record in this case fails to support the conclusion that the tetanus vaccine is the most likely explanation for Mr. Greene's injury."), *22 ("But after considering the expert witnesses and evidence upon which they relied, it is my reasoned conclusion that Petitioner has failed—despite abundant opportunity—to preponderantly substantiate his contention that a forty-one-day onset period for his brachial neuritis was medically acceptable . . . .").

Because the court rejects petitioner's factual and legal objections relating to the third prong of the Althen test, it does not disturb the special master's conclusion that petitioner failed to establish the third prong by a preponderance of the evidence. The failure to prove one prong of the Althen test is fatal to petitioner's attempt to prove that the Td vaccine caused his brachial neuritis. Accordingly, the court need not address petitioner's contention that the special master improperly raised his burden of proving the second prong of the Althen test.[10]

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[9] Another of petitioner's experts, Dr. Steinman, concluded that a forty-two-day risk interval is "acceptable," "entirely appropriate," and "standard for the timing on immunization induced brachial neuritis." Pet'r's Ex. 68.

[10] However, the court makes two observations. First, the special master's statement that "the record in this case fails to support the conclusion that the tetanus vaccine is the most likely explanation for Mr. Greene's injury," Greene, 2019 WL 4072110, at *21, is not necessarily incompatible with the applicable legal standard of demonstrating that, more likely than not, the vaccine did cause the injury. See Moberly, 592 F.3d at 1322 n.2 ("The burden of showing something by a 'preponderance of the evidence,' . . . simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence . . . ." (quoting Concrete Pipe & Prods. of Cal., Inc., 508 U.S. at 622)); Pafford, 451 F.3d at 1356 (remarking that under the second prong of the Althen test, a petitioner must show "that the vaccine was the 'but for' cause of the harm" or, in other words, "'that the vaccine actually caused the alleged symptoms in [the] particular case'" (quoting the decision of the special master as recited by the trial court)). Furthermore, the special master accurately described petitioner's burden of proof and remarked

III. CONCLUSION

Although the court likely would have reached a different conclusion on the merits of petitioner's claim that the Td vaccine caused his brachial neuritis,[11] it is constrained by binding Federal Circuit precedent dictating that it is not to reweigh the evidence when the special

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in his concluding paragraph that petitioner "failed . . . to preponderantly substantiate his contention . . . that the tetanus vaccine more likely than not 'did cause' his subsequent injury." Greene, 2019 WL 4072110, at *22.

Second, petitioner's counsel contended during oral argument that the special master's discussion and conclusions regarding the second prong of the Althen test were unexpected because he had previously found the existence of a "logical cause-and-effect relationship between Mr. Greene's receipt of the vaccine and development of brachial neuritis" and that the focus of the special master and the parties leading up to the postremand fact hearing was on Althen prong three. Reliance on the special master's prior holding is problematic for two reasons. First, the special master's statement was dicta included in a footnote. See Greene v. Sec'y of HHS, No. 11-631V, slip p. at 12 n.5 (Fed. Cl. Spec. Mstr. May 26, 2017) ("Because I have found that Petitioner's claim did not satisfy one of the three Althen prongs, I include no further discussion of the remaining two prongs. However, I do find that the first, "can cause" prong was met, given the ample prior decisions associating the Td vaccine with brachial neuritis, as well as the showing made in this case by Petitioner's experts. I also note that (with respect to the second Althen prong) there is a logical cause-and-effect relationship between Mr. Greene's receipt of the vaccine and development of brachial neuritis—although that showing is undercut by Petitioner's inability to explain the reasonableness of the temporal interval at issue. Accordingly, this prong is not met." (emphasis added) (citations omitted)); see also Co-Steel Raritan, Inc. v. Int'l Trade Comm'n, 357 F.3d 1294, 1307 (Fed. Cir. 2004) (explaining that dicta are "statements made by a court that are 'unnecessary to the decision in the case, and therefore not precedential (though [they] may be considered persuasive)'" (alteration in original) (quoting Obiter dictum, Black's Law Dictionary 1100 (7th ed. 1999))). Second, as petitioner's counsel acknowledged, the special master withdrew the May 26, 2017 decision that included the statement at issue, rendering it void for all purposes. See Vaccine Rule 10(e)(3)(A). Furthermore, even though respondent's counsel did not dispute petitioner's counsel's observation that the focus of the postremand proceedings before the special master was Althen prong three, counsel for both parties represented that there is nothing in the record indicating that petitioner would not be required to satisfy Althen prong two upon the withdrawal of the May 26, 2017 decision. Consequently, petitioner's hearing counsel's failure to focus on all three prongs of the Althen test cannot be attributed to any fault of the special master.

[11] The court is unaware of any decision in which a special master awarded compensation to a petitioner alleging that his or her brachial neuritis was caused by a tetanus-containing vaccination administered more than twenty-eight days earlier. However, the lack of such a decision is not dispositive. See Boatmon, 941 F.3d at 1358 (holding that special masters are not bound by the decisions of other special masters and, "[b]y extension, are not required to distinguish non-binding decisions of other special masters.").

master's fact findings are based on evidence that is not "wholly implausible." Thus, for the reasons stated above, the court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master. The clerk is directed to enter judgment accordingly.

In addition, pursuant to Vaccine Rule 18(b), the parties shall review this decision and submit any proposed redactions, by providing the court with redlined pages showing the redactions, by **no later than Tuesday, February 11, 2020**.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Chief Judge