In the United States Court of Federal Claims

No. 11-631V (Filed Under Seal: February 27, 2018) (Reissued for Publication: March 14, 2018)¹

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ROY GREENE,	*
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Petitioner,	*
*	*
V.	*
	*
SECRETARY OF HEALTH AND	*
HUMAN SERVICES,	*
	*
Respondent.	*
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Vaccine Act; Motion for Review; Tetanus-Diphtheria Vaccine; Brachial Neuritis; Causation-in-Fact; <u>Althen</u> Prong Three; Motion for Reconsideration Under Vaccine Rule 10(e)

Richard Gage, Cheyenne, WY, for petitioner.

Robert P. Coleman III, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, 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 (2012), for an alleged vaccine-caused injury. Before the court is petitioner's motion for review of the special master's decision denying compensation. Because the special master applied the incorrect legal standard when evaluating the evidence offered by petitioner, the court grants petitioner's motion and vacates the special master's 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

¹ Vaccine Rule 18(b), contained 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.

("Td") vaccination.² 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 brachial neuritis. In a July 31, 2015 decision, the special master 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., 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.

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.). 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.

Vaccine Rule 10(e)(3) provides that a "special master has the discretion to grant or deny" a motion for reconsideration "in the interest of justice." If a special master grants a motion for reconsideration, Vaccine Rule 10(e)(3)(A) provides that "the special master must file an order

² The court derives much of the background from the special master's September 26, 2017 decision. <u>See generally Greene v. Sec'y of HHS</u>, No. 11-631V, 2017 WL 5382856 (Fed. Cl. Spec. Mstr. Sept. 26, 2017). The remaining background is taken from the docket of the case.

withdrawing the challenged decision" and that the withdrawn decision "becomes void for all purposes and the special master must subsequently enter a superseding decision." Pursuant to Vaccine Rule 10(e)(3)(A)(ii), "[t]he special master may not . . . issue a superseding decision reaching a different result from the original decision without affording the nonmoving party an opportunity to respond to the moving party's arguments."

The special master granted petitioner's motion for reconsideration in a June 19, 2017 order, which provided:

ORDER GRANTING PETITIONER'S MOTION FOR RECONSIDERATION

On May 26, 2017, I issued a decision denying Petitioner's request for compensation and dismissing his claim. ECF No. 93. Petitioner then filed a motion for reconsideration of my decision on June 16, 2017, along with a supplemental (albeit unauthorized) expert report and several items of previously-unfiled medical literature. ECF Nos. 94-97.

I hereby grant the motion for reconsideration. Accordingly, the clerk of the Court is hereby instructed to withdraw the original decision issued on May 26, 2017.

I will discuss the next steps for resolving this claim with the parties during the status conference currently set for June 28, 2017.

In accordance with this order, the docket entry for the May 26, 2017 decision was amended to reflect that the decision had been withdrawn. Specifically, the following language was added at the beginning of the docket entry: "**VACATED PURSUANT TO ORDER . . . OF 6/19/2017.**"

The special master conducted a status conference with the parties on June 28, 2017, and issued an order later that day memorializing the proceedings:

The status conference was held to discuss Petitioner's recent motion for reconsideration and supporting materials filed on June 16, 2017. ...

... [After I granted Respondent's motion for a ruling on the record], Petitioner filed a fourth supplemental expert report and numerous additional pieces of literature aimed at bulwarking the onset/timing issue. Although these materials were filed late, I have determined that in fairness to Petitioner I must at least consider them (although I will weigh their persuasiveness against the fact of their dilatory submission), and therefore I am reconsidering my dismissal decision. Prior to deciding reconsideration, however, I informed the parties that I would give them one <u>final</u> opportunity to engage in litigative risk settlement negotiations. . . . If petitioner cannot compromise on the amount of requested damages, <u>he risks a determination on reconsideration that the new evidence is</u> simply too dilatory to change my previous decision. . . .

If the parties fail to reach an agreement, Respondent will have the opportunity to submit an opposition to Petitioner's motion for reconsideration.

(first and third emphasis added). The parties were unable to reach a settlement, and thus respondent filed a response to petitioner's motion for reconsideration on August 23, 2017.

On September 26, 2017, the special master issued a "Decision on Reconsideration Denying Entitlement." At the outset of the decision, he stated that he had withdrawn his earlier entitlement decision "to evaluate the merits of the reconsideration request." <u>Greene</u>, 2017 WL 5382856, at *1. Then, in a section containing the case's factual and procedural history, the special master indicated that he was "incorporat[ing] by reference" the facts and procedural history set forth in his withdrawn decision. <u>Id.</u> He also succinctly described the conclusion he reached in the withdrawn decision, indicating that he had cautioned petitioner that he could not "rely on a timeframe set for a Table claim to justify the timeframe for a comparable non-Table claim," that petitioner's experts nevertheless relied solely on the Vaccine Injury Table's twenty-eight-day time frame to support the reasonableness of a forty-one-day time frame, that "neither of Petitioner's experts "merely set forth an opinion on timeframe based on their <u>ipse dixit</u>." <u>Id.</u> at *2.

The special master then described the arguments advanced by petitioner in his motion for reconsideration and the new evidence submitted by petitioner in conjunction with his motion. With respect to the latter, the special master remarked:

[O]f the 19 [documents] filed [in support of Dr. Kinsbourne's supplemental expert report], only seven directly involve brachial neuritis or an arguably parallel condition. Some are inapposite case studies in which the affected individual experienced a possible vaccine-related reaction far sooner than relevant herein. Dr. Kinsbourne nevertheless argues that the risk interval incorporated into the Table's brachial neuritis claim would have been longer if the relevant studies when the Table claim was created had not over-relied on such limited instances (or excluded longer timeframe occurrences outright). Of course, in making that argument, Petitioner was once again attempting to leverage the adequacy of the Table timeframe in his favor–a posture I have already rejected in my initial entitlement decision.

Dr. Kinsbourne also attempts to analogize brachial neuritis to other autoimmune diseases such as [Guillain-Barré syndrome ("GBS")], given the fact the both involve peripheral nerve damage, and possibly the same autoimmune target and/or antibodies. But to do so, he invoked scientific or medical literature that upon close inspection was not reliable for the purpose cited. Thus, Dr. Kinsbourne cites [an article by R. Verma] ("Verma") as helping establish the association between GBS and brachial neuritis mechanistically (and therefore in turn allowing for the conclusion that timeframes associated with one could be applied to the other). Verma, however, not only involved a three-person case study (a type of evidence that [Vaccine] Program case law generally gives less weight), but addressed brachial neuritis arising after an active dengue fever infection rather than post-vaccination. And each case study evaluated in Verma involved post-infectious onset occurring in a far more acute manner than herein.

In seeking to establish a longer timeframe for Td-induced brachial neuritis, Petitioner offered some reliable items of literature discussing the timeframes accepted in the medical community for autoimmune illnesses. [An article by A. Rowhani-Rahbar ("Rowhani-Rahbar")] proposed risk interval estimates for two adverse events following vaccine administration—febrile seizures and acute disseminated encephalomyelitis ("ADEM"). For ADEM (the closest analog to Petitioner's brachial neuritis, given its neurologic nature), Rowhani-Rahbar concluded that the likely time period from vaccination to onset "best substantiated by available biological and epidemiologic data" was five to 28 days. A secondary, longer interval of two to 42 days was also deemed "biologically plausible," and therefore worthy of consideration in order to fully assess a potential safety problem, but was more uncertain, since "there might be reason to suspect that most of the excess risk, if any, is concentrated in a much shorter period of time." This secondary interval has nevertheless been found persuasive by other special masters despite its admitted foundational limitations.

Id. at *3 (citations and footnote omitted).

After describing the parties' arguments on reconsideration, the special master set forth his analysis. He began by noting that he would be applying the standard set forth in Vaccine Rule 10(e)(3) for ruling on a motion for reconsideration (the "interest-of-justice standard"), explaining: "Although I voluntarily withdrew my earlier decision, I shall still apply and consider the standards for reconsideration, since the underlying merits of Petitioner's request have not yet been resolved." <u>Id.</u> at *4. Then, after setting forth the standard, he stated: "Having reviewed the materials offered by Petitioner relevant to onset, I do not find that he has established persuasive grounds for reversing my earlier entitlement decision, and therefore I will reinstitute my initial decision denying compensation." <u>Id.</u>

The special master proceeded to explain his decision in more detail. Initially, he found that "Petitioner was unreasonably dilatory in substantiating the long-identified deficiencies" in his showing that forty-one days was a medically acceptable time period between a Td vaccination and the onset of brachial neuritis. <u>Id.</u> at *5. Then, noting that he was "loathe to reject Petitioner's reconsideration request solely on the unjustifiably dilatory nature of [that] showing," the special master "reviewed and considered the 20-plus pieces of literature, plus supplemental report, filed after [his withdrawn] Decision, to evaluate if they fill[ed] the evidentiary hole in [Petitioner's] overall showing." Id. at *6. He found that they did not:

Petitioner has offered little evidence directly relevant to the injury at issue–a failing not completely fatal to his claim, but still a factor to be taken into account in determining how much weight to give the evidence offered overall. He has offered case studies which largely underscore the reliability of the Table's timeframe, but do not bulwark his claims that a longer period is acceptable. He has also made an inadequately specific showing with respect to either the illness in question or the Td vaccine. And he has done all the above utilizing an expert, Dr. Kinsbourne, who has not been demonstrated to have specific, applicable experience with peripheral neuropathies of any kind, or brachial neuritis itself, sufficient to render his interpretation of the facts of this case or background science persuasive in the absence of other direct convincing proof.

By contrast, there is applicable law relating to what is medically reasonable for onset of post-vaccination brachial neuritis-but it is not favorable to Petitioner. For example, in <u>Garner</u>..., I considered a claim that the Hepatitis A and B vaccines caused Parsonage-Turner Syndrome (a parallel descriptor for brachial neuritis). The earliest onset possible in <u>Garner</u> was 45 days after vaccination.... Respondent's expert, however, argued that the condition was far more acute in nature (and in terms of the causative mechanism), making in his opinion four weeks the outer limit for latency. I found this point to be dispositive Nothing Petitioner has argued in this case is any more persuasive than what I have previously rejected in like circumstances.

I acknowledge that Petitioner has offered some reliable evidence supporting the medical acceptability of a 41-day onset for <u>other</u> autoimmune conditions. Rowhani-[Rahbar], for example, supports the assertion that an autoimmune process could begin in the same timeframe that [Petitioner] experienced. But the fact that this article does not involve brachial neuritis, or any comparable peripheral neuropathic injury, does somewhat limit its applicability. More generally, it is too sweeping to maintain that there is a single temporal yardstick applicable to any autoimmune illness. To so argue is to ignore the different ways in which specific kinds of injuries unfold. ... Petitioner's showing is thus too nonspecific to the injury at issue, even if it is based in reliable science. <u>Id.</u> (citations omitted). Considering his procedural and substantive objections together, the special master stated:

Although I have attempted to avoid resolving this reconsideration request solely on the basis of Petitioner's untimely acts, <u>my weighing of the late-filed</u> <u>substantive evidence is nevertheless reasonably informed by the temporal</u> <u>circumstances of its filing</u>. If Petitioner had been able to marshal more straightforward and/or compelling evidence supporting the conclusion that the timing of onset of his brachial neuritis was medically acceptable–either due to directly on-point literature or by citing prior decisions involving the same injury–<u>the strength of that showing would not be as diminished by its dilatory</u> <u>character</u>. Here, however, the evidence is mixed at best, and requires too much reliance on timeframes relevant to distinguishable autoimmune illnesses. Such evidence is thus insufficiently novel or persuasively striking enough on its own to ignore its unjustifiably late assertion.

Id. (emphasis added).

Thus, at the end of his decision, the special master concluded:

The record does not support Petitioner's allegation that his Td vaccine more likely than not caused his brachial neuritis 41 days following the vaccination. Petitioner has not established entitlement to compensation, and therefore I must DISMISS the claim.

In the absence of a timely-filed motion for review . . . , the Clerk shall enter judgment in accordance with this decision.

<u>Id.</u> at *7. Notably, the special master did not direct the clerk to reinstate or refile his withdrawn decision (or to remove the text from the docket entry for the May 26, 2017 decision indicating that the decision had been withdrawn³). Nor does the withdrawn decision appear on the website of the United States Court of Federal Claims ("Court of Federal Claims") or in the online databases maintained by Westlaw and LexisNexis.

Petitioner timely filed a motion for review of the special master's September 26, 2017 decision on reconsideration, which respondent opposes. Upon reviewing the record that was before the special master and hearing argument on February 13, 2018, the court is prepared to rule.

³ Instead, a note was added to the docket entry for the May 26, 2017 decision to indicate that the entry was modified on September 26, 2017 "to correct docket text and to remove restriction on [the] attachment."

II. DISCUSSION

A. Standard of Review

The Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The 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." <u>Munn v. Sec'y of HHS</u>, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In the instant case, petitioner enumerates, pursuant to Vaccine Rule 24, two objections to the special master's September 26, 2017 decision. First, petitioner contends that "[t]he special master erred as a matter of law in applying the standard for considering a motion for reconsideration under Vaccine Rule 10(e) to his actual consideration of the case on the merits after granting a Vaccine Rule 10(e) motion." Mot. 1. Second, petitioner asserts that "[t]he special master erred as a matter of law by increasing the burden of proof on Petitioner to supply direct evidence instead of circumstantial evidence of a medically appropriate time frame for onset" Id. Petitioner accordingly requests that the "Court rule that Petitioner has made a legally adequate showing of causation and remand this case [to the special master] for a determination of damages." Id. at 20. Petitioner further requests that the "Court order that this case be reassigned to a new special master." Id.

B. The Special Master's Application of the Interest-of-Justice Standard Was Legal Error

Petitioner first argues that the special master, in his September 26, 2017 decision, should not have applied the interest-of-justice standard because the special master had already ruled on petitioner's motion for reconsideration on June 19, 2017. Respondent disagrees, asserting that the special master explained in his June 28, 2017 order that he considered the merits of petitioner's motion for reconsideration to be unresolved, and that the special master's application of the interest-of-justice standard in his September 26, 2017 decision did not prejudice

petitioner.⁴ As explained below, the court concludes that the special master erred by applying the interest-of-justice standard in his September 26, 2017 decision, and that in doing so, he prejudiced petitioner.

Pursuant to Vaccine Rule 10(e)(3), special masters have "the discretion to grant or deny" a motion for reconsideration "in the interest of justice." As the special master noted in his September 26, 2017 decision, there is a paucity of case law construing the interest-of-justice standard. The prevailing assumption is that the standard "is congruent with the 'manifest injustice' standard utilized under Rule 59(a) of the Rules of the Court of Federal Claims, which has been defined to be unfairness that is 'clearly apparent or obvious.'" <u>Greene</u>, 2017 WL 5382856, at *4 (quoting <u>Amnex</u>, Inc. v. United States, 52 Fed. Cl. 555, 557 (2002)). <u>But see Krakow v. Sec'y of HHS</u>, No. 03-632V, 2010 WL 5572074, at *5 (Fed. Cl. Spec. Mstr. Nov. 12, 2010) ("[T]he 'interest of justice' standard is likely less onerous than 'manifest injustice.'"). According to the special master, "[a]t bottom, the question is whether reconsideration would provide a Vaccine Act petitioner a full opportunity to prove her case." <u>Greene</u>, 2017 WL 5382856, at *4. As such, the interest-of-justice standard is separate and distinct from the standard for resolving the merits of the underlying claim for compensation.⁵

⁵ Petitioner seeks compensation under a theory of actual causation. 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.

<u>Althen v. Sec'y of HHS</u>, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Establishing the third element of the <u>Althen</u> test "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." <u>de Bazan v. Sec'y of HHS</u>, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

"The 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." <u>Knudsen v. Sec'y of HHS</u>, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Thus, causation can be established with circumstantial evidence–in other words, with medical records or medical opinion. <u>Althen</u>, 418 F.3d at 1279-80 (citing 42 U.S.C. § 300aa-13(a)(1)). A petitioner "need not produce medical literature or epidemiological evidence to establish

⁴ Although respondent observes that petitioner did not object to the special master's characterization of the motion for reconsideration as unresolved, he does not advance a waiver argument. Accordingly, the court need not consider whether petitioner waived his objection.

In his June 19, 2017 order, the special master unambiguously and unconditionally granted petitioner's motion for reconsideration. Although the special master subsequently stated, in his June 28, 2017 order, that he had not yet "decid[ed] reconsideration," the June 19, 2017 order granting reconsideration did not explicitly or implicitly indicate that the motion had not been fully resolved.⁶ In other words, the special master's June 28, 2017 statements regarding the status of petitioner's motion for reconsideration did not alter the legal effect of the June 19, 2017 order granting reconsideration.⁷ Thus, the special master should not have applied the interest-of-justice standard in his September 26, 2017 decision.⁸

⁷ The special master did not amend or reissue his June 19, 2017 order granting reconsideration to accurately reflect his purported intent.

⁸ The court also has a housekeeping concern not raised by petitioner in his motion for review: it is not convinced that the special master's September 26, 2017 decision constitutes the "superseding decision" required by Vaccine Rule 10(e)(3)(A). That rule provides: "If the special master grants the motion for reconsideration, the special master must file an order withdrawing the challenged decision. The decision, once withdrawn, becomes void for all purposes and the

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." <u>Andreu v. Sec'y of HHS</u>, 569 F.3d 1367, 1379 (Fed. Cir. 2009); <u>see also id.</u> at 1380 (remarking that a special master may assess "the relevant scientific data" when determining whether a petitioner has offered a reputable and reliable explanation supporting his theory of causation); <u>Capizzano v. Sec'y of HHS</u>, 440 F.3d 1317, 1325 (Fed. Cir. 2006) ("[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in <u>Althen[</u>, and] impermissibly raises a claimant's burden under the Vaccine Act"). <u>But see LaLonde v. Sec'y of HHS</u>, 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.").

Furthermore, the special master's application of the interest-of-justice standard prejudiced petitioner. The special master explicitly stated in his decision, when assessing the probative value of petitioner's newly submitted evidence, that his "weighing of the late-filed substantive evidence [was] . . . reasonably informed by the temporal circumstances of its filing," and that had petitioner "been able to marshal more straightforward and/or compelling evidence supporting the conclusion that the timing of onset of his brachial neuritis was medically acceptable . . . the strength of that showing would not [have been] as diminished by its dilatory character." <u>Id.</u> at *6. While special masters have the discretion to determine the probative value of evidence, <u>Munn</u>, 970 F.2d at 871, the timing of the submission of an expert report and medical and scientific literature should not affect their probative value. Because the special master did not weigh all of the evidence offered by petitioner based solely on its quality, his assessment of the evidence as a whole is compromised, prejudicing petitioner.

III. CONCLUSION

Because the special master's application of the interest-of-justice standard tainted his entire entitlement decision, the court need not address petitioner's second objection–that the special master improperly increased petitioner's burden of proving a medically acceptable time frame for onset by requiring him to produce direct, rather than just circumstantial, evidence.⁹

⁹ It bears noting, however, that although the special master never explicitly stated that petitioner was required to submit direct evidence of a medically acceptable onset period for post-

special master must subsequently enter a superseding decision." Vaccine Rule 10(e)(3)(A). When the special master granted petitioner's motion for reconsideration, he withdrew his initial entitlement decision, rendering that decision "void for all purposes" and triggering the requirement to issue a "superseding decision." By definition, a "superseding decision" is a decision that replaces the withdrawn, void decision. See The American Heritage College Dictionary 1386 (4th ed. 2004) (defining "supersede" as "[t]o take the place of; replace"). The special master obviously intended his September 26, 2017 decision-in which he "incorporated by reference" the facts and procedural history included in his initial entitlement decision and then purported to "reinstitute" the initial entitlement decision-to be a replacement decision. However, the special master's initial entitlement decision remains "vacated" on the case's docket and is unavailable on the court's website or in online databases-circumstances that may be attributable to the fact that the special master did not specifically direct the clerk, in the summation section of his September 26, 2017 decision, to reinstate or reissue his initial entitlement decision. See, e.g., Cozart v. Sec'y of HHS, No. 00-590V, 2015 WL 6746499, at *10 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) ("For the aforementioned reasons, the undersigned hereby DENIES petitioners' Motion for Reconsideration. The Original Decision will be reinstated and considered filed as of today's date, October 15, 2015."). Consequently, because the September 26, 2017 decision does not contain both the special master's original findings and conclusions (in their entirety) and the special master's new findings and conclusions, it appears not to constitute a replacement decision as contemplated by Vaccine Rule 10(e)(3)(A).

Thus, for the reasons stated above, the court **GRANTS** petitioner's motion for review, **VACATES** the special master's September 26, 2017 decision, and **REMANDS** the case to the special master to issue a new entitlement decision.¹⁰ In the new entitlement decision, the special master shall address all of the evidence offered by petitioner in support of his position that a forty-one-day onset period is medically acceptable, and not just the evidence submitted by petitioner with his motion for reconsideration. <u>See</u> Vaccine Rule 10(e)(3)(A); <u>supra</u> note 8. Further, the special master shall evaluate that evidence under the proper legal standard. <u>See</u> <u>supra</u> note 5. Finally, the special master shall issue his new entitlement decision within **ninety days** of the date of this decision. <u>See</u> 42 U.S.C. § 300aa-12(e)(2); Vaccine Rule 28(b).

IT IS SO ORDERED.

s/ Margaret M. Sweeney MARGARET M. SWEENEY Judge

Td vaccination brachial neuritis, and did acknowledge that petitioner's "offer[ing of] little evidence directly relevant to the injury at issue [was] a failing not completely fatal to his claim," Greene, 2017 WL 5382856, at *6, he strongly suggested that direct evidence from medical or scientific literature was necessary, see, e.g., id. at *3 ("[O]f the 19 new items filed, only seven directly involve brachial neuritis or an arguably parallel condition." (emphasis added)), *6 ("[Petitioner] has . . . made an inadequately specific showing with respect to either the illness in question or the Td vaccine. ... [He has] utiliz[ed] an expert, Dr. Kinsbourne, who [lacks the] specific, applicable experience . . . sufficient to render [his opinion] persuasive in the absence of other direct convincing proof. ... Rowhani-Rahbar ... does not involve brachial neuritis, or any comparable peripheral neuropathic injury.... Petitioner's showing is thus too nonspecific to the injury at issue, even if it is based in reliable science. ... If Petitioner had been able to marshal more straightforward and/or compelling evidence supporting the conclusion that the timing of onset of his brachial neuritis was medically acceptable-either due to directly on-point literature or by citing prior decisions involving the same injury-the strength of that showing would not be as diminished by its dilatory character." (emphasis added)). Such a requirement would be an improper heightening of petitioner's burden of proof.

¹⁰ The court denies petitioner's request for an order directing that the case be reassigned to another special master.