# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

No. 11-631V

(to be published)

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| ROY GREENE, | * | |
| | * | |
| Petitioner, | * | Filed: May 7, 2018 |
| | * | |
| v. | * | |
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| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Tetanus-Diphtheria ("Td") Vaccine; Evidentiary Support for Onset Timeframe; Expert Opinions; Remand Decision; |
| Respondent. | * | |

*Richard Gage*, Law Offices of Richard Gage, Cheyenne, WY, for Petitioner.

*Ann Martin*, U.S. Dep't of Justice, Washington, DC, for Respondent.

## RULING ON REMAND DENYING RESPONDENT'S MOTION FOR RULING ON RECORD[1]

On September 29, 2011, Roy Greene filed a petition for compensation in the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] alleging that he developed brachial neuritis as a result of his receipt of the tetanus-diphtheria ("Td") vaccine on July 22, 2009. Pet. (ECF No. 1). Mr. Greene originally alleged both a Table injury claim and a "non-Table" causation-in-fact claim *(id.* at 2), but I dismissed the Table claim after a March 2015 fact hearing,

[1] This Ruling has been designated "to be published," and will therefore be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (Dec. 17, 2002) (current version at 44 U.S.C. § 3501 (2014)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling in its present form will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

at which time I determined that Petitioner's symptoms arose 41 days after the vaccination, and thus occurred outside the 28-day limit for the Table claim. 42 C.F.R. § 100.3(a)(I)(B)).

After the parties were unsuccessful in settling the matter, in 2017 Respondent moved for a ruling on the record dismissing the claim due to Petitioner's purported inability (under the third prong of the Federal Circuit's test for entitlement established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)) to offer preponderant support for his contention that a 41-day timeframe for onset of brachial neuritis was medically acceptable. *See* Motion to Dismiss, dated March 31, 2017 (ECF No. 90) ("Mot.")

On May 26, 2017, I issued a decision denying Petitioner's request for compensation in this case and dismissing his claim.[3] Petitioner then filed a motion for reconsideration of that decision on June 16, 2017, along with two supplemental expert reports as well as several items of previously-unfiled medical literature. ECF Nos. 94-97. I withdrew my Decision in order to evaluate the merits of the reconsideration request. *See* Order, dated June 19, 2017 (ECF No. 98) ("Reconsideration Order"). I subsequently denied entitlement a second time (*see Greene v. Sec'y of Health & Human Servs.*, No. 11-631, 2017 WL 5382856 (Fed. Cl. Spec. Mstr. Sept. 26, 2017)("Second Dismissal Decision") – although in doing so I erroneously conflated the standards applied to evaluating a reconsideration request with the legal standards applied to entitlement claims generally. Petitioner sought review of the Second Dismissal Decision, and the Court of Federal Claims granted his motion on February 27, 2018, remanding this matter back to me for a new disposition of Respondent's original motion, based on all evidence Petitioner has submitted to date and applying the proper legal standards. *Greene v. Sec'y of Health & Human Servs.*, No. 11-631, 2018 WL 1514440 (Fed. Cl. Feb. 27, 2018) ("Review Order").

For the reasons stated below, I hereby DENY Respondent's Motion, because Petitioner has now offered sufficient evidence to support his claim on the timing prong of the *Althen* test. However, I do not find that Petitioner is at this time entitled to an award of damages, because the record remains incomplete - Respondent has requested the opportunity to offer his own expert on the third *Althen* prong, and fairness requires me to permit him to do so.

## Factual History

The facts relevant to the present decision are set forth in my earlier onset fact ruling. *See Greene v. Sec'y of Health & Human Servs.,* No. 11-631, 2015 WL 9056034, at *1-4 (Fed. Cl. Spec. Mstr. July 31, 2015 ("Fact Ruling"). They are incorporated by reference herein. That fact ruling was issued after a 2015 hearing at which several witnesses testified, including the Petitioner.

[3] After I issued the order granting Petitioner's motion for reconsideration that later resulted in the present remand, my prior entitlement decision was withdrawn from the docket, and thus can no longer be cited.

For present purposes, the most important findings reached at the Fact Ruling are as Follows:

(a) Petitioner received the Td vaccine on July 22, 2009, in his right arm after an injury at his workplace;

(b) Petitioner saw no other healthcare providers in connection with his injury until September 7, 2009 (Labor Day of that year), when he went to a hospital emergency room in Houston, Texas, complaining of sharp pain in his right upper arm that had begun a few days before (and not any time in the month of July or August); and

(c) after hearing witness testimony and comparing it to the medical records filed in the case, I determined that onset of Petitioner's subsequently-diagnosed brachial neuritis had occurred no earlier than September 1, 2009 (or 41 days post-vaccination).

*See generally* Fact Ruling at *1-4, *17.

**Brief Procedural Review Summary**

Between the time of the Fact Ruling and the fall of 2016, the parties had no success in settling the non-Table claim despite their concerted efforts. In that period, Petitioner submitted two expert reports from an orthopedist, Thomas W. Wright, M.D. *(see* Report dated December 18, 2015, ECF No. 62 (Ex. 22) ("First Wright Rep."); Report dated April 25, 2016, ECF No. 66 (Ex. 29) ("Second Wright Rep.")). But Respondent took issue with the adequacy of the opinions expressed therein – arguing in particular that more was needed on the third *Althen* prong because of the conclusory nature of Dr. Wright's opinion, which relied heavily on the fact that a 41-day onset was only about two weeks longer than what the Table contemplates as a reasonable timeframe for onset, rendering the additional time period a *de minimis* difference.

In response to Respondent's objections, I proposed that Petitioner obtain an additional expert report addressing the *Althen* prong three issue. *See* Status Conference Order, dated September 29, 2016 (ECF No. 72). Mr. Greene filed the supplemental report, from Dr. Marcel Kinsbourne, on January 6, 2017. *See* ECF No. 82-1 (Ex. 38) ("Kinsbourne Rep."). Respondent, however, deemed this report also inadequate and conclusory. In response (and mindful that the case was now nearly six years old) I proposed that Respondent either consider the matter contested and file his own expert report, or in the alternative move for a ruling on the record as it stood. *See* Status Conference Order, dated January 26, 2017 (ECF No. 86).

Respondent took the second option and filed a motion to dismiss in March 2017. *See generally* Mot. Importantly, Respondent based his request for dismissal at that time *solely* on Petitioner's purported inability to carry his initial burden of proof. Thus, Respondent argued that the record itself (which included *only* the two Wright expert reports plus the supplemental Kinsbourne report, as well as my fact determination on onset) established "legally insufficient

proof" for a favorable entitlement decision and should therefore be dismissed. Mot. at 1. In particular, Respondent challenged Dr. Wright's attempt to "piggyback" on the Table timeframes for appropriate onset. *Id.* at 5-6. Respondent also maintained that Dr. Kinsbourne's report set forth a scientifically unreliable opinion, and was just as conclusory as Dr. Wright's reports in assuming that a 41-day onset period was within what is "generally recognized" as medically reasonable for other autoimmune illnesses, without providing reliable scientific or medical substantiation for that proposition. *Id.* at 8-9.

Petitioner opposed Respondent's motion. *See* Opposition, dated April 17, 2017 (ECF No. 92). He argued that he had "done everything necessary" to establish his claim, pointing out that he had offered two experts, and three reports, in comparison to Respondent's none, and urging me to rule in his favor based upon such evidence, which he deemed "unrebutted." Opp. at 5. As noted above, I originally granted Respondent's Motion in late May of 2017, finding that Petitioner's expert reports had not offered persuasive or reliable arguments as to the *Althen* prongs – and in particular with respect to timing – sufficient to find he had carried his preponderant evidentiary burden.

About 20 days later, however, Petitioner filed a timely motion under Vaccine Rule 10(e) requesting reconsideration of my dismissal decision. *See* Motion for Reconsideration, dated June 16, 2017 (ECF No. 97) ("Reconsideration Request"). In so doing, Petitioner argued that the expert reports he had previously filed did in fact meet the legal standards necessary for a decision in his favor. Reconsideration Request at 2-3. He also noted the existence of other Program decisions finding 42 days for onset of other autoimmune illnesses (although not brachial neuritis specifically) to be medically acceptable. *Id.* at 4. At the same time, however, Petitioner offered new evidence to support his claim: (a) a supplemental expert report from Dr. Kinsbourne; (b) an expert report from an immunologist, Dr. Vera Byers; and (c) 19 additional pieces of previously-unfiled medical literature. *See* Kinsbourne Supplemental Report, dated June 13, 2017, filed as Ex. 45 (ECF No. 94-1) ("Kinsbourne Supp. Rep.")); Byers Report, dated June 15, 2017, filed as Ex. 46 (filed as ECF No. 94-2) ("Byers Rep.");[4] ECF Nos. 94-96 (Exs. 46-66). These materials did a far superior job in providing substantiation for Petitioner's *Althen* prong three arguments than the previously-filed expert reports.

In response, I opted to grant Petitioner's request for reconsideration. *See generally* Reconsideration Order. A few days later, I held a status conference with the parties in which I elaborated on my reasoning for so doing. *See* Scheduling Order, dated June 28, 2017 (ECF No. 99). In particular, I stated that (although I considered the new expert reports and literature to have been filed unjustifiably late), I believed fairness required me to give them consideration. *Id*. at 1. I also asked Respondent (in the event the newly-filed literature and expert reports did not convince him to revisit settlement) to file a brief responding to the arguments set forth therein – but,

[4] The Byers report (which was accompanied by five items of literature) was mistakenly filed twice. *See* Ex. 59.

importantly, *not* to file an expert report until I had addressed the substantive evidentiary value of Petitioner's supplemental filings. *Id.* at 2. Specifically, I stated that "I would prefer that Respondent first attempts to oppose the motion without the need for an expert's opinion (*although Respondent may express in his opposition the desire to offer an expert report later*)." *Id.* (emphasis added).

Respondent filed the requested brief on August 23, 2017. *See* Response (ECF No. 101). In it, Respondent argued that the legal grounds for reconsideration under Rule 10(e) had not been met – in particular because of the grossly dilatory nature of the newly-filed evidence. Response at 1-5. He maintained as well that the additional expert reports and literature did not make persuasive points, or relied on inapposite comparisons (in arguing that a 41-day timeframe was acceptable) to other autoimmune illnesses. *Id.* at 6-11. In addition - in the event that I were inclined to reverse my earlier entitlement decision, based on the newly-submitted evidence, and consistent with his previously-expressed desire - Respondent asked that he be provided the chance to obtain and file an expert report of his own. *Id.* at 5, 11.

After reconsidering my original decision, I issued a second decision dismissing Petitioner's claim. *See generally* Second Dismissal Decision. Relying in part on the Rule 10(e) standard for reconsideration, I deemed the newly-filed materials as too dilatory in character to establish persuasive grounds for a different outcome, especially given the extent to which they largely were inapposite to present circumstances. I also found that Petitioner's existing evidence did not meet his burden of proof, especially with respect to the third *Althen* prong, in some part because it was too circumstantial in character, and thus (under the reconsideration standard)[5] not evidence that should be given much weight so late in the case's procedural life.

I did, however, note that *some* of the newly-filed evidence was more reliable or persuasive than what Petitioner had previously offered. *See, e.g.*, A. Rowhani-Rahbar, et al., *Biologically Plausible and Evidence–Based Risk Intervals in Immunization Safety Research*, 31 Vaccine 271, 271–77 (2012), filed as Ex. 48 (ECF No. 94-4) ("Rowhani-Rahbar"). Rowhani-Rahbar proposes risk interval estimates for two adverse events following vaccine administration – febrile seizures and acute disseminated encephalomyelitis ("ADEM"). *Id.* at 273. For ADEM (an inexact, but not unreasonable, 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. *Id.* at 274. 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." *Id.* at 275. This secondary interval has nevertheless been found persuasive

[5] The standard applied to motions for reconsideration permit special masters to take into account the character of newly-filed evidence – including whether it could have been filed earlier, as well as its probative value. *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1348 (Fed. Cir. 2010) (finding that the special master "did not abuse his discretion in declining to grant reconsideration in view of evidence that was previously available").

by other special masters in cases alleging autoimmune injuries (albeit *not* involving brachial neuritis). *See, e.g.*, *Day v. Sec'y of Health & Human Servs.,* No. 12-630V, 2015 WL 8028393, at *22 (Fed. Cl. Nov. 13, 2015) (applying Rowhani-Rahbar secondary risk interval to case alleging that petitioner's multiple sclerosis was vaccine-caused).

## Court's Adjudication of Motion for Review

Petitioner filed a timely motion for review of my second Decision dismissing the case. Motion for Review, dated October 26, 2017 (ECF No. 103). After considering it and Respondent's opposition, the Court granted the motion by Order dated February 27, 2018. *See generally* Review Order. The Court determined that I erred in misapplying the "interests of justice" standard, which is relevant only to a Rule 10(e) motion for reconsideration, to the legal merits of Petitioner's claim itself and to the evidence offered in its support. Review Order at *7. Once I had decided to permit reconsideration at all, I could no longer take into account issues like the dilatory nature of Petitioner's supplemental expert filings, and thus in doing so I had prejudiced Petitioner. *Id.* at *8.

The Court therefore vacated the Second Dismissal Decision, remanding the matter to me to be re-determined in light of the proper legal standards applicable in entitlement cases. Review Order at *6 n.5, *8. The Review Order also specifies that (in accordance with Section 12(e)(2) of the Act and Vaccine Rule 28(b)) I am to "issue [the] new entitlement decision within **ninety days** of the date of this decision," or by May 29, 2018. *Id.* at *8 (emphasis in original).

## Applicable Legal Standards

### A. *Claimant's Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[6] As already noted, Petitioner's Table claim was dismissed after issuance of the Fact Ruling.

[6] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121,

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim (which is the kind of claim asserted in this matter), a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(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.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, the petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

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124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical 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'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant

proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

The fact that a claimant offers an expert opinion does not render the opinion that expert espouses scientifically reliable or persuasive. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is

simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

C. *Standards for Deciding Entitlement on the Record*

The Vaccine Act and Rules permit special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). Hearings are not required in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs., 38 Fed. Cl. 397, 402-03 (1997)* (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417*; Murphy v. Sec'y of Health & Human Servs.,* No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

Deciding if a case requires a hearing can often turn on what the special master expects will be accomplished by allowing live testimony. Hearings are most helpful where witness credibility is at issue, or where posing questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings is likely to illuminate matters in dispute. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon points already set forth in paper filings, or respond to unanticipated questions raised in the matter – but again, only where necessary to reach a decision.

In addition, prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400-01 (citing Rule 3(b)). But that rule also includes the obligation to create a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case).

## ANALYSIS

As already noted, my now-vacated resolution(s) of Respondent's dismissal motion turned on the adequacy of Mr. Greene's *Althen* prong three showing.[7] In particular, I determined that the expert opinion evidence he had submitted from Drs. Wright and Kinsbourne was conclusory and unreliable in asserting that a 41-day post-vaccination onset was medically acceptable, and that Petitioner unreasonably relied on the Table's timeframe to argue that a timeframe 13 days longer was still acceptable.

Petitioner's more recently-filed expert reports and associated literature provide a variety of additional evidence to support his position with respect to timing. He has now offered reliable literature, like Rowhani-Rahbar, that supports his contention that a longer onset for autoimmune conditions is medically acceptable. He has also offered a more fleshed-out report from Dr. Kinsbourne, and a report from a third expert, Dr. Byers, also having some bearing on the timing question. For such reasons, it is appropriate, based upon all such evidence, to deny Respondent's March 2017 motion for a ruling on the record. There is sufficient evidence in the record that, *if unrebutted*, would allow me to conclude that Petitioner has met his preponderant burden of proof. The circumstances are now considerably different from when Respondent (based solely on the two conclusory Wright reports plus Dr. Kinsbourne's initial report) first moved to dismiss the claim.

*This does not mean*, however, that the opposite is true – that Petitioner has carried *his* burden based solely upon the existing record (which includes the supplemental expert reports and literature). Instead, I must in fairness permit Respondent the opportunity to rebut Petitioner's expert showing before I can fully rule on entitlement in this case.

My determination herein is the product of both substantive and procedural considerations. Substantively, I do not find that a 41-day timeframe for onset of brachial neuritis is a settled matter in the Program, as Petitioner has argued. Indeed – I have found the *opposite* to be true in other cases I have decided involving precisely the same injury. For example, in *Garner v. Sec'y of Health & Human Servs*., No. 15-063V, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *mot. for review den'd*, 2017 WL 3483352 (Fed. Cl. July 31, 2017), I considered a claim that the Hepatitis A and B vaccines had caused Parsonage-Turner Syndrome (a parallel descriptor for brachial

[7] My two decision(s) to dismiss the case included no in-depth discussion of the remaining two *Althen* prongs. However, it did appear to me, and does now as well, that the first, "can cause" prong has been met, given the ample prior decisions associating vaccines with a tetanus component with brachial neuritis, as well as the showing made in this case by Petitioner's experts. *See, e.g.*, *Devonshire v. Sec'y of Health & Human Servs.*, No. 99-031V, 2006 WL 2970418, at *15 (Fed. Cl. Spec. Mstr. Sept. 28, 2006) (stating that it is well known that brachial neuritis can occur following a tetanus vaccination), *aff'd*, 76 Fed. Cl. 452 (2007); *DeGrandchamp v. Sec'y of Health & Human Servs.*, No. 01-413V, 2003 WL 21439670, at *7 (Fed. Cl. Spec. Mstr. May 15, 2003) (relying on Institute of Medicine publications to find that in theory, the tetanus toxoid in Td can cause brachial neuritis). The future disposition of Petitioner's claim will not likely turn on the first *Althen* prong.

neuritis). The earliest onset possible in *Garner* was 45 days after vaccination, based on the first record documentation of any complaints by petitioner about arm or shoulder pain. *Garner*, 2017 WL 1713184, at *1. Respondent's expert, however, persuasively argued that the condition was far more acute in nature (and in terms of the causative mechanism as well), making in his opinion four weeks, or 28 days, the outer limit for latency. *Id.* at *8. I found this point to be dispositive, even though the claimant's *Althen* prong one showing was (as here) sufficient, and dismissed the case on the record. *Id.* at 16.

Nothing Petitioner has argued in this case is any more persuasive facially than what I have previously rejected. Tellingly, Petitioner has cited no contrary cases involving brachial neuritis and a timeframe equivalent to that herein, and although I am not bound by the decisions of other special masters, they can be persuasive and relevant in understanding whether a claimant has met his burden. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). I thus have doubts about the sufficiency of Petitioner's current evidentiary showing, and those doubts are best resolved by permitting Respondent the opportunity to offer his own expert views on the subject.[8]

I also note that I have reasonable misgivings about the weight to give the existing expert support offered on this point based on questions regarding expert credentials and competency. For example, I must evaluate whether Dr. Kinsbourne's lack of direct expertise in studying, researching, and/or treating brachial neuritis (let alone *any* patients for many years) is grounds for giving his views less weight. *Holmes v. Sec'y of Health & Human Servs.*, No. 08-185V, 2011 WL 2600612, at *2 n.9 (Fed. Cl. Spec. Mstr. April 26, 2011) (noting that Dr. Kinsbourne has not had a clinical neurology practice for 37 years), *aff'd* 115 Fed. Cl. 469 (2014). I also wish for Petitioner's experts to explain why literature offered relating to other autoimmune conditions, and the timeframe in which a vaccine would cause the relevant pathogenic reaction, can be analogized to brachial neuritis. In addition, should Petitioner call Dr. Wright at hearing, I would expect to probe the degree to which the opinion he previously offered on the timing issue relied on his own experience treating individuals with brachial neuritis, as opposed to his conclusory determination that the Table time periods were not that far off the time period in question (something Program law says is not permitted). All of the above will likely require a hearing, in order to assess expert credibility and probe the extent to which their opinions deserve the weight requested. Under such circumstances, I cannot rule favorably for Petitioner on entitlement without a more complete opportunity to weigh all the evidence together – which means directing Respondent to file an expert report.

Procedurally, I find that the present record remains incomplete on the timing issue. Respondent has not had the opportunity to offer his own expert to address the points raised in

[8] Of course, if Respondent opted *not* to file an expert report in this case, but were instead simply to ask me to decide the case based on the evidence as it stands, I would likely be compelled despite my doubts to find that he had met his burden, if barely. But Respondent *has* indicated the desire to file an expert report.

Petitioner's existing evidentiary showing. This is not something that I am raising *sua sponte*. Rather, the potential utility and necessity of a counter-expert was *raised by Respondent* in opposing the reconsideration request, in the event his motion to dismiss were denied after reconsideration. *See* Response at 5. Respondent wishes to offer an expert report of his own, and fairness dictates that I allow Respondent that opportunity.[9] *See* Rule 3(b)(2).

I also find that a hearing *will* likely be necessary before I can reach an entitlement decision in this case, given the present record (which in my estimation is incomplete for the reasons stated). As noted above, it is within a special master's discretion to decide when a hearing is required – and that decision can turn on whether the chosen form of adjudication "affords each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400-01 (citing Rule 3(b)). In some cases, I have decided that the matters presented could be reasonably resolved without hearing. *See, e.g., D'Toile v. Sec'y of Health & Human Servs.,* No. 15-85V, 2016 WL 7664475, at *25-28 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (resolving claim based on expert submissions and without hearing), *mot. for review den'd,* 132 Fed. C. 421 (2017), *aff'd*, No. 2017-1982, *slip op.* (Fed. Cir. Apr. 12, 2018). Here, I reach the opposite conclusion – to afford Respondent a "full and fair" opportunity to articulate his defense, and also to permit Petitioner to examine Respondent's experts, I will require an entitlement hearing mainly focused on the third *Althen* prong, in order to assess expert credibility and probe the bases for the opinions offered.

Petitioner's reconsideration request also suggested that Respondent's failure to offer an expert report requires me to find that Petitioner's evidence is unrebutted, but such arguments fly in the face of the evidentiary weighing and credibility determinations afforded to the special masters. As a general matter, I am *not* required to adopt the opinions of a petitioner's experts wholesale - even where Respondent chooses not to offer a rebuttal expert. S*ee Barone v. Sec'y of Health & Human Servs.*, No. 11-707, 2014 WL 6834556, at *12 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (evaluating reasonableness and reliability/persuasiveness of Petitioner's expert showing, despite the fact that Respondent had offered no rebuttal expert of his own). Indeed, in discussing the duties of the special masters, the Court of Federal Claims has previously noted that "[n]o judge or jury can be forced to accept or reject an expert's opinion or a party's theory at face value," and that to propose that special masters must do otherwise "is to neglect the Special Master's duty to 'vigorously and diligently investigate the factual elements' underlying [a] petition." *Sword v. United States*, 44 Fed. Cl. 183, 188 (1999), *citing Mills v. Sec'y of Health & Human Servs.,* 27

[9] In opting to seek a ruling on the record, Respondent has not waived the right to offer his own expert. Respondent's brief reacting to the Reconsideration acknowledges that Respondent was willing to forego offering an expert at the time of the *first* motion to dismiss, filed in March 2017. Response at 5. But once Petitioner offered supplemental expert reports and additional literature in the context of his reconsideration request, Respondent was explicit in asking that he too be permitted to obtain an expert opinion. *Id.* I in fact asked that Respondent forestall that effort, since I was unsure the degree to which I would find the Petitioner's new evidence persuasive. Scheduling Order at 2 (ECF No. 99). Now, applying the correct legal standard, I find the newly-filed evidence to be sufficient to defeat Respondent's motion – but not enough to result in judgment for Petitioner.

Fed. Cl. 573, 578 (1993). I may thus weigh the evidence offered by a petitioner in determining in the first instance if he has met his burden of proof.

In addition, I am empowered to permit, and to request, the filing of additional evidence in my role as special master – even at the later stages of a proceeding. Parties in Program cases are allowed *many opportunities* to supplement a record with expert support, and have been permitted to do so even immediately before or after a hearing's completion, or after issuance of an entitlement decision. *See, e.g., Cedillo v. Sec'y of Dep't of Health & Human Servs.*, No. 98–916V, 2009 WL 331968, *62 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010) (special master permitted two expert reports to be filed only four days before the hearing in the case was to commence); *Vant Erve v. Secretary of Department of Health & Human Services,* 39 Fed. Cl. 607 (1997), *aff'd after remand*, 232 F.3d 914 (Fed. Cir. 2000) (unpublished table decision) (special master's refusal to reopen a question of liability was an abuse of discretion even though three years had passed since decision; information offered by Respondent was highly probative, there was no showing of prejudice to Petitioners, and Respondent was not at fault for the delay). Such discretion flows from the special master's authority to determine whether, when, and how to take and consider evidence in resolving a petitioner's entitlement to damages. *Hovey*, 38 Fed. Cl at 400 (concluding that it was within the special master's discretion to determine whether to allow in new evidence after an evidentiary hearing in the case); Section 12(d)(3)(B) (special master afforded discretion when making determinations regarding admission of evidence).

Here, my misgivings about the adequacy of Petitioner's current evidentiary showing make it impossible for me to decide the case on the existing record, and may best be addressed by permitting a counter-expert's testimony. Allowing Respondent to file an expert report under the present circumstances would not otherwise prejudice Petitioner. I have previously in this case bemoaned the excessive amount of time it is taking to resolve the matter, so it pains me to increase delay – but Petitioner's refusal earlier in the case to substantiate a critical element of his claim, coupled with his last-minute filing of the materials necessary to do so, remain the proximate cause of delayed resolution. Petitioner will be afforded a reasonable opportunity to respond to the additional expert report as well. A reasoned determination of the timing issue is most likely if *all parties* have had a full and fair opportunity to make their respective cases.

Petitioner has also maintained[10] that I am constrained by the Court's Review Order to decide entitlement based solely on the record before me, and therefore cannot allow Respondent to file his own expert report at this point. *See* Status Report, dated March 16, 2018 (ECF No. 115).

[10] After the issuance of the Court's Review Order, I held a status conference with the parties to discuss the best means of proceeding. *See* non-pdf Scheduling Order, dated March 12, 2018. At the time, I informed Petitioner of my preliminary view that I should permit Respondent to file an expert report before I decided entitlement in the matter again. Petitioner objected, however, to my proposal, as indicated in his March 16th Status Report.

Such a reading of the Review Order is too narrow. The Order required me to resolve Respondent's motion to dismiss by applying the proper evidentiary standard, and to so act in the 90-day period defined by the Vaccine Act and Rules upon remand. *See* Rule 28(b).[11]

I have done precisely as ordered – and am now denying a summary disposition of this case in favor of *either* party. The Review Order does not state that I am to determine entitlement based only on the record as it stands, or to close the record to additional proof. I have in fact found that I cannot decide the case at this time without evidentiary inputs from Respondent, consistent with my discretion and in accordance with what has occurred in many other Program cases – even after trial and even after a decision has issued. Declining to decide this case at the present, *before* an entitlement hearing has been held on the disputed matter, arguably constitutes stronger grounds for the obtaining of additional evidence. Fairness must be a two-way street in Vaccine Program cases, and concerns for fairness compel me, consistent with Vaccine Rule 3(b), to provide Respondent the same opportunities that Petitioner has obtained, and that Program claimants are allowed frequently.

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[11] I acknowledge that the Court's Review Order specifically directs me to issue a "new entitlement decision," and thus my present disposition, taken literally, does not accomplish this – but only if the term "decision" is given the technical meaning employed in the Vaccine Program for the reasoned determinations of special masters. In the Program, "decisions" trigger issuance of judgments by the Clerk of the Court, and must therefore involve either the denial of entitlement (in effect, a judgment awarding $0) or the awarding of a specified sum of damages. *See* 42 U.S.C. §300aa-12(d)(3)(A);Vaccine Rule 10. Because I am no longer granting the relief requested by Respondent (dismissal of the claim), however, I am only "ruling" on entitlement, and thus not yet issuing a decision. At the same time, granting Petitioner's counter-request for a favorable ruling on the record would *also* not constitute a "decision" until damages were resolved (a matter than in my experience can take a year or more) – and would therefore be just as much a technical abrogation of the Review Order. My disposition of this matter on remand is consistent with the spirit of the Court's Review Order (parsing the Court's usage herein of the word "decision" for its more broadly-understood meaning, i.e. to resolve an outcome of a disputed matter).

This raises an additional concern – the fact that my disposition of Respondent's pending motion will not result in the complete resolution of this case in the 90-day period prescribed for special masters to act upon remand under Rule 28(b). Review Order at 12. By permitting Respondent the time to obtain an expert report and setting the matter for hearing, the case is unlikely to be resolved in so short a period. But there are two countervailing considerations that suggest this too is not an abrogation of my responsibilities in carrying out the mandate of the Court's Review Order. First, the present ruling *is* being issued within 90 days of the Court's February 27, 2018 Review Order (a time period that would expire no sooner than May 29, 2018). Second, there is persuasive dicta from other Court decisions observing that "the Vaccine Act *does not identify any consequences* for failure to act within the ninety-day remand period," and therefore parties to a litigation, in consultation with the relevant special master, can agree to extend the period if to do so would be in the "interests of justice" and that the Court of Federal Claims would likely support such a determination. *See Hodge v. Sec'y of Health & Human Servs.,* No. 09-453V, *slip. op*. at 1-2 (Fed. Cl. Nov. 9, 2015) (emphasis added), *citing Paluck v. Sec'y of Health & Human Servs.,* 111 Fed. Cl. 160,165-66 (2013).

If Petitioner deems the 90-day time period to require total and complete resolution of his claim, and is therefore unwilling to accede to the necessity of this matter taking more time to resolve, he may so argue in another motion for review, after I have resolved entitlement (and assuming I do so against him), or in response to a motion to the Court by Respondent to extend the 90-period.

## CONCLUSION

Petitioner has now offered adequate evidentiary support for his claim that the 41-day onset period for his brachial neuritis was medically acceptable, thereby removing the former grounds upon which I dismissed his claim, and causing me to **DENY** Respondent's Motion. However, I cannot otherwise rule on whether Petitioner has carried his burden of proof on the record as it stands, and therefore do not decide entitlement at this time in his favor either.

The parties shall contact chambers and request a status conference, at which time a schedule for Respondent's filing of an expert report, as well as a final response to that report from Petitioner's expert(s) and then trial of this matter, shall be discussed.

**IT IS SO ORDERED.**

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master