In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1375V
(not to be published)

* *
ROBERT ANTHONY SIMEONE, III, *
on behalf of R.S., a minor, *
*
Petitioner, *
*
v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
*
* *

Chief Special Master Corcoran

Dated: February 24, 2023

Reissued for Public Availability: August 17, 2023

Robert Anthony Simeone, III, pro se, Savannah, TX, Petitioner.

Kyle Edward Pozza, U.S. Dep't of Justice, Washington, DC, Respondent.

DECISION DISMISSING PETITION[1]

This vaccine injury claim was initiated under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] by *pro se* Petitioner Robert Anthony Simeone III, on behalf of his minor child, R.S., on October 13, 2020. Petition (ECF No. 1); amended on April 12, 2022 (ECF

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[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. 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 (14) 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 entire Decision will be available to the public in its current form. *Id.*

Pursuant to Vaccine Rule 18(b), this Decision was initially filed on February 24, 2023, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this Decision is reissued in its original form for posting on the court's website.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

No. 40) ("Pet."). Mr. Simeone alleges that R.S. suffered an acute encephalopathy three days after receiving the diphtheria, tetanus, acellular-pertussis ("DTaP") vaccine, administered on September 1, 2017. Pet. at 7.

After a preliminary review of the Petition and the filed records, questions were raised as to whether the claim was time-barred under the Program's three-year limitations period for bringing claims. Section 16(a)(2). The parties thereafter spent time addressing the procedural issues involved in that question; after reviewing their arguments, I noted during a status conference that Petitioner had set forth a potentially-meritorious argument for why his case should not be dismissed despite its somewhat untimely filing date. *Order*, January 6, 2022 (ECF No. 36) ("Order to Show Cause") at 1.

I deferred ruling on the statute of limitations issue, however, because of fundamental substantive concerns regarding the claim's merits. The Petition appeared to allege a kind of claim that has only rarely resulted in a favorable entitlement decision in prior cases, and my preliminary review of the record did not suggest this was one of those rare cases. I therefore ordered Petitioner to Show Cause why the case should not be dismissed. Order to Show Cause at 3. Both parties have now filed briefs in reaction. Petitioner's Brief in Support of Claim, dated April 12, 2022 (ECF No. 39) ("Br."); Respondent's Brief, dated June 28, 2022 (ECF No. 50) ("Opp."); Petitioner's Reply, dated August 8, 2022 (ECF No. 53) ("Reply").

For the reasons set forth below, I hereby dismiss this case. Petitioner cannot demonstrate based on the medical record that R.S. experienced the kind of "encephalopathy" required in Program Table and non-Table cases to deem subsequent developmental regression associated with it, and therefore has not established a compensable injury. Accordingly, permitting equitable tolling of the limitations period to save the claim from its untimely filing would nevertheless be futile.

I. Medical History[3]

R.S. was born two-months prematurely (at thirty-two weeks and two days gestational age) on May 21, 2016. Ex. 1 at 2. Post-delivery, he was immediately transferred to the neonatal intensive care unit ("NICU") due to prematurity with respiratory distress and possible sepsis. *Id.* R.S. was in the NICU for twenty-eight days where he underwent two days of continuous positive airway pressure ("CPAP") due to initial respiratory distress, and four days of phototherapy due to spontaneous apnea and neonatal jaundice. *Id.* at 3, 7–8, 11–13, 23. In infancy, R.S. had repeated upper respiratory tract infections ("URI") and was diagnosed with gross motor development delay and esotropia. Ex. 2 at 7; Ex. 5 at 2. Petitioner noted that during his infancy, "R.S. was often sick." Pet. at 13.

[3] The medical records are summarily addressed to focus on those most relevant to my Order to Show Cause.

On September 1, 2017, at fifteen-months old, R.S. had an appointment with a new primary care physician, David Moberly, M.D., and was given the subject DTaP vaccine, as well as the haemophilus influenzae type B ("HiB") and Hepatitis A ("Hep A") vaccines. Ex. 3 at 1; Ex. 8 at 4–5. Petitioner recalls that R.S. was also sick when receiving these vaccines ("R.S. was battling bilateral otitis media, requiring antibiotics, a viral syndrome with a cough, requiring albuterol and budesonide…"). Pet. at 28.

According to the Petition, R.S. allegedly developed a fever within a few hours of vaccination. Pet. at 13. R.S. "did not take all of his bottles as he typically did, was overly fussy, [and] cried and whined excessively." *Id.* R.S.'s parents did not seek immediate medical attention, however, because it was not overly surprising or alarming that R.S. was exhibiting sickly or ill behaviors and symptoms. *Id.* at 14. But thereafter, the Petition contends, "[o]ver the next 3 days, R.S. experienced an acute encephalopathy, later resulting in chronic, autoimmune encephalitis and regressive encephalopathy which still persists to this day." *Id.* at 12. No filed medical records from this timeframe corroborate these allegations.[4]

Eighteen months-post vaccination (when R.S. was thirty-three months old), on February 22, 2019, R.S. was brought to developmental-behavioral pediatrician Fadiyla Dopwell, M.D. Ex. 15 at 1. He was evaluated for developmental needs associated with preterm birth, developmental delay, and issues with his social communication skills. *Id.* R.S.'s parents were referred to websites for further information about autism spectrum disorder. *Id.* at 5. R.S. saw Dr. Dopwell again on May 10, 2019, where she made similar observations. Ex. 16 at 1–5.

On September 30, 2019, R.S.'s parents sought a genetics consultation, and the family presented to Rachel Lombardo, M.D., at the Children's Dallas Genetics/Metabolic/Down Syndrome Clinic. Ex. 55 at 3–5, 11. The history of present illness allegedly noted that Petitioner was referred because of R.S.'s global delays and concern for possible autism spectrum disorder. *Id.* According to Respondent, Dr. Lombardo did not identify any obvious genetic syndrome, but R.S.'s parents expressed interest in methylenetetrahydrofolate reductase ("MTHFR") testing and stated that "obtain[ing] MTHFR testing" was their "main goal." *Id.* at 3, 11. Dr. Lombardo apparently advised against it, explaining the lack of clinical utility or "evidence that homozygosity for known polymorphisms increase(s) the risk for stroke, myocardial infarct, or thrombus formation in childhood, adolescence, or adulthood, nor does it convey risk for autism spectrum disorder." *Id.* at 11. Despite Dr. Lombardo's advice, the family stated that they would pursue MTHFR testing independently. *Id.* at 6

[4] Respondent also maintains that none of R.S.'s treating physicians indicated that R.S.'s health problems were associated with the September 1, 2017 DTaP vaccination. ECF No. 29 n.2.

On January 27, 2020, R.S.'s parents sought assistance from an "integrative medicine" family practitioner, Kenneth Bock, M.D. Ex. 29 at 5–6. Dr. Bock performed a minimal neurologic evaluation and diagnosed R.S. with suspected neuroimmune disorder and regressive encephalopathy. *Id.* at 7. The family returned to Dr. Bock in May 2020 for a range of treatments including IVIG.[5] Pet. at 27; Ex. 29 at 15, 20, 26–28. Since filing the petition, R.S.'s symptoms remain largely unchanged. Pet. at 17.

II. Procedural History

As noted above, the case was initiated in October 2020. After Petitioner filed the requisite medical records, I held a status conference to discuss the claim's timeliness, setting forth a briefing schedule on the issue. *See* Order, dated June 22, 2021 (ECF No. 23). Because the vaccination at issue was received on September 1, 2017, and was alleged to have caused symptoms that manifested hours to a few days post-vaccination, but the matter was not filed before October 13, 2020, the claim had been filed outside of the Vaccine Act's three-year limitations period. Section 16(a)(2). The parties thereafter briefed the matter.[6]

After reviewing the briefing, I deferred ruling on the issue, because of my additional substantive concerns regarding the claim's ultimate merits. I held a status conference in January 2022 at which time I expressed my concerns about the claim's viability and asked Petitioner to file a brief showing cause why the claim should not be dismissed and set forth a briefing schedule. ECF No. 36 at 2–3. The parties have now filed their briefs, and the matter is ripe for resolution.

III. Parties' Arguments

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[5] Other treatments included IV chelation (a process of removing metals from the blood), oral chelation, IV vitamin C, IV glutathione, IV magnesium, and IV phosphatidylcholine. Pet. at 17.

[6] The initially-filed version of the Petition in this case (as well as the parties' briefs in response to my Order to Show Cause) sets forth some of the allegations relevant to its filing. *See generally* ECF No. 1. In summary, Mr. Simeone *mailed* his petition to the U.S. Department of Health and Human Services ("HHS")—the literal "respondent" in all Vaccine Act cases—on August 28, 2020, via overnight mail. *Id.* at 19. Had the claim been filed on that date, it would have been timely (since R.S.'s symptoms were not alleged to have manifested until hours after his September 1, 2017 vaccination).

However, vagaries of the express mail system, along with the fact that the mailing occurred on a weekend, resulted in the Petition not being received by HHS until September 2, 2020 (even though it had been scheduled for an August 31st delivery). Ex. 61 at 1; Opp. at 2. Thus, HHS did not even receive the Petition within the three-year limitations period. Then, on September 24, 2020, HHS mailed Petitioner a letter informing him that the petition and documents needed to be filed with the United States Court of Federal Claims. *Id.* at 23. Petitioner wrote a letter, dated October 3, 2020, to the Court stating that he had originally mailed the petition to HHS, and enclosed a petition with documents for filing. *Id.* at 22. It appears that the package was mailed via FedEx on October 10, 2020. *Id.* at 24. The instant petition was ultimately received by the Court and marked as filed by the clerk on October 13, 2020—almost six weeks after the limitations cut-off date. *Id.*

Petitioner's response to my Order to Show Cause focuses on the Table Claim requirements for an encephalopathy, with a brief discussion of Off-Table elements. For his Table Claim, he highlights affidavits filed by R.S.'s parents expressing their belief that R.S. experienced an acute encephalopathy within 72 hours of vaccination. Br. at 3–10. Petitioner, however, acknowledges that he can point to no medical records establishing an acute encephalopathy occurred in that timeframe. *Id.* at 2. And although Petitioner attempts to cite favorable Program decisions, he mostly points to a Circuit case involving attorney's fees, to support his contention that parent affidavits can provide objective proof of medical history or issues. Br. at 3–5; *James-Cornelius on Behalf of E. J. v. Sec'y of Health & Hum. Servs.*, 984 F.3d 1374, 1379 (Fed. Cir. 2021). But I note that the standards used to determine if a claim possesses sufficient objective support to support a fees award, based on the "reasonable basis" standard applied to unsuccessful cases, is not equivalent to the preponderant standard that claimants must meet to obtain entitlement. *See Sterling v. Sec'y of Health & Hum. Servs.*, No. 16-551V, 2020 WL 549443, at *4 (Fed. Cl. Spec. Mstr. Jan. 3, 2020) ("[t]he standard for reasonable basis is lesser (and inherently easier to satisfy) than the preponderant standard applied when assessing entitlement, as cases with reasonable basis (because they have objective proof supporting the claim) can nevertheless still fail to establish causation-in-fact.").

Respondent asks for dismissal of the claim, arguing that even Petitioner has conceded that there is a lack of record evidence establishing that R.S. reacted to the DTaP vaccine close-in-time to vaccination, let alone months later. Opp. at 2. And Petitioner's newly-filed exhibits do not rectify this evidentiary omission. *Id.* at 2–3. Respondent also denies that *James-Cornelius* is on point or otherwise supportive of the continued maintenance of this claim, as it involves the weight to be given evidence offered to support an attorney's fees award only. Opp. at 2. Respondent otherwise observes that the cases I referenced in my Order to Show Cause (which are discussed again below) provide more useful guidance, and they support the dismissal of this matter. Opp. at 3–4.

Petitioner filed a brief reply, reiterating his contention that *James-Cornelius* establishes that his testimonial evidence (including parent affidavits, along with text messages and videos) warrants weight. Reply at 1–5. Petitioner differentiates his case from those cited in my Order to Show Cause because even though a lack of medical record corroboration of encephalopathy was deemed grounds for dismissal of such claims, *in this case* he can reference contemporaneous text messages and videos of R.S. with insomnia, among other symptoms. *Id.* at 6–8 (discussing *Bello v. Sec'y of Health & Hum. Servs.,* No. 20-739V, 2021 WL 5070179 (Fed. Cl. Spec. Mstr. Sept. 10, 2021), *mot. for review den'd*, 158 Fed. Cl. 734 (2022)). Petitioner also clarifies that he is alleging not only a Table encephalopathy but an Off-Table autoimmune encephalitis (in which case the rigid Table standards are less relevant). Reply at 8.

IV. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a "Table Injury"); or (2) they suffered an injury actually caused by a vaccine (i.e., 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 & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano*, 440 F.3d at 1320. In this case, Petitioner does assert a Table claim.

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., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, 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 & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. 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, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(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 proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

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, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. 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.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. 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." *Andreu,* 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon,* 941 F.3d at 1359-60.

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 v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). 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 & Hum. 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 & Hum. 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 & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (stating it is 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); *Veryzer v. Sec'y of Health & Hum. 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, 356–57 (2011), *aff'd without opinion*, 475 F. 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." *de Bazan v. Sec'y of Health & Hum. 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 & Hum. 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 & Hum. 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. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony

surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people are likely to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are automatically deemed accurate, or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should

be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Disposition of Case Without Hearing*

I am resolving this claim on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage 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. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. 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 case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Encephalopathy, Regression, and Prior Relevant Decisions[7]

Petitioner alleges both a non-Table and Table claim, so I shall discuss the two versions of such a claim in some detail. The Table definition of "encephalopathy" provides some insights into the factors deemed sufficient by Respondent to establish a claim in which causation is presumed—and thus what would be particularly strong evidence of a vaccine injury even for a non-Table, causation-in-fact claim. *See* 42 C.F.R. § 100.3(a)(II)(B) (2018).

Table claimants seeking to prove a vaccine-caused encephalopathy must establish *both* that the injured party experienced an "acute" encephalopathy—typically evidenced by a decreased change in consciousness (as that term is defined in the Qualifications and Aids to Interpretation, 42 C.F.R. § 100.3(c)(2) (2018)) of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became "chronic" (that is, it lasted for at least six months). *Thompson v. Sec'y of Health & Hum. Servs.*, No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017). The acute encephalopathy must manifest within three days/seventy-two hours, and if alleged to have been experienced by a child less than eighteen months old, must be "indicated by a significantly decreased level of consciousness that lasts at least 24 hours." 42 C.F.R. §100.3 (2017). In my Order to Show cause, I cited one case as an example of the rare circumstances in which such elements have been met. *Wright v. Sec'y of Health & Hum. Servs.*, No. 12-423V, 2015 WL 6665600, at *30–31 (Fed. Cl. Spec. Mstr. Sept. 21, 2015).

A causation-in-fact claim alleging encephalopathy, by contrast, is not subject to the Table's stringent defined requirements. But where encephalopathy as the injury is alleged, it must be supported by preponderant proof, and that evidence must establish *more* than simply a subsequent neurologically-derived symptom (since virtually any injury impacting the brain could credibly be deemed *some* form of encephalopathy). Specific evidence that would suggest an individual had experienced an encephalopathy sufficient to meet the preponderant test in a non-Table context includes proof of crying, insomnia, fever, moodiness, and irritability. *Noel v. Sec'y of Health & Hum. Servs.*, No. 99-538V, 2004 WL 3049764, at *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004).

I have decided many Table and non-Table cases in which a claimant alleged a child

[7] Decisions from different cases do not *control* the outcome herein, with only Federal Circuit decisions setting legal standards to which new claims must adhere. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1358-59 (Fed. Cir. 2019); *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). Nevertheless, special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.*, 76 Fed. Cl. 328, 338-39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

experienced developmental regression following vaccination, in the absence of evidence of a seizure disorder—and in all such matters have denied entitlement. *See, e.g.*, *Bello*, 2021 WL 5070179; *A.S. v. Sec'y of Health & Hum. Servs.*, No. 16-551V, 2019 WL 5098964 (Fed. Cl. Spec. Mstr. Aug. 27, 2019) (no evidence of post-vaccination encephalopathic reaction to vaccine that could later have produced expressive language disorder or autism); *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, No. 08-209V, 2018 WL 3679843 (Fed. Cl. Spec. Mstr. June 22, 2018), *mot. for review den'd*, 141 Fed. Cl. 138 (2018), *aff'd*, 945 F.3d 1362 (Fed. Cir. 2020) (affirming dismissal where petitioners could not demonstrate vaccine-caused mitochondrial disorder resulting in developmental harm); *Austin v. Sec'y of Health & Hum. Servs.*, No. 05-579V, 2018 WL 3238608 (Fed. Cl. Spec. Mstr. May 15, 2018), *mot. for review den'd,* 141 Fed. Cl. 268 (2018), *aff'd,* 818 F. App'x 1005 (Fed. Cir. 2020) (affirming denial of entitlement for a claim in which the medical record did not support the alleged injury of encephalopathy, vaccine induced or otherwise, resulting in developmental regression).

Such petitioners have frequently pointed to the temporal relationship between evidence of developmental decline and vaccination, and often placed considerable emphasis on witness testimony that a child experienced a concerning reaction right before showing signs of regression, but without being able to corroborate their contentions through reference to any medical records. Indeed, in such cases petitioners often could point to *no* contemporaneous medical evidence (meaning close in time to vaccination—since an encephalopathy should manifest right away after being triggered) that the child had ever been suspected by medical treaters of suffering any kind of neurologic brain injury. *See Austin*, 2018 WL 3238608, at *27. The claimants simply maintained that the evidence of post-vaccination developmental regression *meant* the child had likely experienced a vaccine-related injury—despite an absence of evidence establishing that injury.

II. Petitioner Cannot Show R.S. Experienced an Encephalopathy Due to Vaccination

In this case, Petitioner argues R.S. experienced a vaccine-induced encephalopathy that later caused his language regression. The vaccines R.S. received could only "cause" language loss if they first harmed the brain—so a finding of this having occurred is a prerequisite to a favorable entitlement finding.

However, it is very evident from *this* record as it stands (which Petitioner has had ample opportunity to supplement) that insufficient preponderant evidence exists that would support a determination that R.S. suffered an encephalopathy in any reasonable post-vaccination timeframe.[8]

[8] Because I am resolving the claim based on its merits, the procedural issue of the claim's timeliness need not be addressed. For what it is worth, however, I note that although the claim was literally untimely by nearly six weeks, the Petitioner's filing error (in which he erroneously mailed a copy to the proper defendant, but within the proper timeframe) could be excused, via the doctrine of equitable tolling, as a "defective pleading." *Askew v. Sec'y of Health & Hum. Servs.*, No. 10-767V, 2012 WL 2061804, at *4, 8 (Fed. Cl. Spec. Mstr. May 17, 2012) (noting that the pro se petitioner timely served a petition to Health and Human Services but did not file in the Court of Federal Claims, but

The parties agree that *no* medical records exist for the period near-in-time to vaccination. Br. at 2; Opp. at 4. There is thus no medical evidence that would establish *either* the rigid requirements of a Table encephalopathy, or even a non-Table one. An encephalopathy is a particularly acute injury, and it must have some record substantiation—meaning *medical* evidence that the allegedly-harmed child was so severely ill that medical treatment was sought. Otherwise, it is beyond speculative to assume that regression or other post-vaccination developmental issues are due to the vaccine, and to rely on evidence solely provided by the parties to a claim or other witnesses. *See, e.g.*, *Bello*, 2021 WL 5070179, at *12 n.7 (finding that petitioners could not show that their child actually experienced the kind of encephalopathy that might arguably lead to developmental harm, so the vaccines he received could not be found causal); *Galindo v. HHS*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed Cir. 1996) ("[b]ut to claim that the temporal link between these events proves that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*").

In rare circumstances, claimants have successfully demonstrated that a vaccine could precipitate an encephalopathy in an infant, leading to similar kinds of injuries as alleged herein. But the facts in such cases underscore the importance of evidence of *immediate* and acute encephalopathy precipitated by a close-in-time vaccination. *See, e.g.*, *Wright*, 2015 WL 6665600, at *10 (finding record evidence established that child had convulsed and vomited during car ride home after receiving vaccinations (possibly evincing a brief seizure), then became listless, unresponsive, and "basically catatonic" by the following day); *Bast v. Sec'y of Health & Hum. Servs.*, No. 01-565V, 2012 WL 6858040, at *35–36 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (discussing case report about a claimant who alleged a Table encephalopathy claim for her minor daughter for her autism-type symptoms; noting that she developed a high fever, inconsolable crying, irritability, and lethargy, and refusal to walk within forty-eight hours after vaccination), *mot. for review den'd*, 117 Fed. Cl. 104, 107, *aff'd*, 579 F. App'x 1001 (Fed. Cir. 2014). That kind of evidence is lacking here.

Petitioner simply cannot overcome such an absence of trustworthy and corroborative evidence with the different items of personally-generated evidence he offers—especially not given the nature of allegations in this case. Certainly, this record establishes that Petitioner and R.S.'s mother regularly demonstrated their concern for R.S.'s health, both before and after the vaccination, as evidenced by their affidavits, text messages, and videos submitted. However, claimants cannot prevail *solely* on the basis of their own claims. Section 13(a)(1). And such other

the special master decided to toll the period based on applicable equitable guidelines). The Petitioner's *pro se* status especially supports tolling the filing period. And I have recently ruled that a *pro se* litigant who showed comparable diligence should be permitted to have the filing period tolled as well. *See Martin v. Sec'y of Health & Hum. Servs.*, No. 22-384V, slip op. (Fed. Cl. Spec. Mstr. Jan. 26, 2023) (granting application of equitable tolling for a *pro se* litigant who filed his petition in a federal district court in a timely manner but did not file his petition in the Court of Federal Claims until *after* the statute of limitations).

items of proof, while somewhat corroborative of Petitioner's contentions, would not be enough to *preponderate* in favor of a finding that R.S. experienced a post-vaccination encephalopathy without direct medical record evidence of *treatment* for the condition. I reiterate the fact (as explained in my original Order to Show Cause) that *many* times in the past, Program petitioners have similarly sought to prove that some kind of post-vaccination developmental change was observed in a child—but without medical record corroboration of it, such claims are highly likely to fail.[9]

III. This Case Was Reasonably Resolved Without a Hearing

I am opting to dismiss this case on the existing record, and without holding a hearing, early on in its "life." Determining how best to resolve a case is a matter that lies generally within my discretion, but I shall explain my reasoning.

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 of creation of 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). Special masters are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

My review of the record plus Petitioner's arguments have convinced me that they cannot preponderantly establish that R.S. suffered a vaccine-induced encephalopathy responsible for his developmental problems. And the case Petitioner cites in response to this Order to Show Cause does not address whether this claim should be dismissed. It is simply a fact that this kind of case is far more often than not *unsuccessful*—because claimants usually cannot establish that the infant or child vaccinee experienced any *acute* injury in the immediate days after vaccination, and instead rely mainly on parent recollection of post-vaccination behavioral changes that are uncorroborated by contemporaneous medical records. *Bello*, 2021 WL 5070179 at *13; *A.S.*, 2019 WL 5098964 at *3–4; *Austin*, 2018 WL 3238608 at *4–6. The relevant records filed in this case do not support

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[9] This is especially so when, as here, it appears treaters have directly diagnosed, or at least considered, an autism spectrum disorder as explanatory. Ex. 15 at 1, 5; Ex. 16 at 1–5; Ex. 55 at 3–5, 11. The Program has fully evaluated the case for vaccines causing autism but rejected the conclusion. *Murphy v. Sec'y of Health & Hum. Servs.*, No. 05-1063V, 2016 WL 3034047, at *25 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) (noting that to date *every* post-Omnibus Autism Proceeding Non–Table claim seeking compensation for autism injuries purportedly related to a vaccine that has been tried has failed (citing *Hardy v. Sec'y of Health & Human Servs.*, No. 08–108V, 2015 WL 7732603, at *4–5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015))).

the conclusion that the onset of R.S.'s condition occurred within a reasonable timeframe following receipt of the September 1, 2017 vaccine.

Because of the foregoing, it would be an unnecessary expenditure of judicial resources to continue the case (no matter how heartfelt Petitioner's good-faith desire to maintain the case might be). It is for this reason that I issued a show-cause order so early in the case's life. The inquisitorial function of special masters in the Vaccine Program means that they must steer cases in the most sensible direction, based on the facts presented as well as the special master's experience with comparable claims. Cases that look favorable are often pushed toward settlement—but cases that plainly are lacking in evidentiary basis should be terminated promptly. Because my preliminary review of the filings did not suggest (based on my experience with comparable cases) that this matter was likely to succeed, I asked Petitioner to establish whether, and how, I might be wrong. Despite due opportunity, Petitioner has not succeeded in doing so.

CONCLUSION

Mr. Simeone has acted diligently and ably in the pursuit of this claim, and I am personally disappointed to have to dismiss it, regardless of my reasoned interpretation of the claim's weaknesses. Petitioner's tolling arguments had merit, and his skill in advancing them reflected his ardor in seeking to address R.S.'s condition. Nevertheless, my experience in the Vaccine Program tells me that the record of this case is not supportive of the asserted claim, and therefore permitting the case to proceed would prove to be a futile act.

Accordingly, for the aforementioned reasons, this claim is dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this Decision.[10]

IT IS SO ORDERED.

Brian H. Corcoran
Chief Special Master

[10] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.