CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-739V
(to be published)

* *	Chief Special Master Corcoran
JEFFREY BELLO *and* OKSANA Y. OGANESOV, *parents of C.J.B., a minor,* *	
*	Filed: September 10, 2021
Petitioners, *	
v. *	
*	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
*	
Respondent. *	
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* *	

Phyllis Widman, Widman Law Firm LLC, Northfield, NJ, for Petitioners.

Benjamin Warder, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On June 22, 2020, Jeffrey Bello and Oksana Y. Oganesov filed a petition for compensation under the National Vaccine and Injury Compensation Program (the "Vaccine Program").[2] (ECF No. 1) ("Petition"). Petitioners allege that their child, C.J.B., developed encephalopathy, speech abnormality, language regression, and/or significant aggravation of an underlying condition, including but not limited to a genetic mutation, as a result of a series of vaccinations he received on June 23, 2017, when he was approximately 15 months old. Pet. at 1.

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[1] This Decision shall be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that 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 Decision'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 Decision 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 at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to Section 300aa of the Act (but will omit the statutory prefix).

After a preliminary review of the Petition and the filed records, I ordered the Petitioners to Show Cause why the case should not be dismissed. Order, dated February 25, 2021 (ECF No. 29) ("Order"). The Petition appeared to allege a kind of claim that had 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. Both parties have filed briefs in reaction. Petitioner's Brief in Support of Claim, dated April 30, 2021 (ECF No. 33) ("Br."); Respondent's Brief, dated June 28, 2021 (ECF No. 39) ("Opp."); Petitioner's Reply, dated August 12, 2021 (ECF No. 42) ("Reply").

Now, for the reasons set forth below, I hereby dismiss this case. Petitioners cannot demonstrate based on the medical record that C.J.B. experienced the kind of true "encephalopathy" required in Program non-Table cases to find subsequent developmental regression associated with it, and therefore have not established a compensable injury.

I. Medical History

Birth and Early History

C.J.B. was born on March 21, 2016, weighing seven pounds, twelve ounces, and having APGAR scores of nine at one minute and at five minutes. Ex. 3 at 1, 11-12. He received his pediatric care from Dr. Edward Rosof at Advocare Marlton Pediatrics ("Advocare"). *See generally* Ex. 3. His first well-child visit was unremarkable, and he returned to Advocare on April 1, 2016, for a weight check and for his first Hepatitis B vaccine dose. *Id.* at 14-16.

In his first 15 months of life, C.J.B. had regular visits to Dr. Rosof at Advocare – both for wellness and sick child treatment. *See generally* Opp. at 4-5 (chart summarizing 21 pediatric visits or telephone call encounters). During this time, he received a number of vaccines without incident, and otherwise displayed no significant health problems (beyond occasional instances of fever or the kind of upper respiratory infections common to infants). C.J.B. otherwise was healthy and displayed no developmental problems in this time period. *See generally* Ex. 2 (Petitioners' joint affidavit).

Vaccinations and Manifestations of Speech Regression

On June 23, 2017, C.J.B. received the Pentacel vaccine (which includes the diphtheria-tetanus toxoid-acellular pertussis, poliovirus, and haemophilus B conjugate vaccine), along with the pneumococcal conjugate vaccines, as part of a 15-month well-child checkup at Advocare. Ex. 1; Ex. 3 at 81-86. He was not taking any medication at this time, and other than a recent ear infection no health problems or concerns were reported. Ex. 3 at 83-84. C.J.B.'s gross and fine

motor assessment noted that he could throw a ball, crawl up stairs, walk well, and feed himself using his fingers. *Id.* And his communication skills were also deemed developmentally correct, with it noted that he then had "3-6 words and follow[ed] simple commands." *Id.*

There is no medical record of any reaction to these vaccinations. However, Petitioners have alleged that C.J.B. began to lose speech within hours of them, with his vocabulary decreasing in the days after. Ex. 2 at 1. The Petitioners also allege that they called their pediatrician for help, but were informed that C.J.B.'s development would be rechecked at his 18-month checkup. Pet. at 1. However, the next chronological medical record (from a June 28, 2017 call to Advocare) contains no reference to dramatic loss of vocabulary or other developmental issues, and only notes that Ms. Oganesov was inquiring about the appropriateness of continuing to breastfeed C.J.B., given that she was now pregnant. Ex. 3 at 88.

The next medical record bearing on this claim is from August 2, 2017 – 40 days post-vaccination – when Ms. Oganesov called Advocare seeking advice about C.J.B.'s sleep issues. Ex. 3 at 89. She informed treaters that for a few weeks (since the time she had weaned him from breastfeeding), C.J.B. had been waking at night screaming, and when she tried to console him, he kicked and bit her, after which he would go back to sleep. *Id.* Sleep training and sleep hygiene were reviewed, but this record does not mention any developmental issues. *Id.* Two weeks later, on August 16, 2017, Ms. Oganesov called Advocare again after C.J.B. fell down and hurt himself. Ex. 3 at 89-91. He cried for a short period of time, but was easily consoled, and otherwise seemed normal after the accident. *Id.* at 89. Ms. Oganesov was advised to monitor C.J.B., and to call if there were any changes in his condition. *Id.* at 90.

The first reference to developmental concerns is found in an August 28, 2017 record of another call Ms. Oganesov placed to Advocare. Ex. 3 at 90. She now reported that C.J.B. had "less words than 1 month ago. All other skills [were] unchanged." *Id.* If onset were as reported in this record, C.J.B. would have first experienced loss of vocabulary in late July, or about one month after the vaccinations at issue (and thus later than what Petitioners have alleged). Ms. Oganesov was advised that all of C.J.B.'s skills would be rechecked at his 18-month check-up. *Id*. Both Petitioners separately called Advocare a second time in early September 2017 about these same kinds of developmental concerns. *Id.* at 90-91. Mr. Bello in particular noted that C.J.B. had received certain vaccines at 15 months, and that he questioned "aluminum toxicity from the vaccines" based on the assertion that onset of speech regression has occurred after vaccination (although the record does not specify a precise date). *Id.* at 91.

Initial Treatment of Alleged Vaccine Reaction

On September 2, 2017, Petitioners opted to bring C.J.B. to the emergency room at Virtua Health Memorial Hospital in Mount Holly, New Jersey. Ex. 4 at 25. They informed emergency

treaters that they had concerns C.J.B. had experienced "possible heavy metal poisoning" due to the June 2017 vaccinations, repeating their prior assertions about his language regression. *Id.* Mr. Bello now, however, reported that onset of regression had been about three weeks before, or right before mid-August rather than in July. *Id.* Petitioners asked that C.J.B.'s blood be tested for the suspected metal poisoning. *Id.* at 27.

Dr. Chung Chiang was the attending physician that afternoon in the emergency department, and she noted that C.J.B. appeared happy and playful with his parents but did not speak, except to say "bye bye" to the nursing staff. Ex. 4 at 27. She contacted a toxicologist at the Children's Hospital of Philadelphia's ("CHOP") department of toxicology, who (after speaking with Dr. Rosof) told her about C.J.B.'s prior vaccinations – including the fact that the vaccines he had received on June 23, 2017, contained no metals other than tiny amounts of aluminum. *Id.* Dr. Chiang sent two vials of blood and a urine sample to the Mayo Clinic for testing, and the results (obtained within a few days) were inconclusive. *Id.* at 40.

A little over two weeks later, Petitioners brought C.J.B. to the CHOP emergency room on September 19, 2017,[3] for "parental concern about aluminum toxicity causing encephalopathy." Ex. 8 at 4. The medical records from this treater visit identify onset of speech regression as "[a]round Labor Day," and also included reports of C.J.B. biting his mother and throwing toys, plus anger and temper tantrums. *Id.*at 3. The treating physician, Dr. Sage Myers, noted that C.J.B. seemed well on exam, "with "[n]o signs of encephalitis or encephalopathy." *Id.* at 6. She opined that C.J.B.'s "[s]peech regression [was] more likely due to [a] genetic or developmental disorder. Aluminum toxicity in otherwise normal child extremely unlikely." *Id.* Dr. Myers also observed in this record that in her understanding, the amounts of aluminum in vaccines were far smaller than what a child was environmentally exposed to otherwise, and that it was unlikely that a child experiencing an encephalopathy would have a fully normal neurological exam like C.J.B. *Id.* at 6.

On October 5, 2017, C.J.B. was taken to see Dr. Mark Magnusson in the Diagnostic and Complex Care Center at CHOP for evaluation of developmental regression. Ex. 10 at 3. Consistent with prior histories provided other treaters, Petitioners informed Dr. Magnusson that C.J.B. had "significant developmental regression with loss of language and [loss] of behavioral control" after the June vaccinations, as well as their ongoing concern that he had experienced some kind of toxic reaction to the aluminum in the vaccines. *Id.* Dr. Magnusson confirmed the existence of some developmental concerns, and proposed some blood work and other testing. *Id.* at 6. Dr. Magnusson nevertheless defined C.J.B. as developmentally normal otherwise, and proposed the Petitioners take C.J.B. to a developmental pediatrician for further evaluation. *Id.* at 9, 35. Petitioners' Advocare pediatrician made the same kind of

[3] Petitioner's Order to Show Cause response erroneously states that this ER visit occurred on July 19, 2017 – *prior* to the August 2017 phone calls to Advocare. Br. at 2.

recommendation later that month, noting that toxicology testing was not confirming any of Petitioners' concerns. Ex. 3 at 108-11.

Petitioners obtained the services of a new pediatrician, Dr. David Bruner, in November 2017, and reported to him their experience of observing C.J.B. lose language in the period after his 15-month-old vaccinations. Ex. 11 at 9. C.J.B. had not yet, however, undergone a neurological or speech evaluation. *Id.* On exam, C.J.B. had a normal gait, "observationally" normal neurological exam, and good eye contact, and also displayed no behavior outbursts. *Id.* at 10-11. Dr. Bruner assessed C.J.B. with "developmental regression in child," and he noted differential diagnoses of autism spectrum disorder, genetic disorder, toxic exposure, and neurological disorder. *Id.*

Treatment in 2018-2020

Over the next several years, Petitioners continued to seek treatment for C.J.B., along with an explanation for his speech regression. In February 2018, for example, C.J.B. was taken to geneticist Dr. Jaya Ganesh to address their concerns that MTHFR gene polymorphisms might explain C.J.B.'s regressive symptoms. Ex. 7 at 4-13. Dr. Ganesh's exam revealed that while "expressive language is definitely behind for age, [C.J.B.] demonstrates age appropriate to advanced gross and fine motor skills and interactive play." *Id.* at 8. MRI and electroencephalogram testing did not reveal anything concerning, and other testing produced largely normal results. *Id.* at 5, 6, 14-17. Dr. Ganesh concluded that "a genetic etiology is not readily apparent." *Id.* at 8. The MRI impressions from the medical record also state that "terminal zones of myelination at the posterior aspect of the lateral ventricles, [are] within normal for age," with no evidence of "acute intracranial abnormality." *Id.* at 5.

Petitioners began obtaining glutathione treatment for C.J.B. and reported improvement, but pediatric treaters like Dr. Bruner identified no abnormal findings otherwise on exam. Ex. 11 at 30-32 (records from May 24, 2018 visit). C.J.B. continued in 2018 to receive speech therapy, and additional MRIs were performed, but no records have been filed to date relating to these medical encounters.

By the spring of 2019 (when C.J.B. was three), Petitioners continued to pursue treatments aimed at addressing their concerns of metal toxicity associated with vaccination, and their concerns about his speech loss continued (although it appears from the record that they resisted obtaining evaluation from schools relating to the extent of the problem). Ex. 11 at 57-59 (records from April 29, 2019 visit with Dr. Bruner). They also disputed prior MRIs that did not confirm the presence of encephalopathy. *Id.* at 5. C.J.B. thereafter began at times when he was tired to experience "motor tics like head shake," accompanied by pain. *Id.* at 80.

In December 2019, Petitioners brought C.J.B. to Nemours Children's Health System, where he was seen by Dr. Stephen Falchek, the Chief of Pediatric Neurology, for concerns about seizures, speech delay, and headaches. Ex. 5 at 4-8. Petitioners now provided a history of pain and temper tantrums within 24 hours of C.J.B.'s 15-month vaccinations (even though the record as discussed above is not consistent with this), followed closely by the previously-reported loss of speech and other symptoms. *Id.* at 5. After completing a physical exam and reviewing available studies from CHOP, Dr. Falchek assessed C.J.B. with speech and language regression, and recommended an EEG and speech therapy consultation. *Id.* at 7.

Petitioners obtained the recommended speech therapy evaluation in February 2020, and it showed mild receptive and expressive language delay in combination with mild speech sound delay, but little evidence of dyspraxia. Ex. 5 at 12-19. Dr. Falchek saw C.J.B. again in April 2020, for "follow-up of chronic encephalopathy." Ex. 5 at 9. He specifically noted that C.J.B. had a "rather complex and confusing medical history." *Id.* After review of a 2019 MRI performed on C.J.B.'s brain, Dr. Falchek deemed the results likely normal. *Id.* at 10. His impression, however, was "complex encephalopathy with history of developmental regression in the context of immunizations and febrile illness." *Id.* at 11. This record does not elaborate on the basis for this conclusion. Petitioners allege that by this time, and despite intense speech therapy, C.J.B.'s speech remains extremely slurred, making him difficult to understand, although he does manage to communicate partially.[4]

II. Procedural History

As noted above, the Petition was filed in the summer of 2020. The matter was released from "pre-assignment review" later that year, once it was determined that sufficient records existed to assess the claim in a general matter. ECF No. 20. After its assignment to my docket, I held the initial status conference in February 2021 referenced previously, at which time I expressed my concerns about the claim's viability and asked the parties to brief the issues identified. In particular, I instructed Petitioners to (a) identify what record evidence already filed supported their claim, and (b) what prior reasoned Program decisions with consistent facts resulted in entitlement determinations favorable to the relevant petitioner(s). Order at 2. They have now filed their briefs, and the matter is ripe for resolution.

[4] A few months ago, Petitioners filed more recent medical records. *See* May 3, 2021 filing (Ex. 12) and May 7, 2021 filing (Ex. 13). The first record is a March 2021 letter from Dr, Bruner stating that C.J.B. is exempt from further vaccination, and adding in conclusory fashion that C.J.B.'s developmental regression was "probably" due to his vaccinations. Ex. 12 at 1. The second set of records are treatment documents from Cooper University Hospital (from the fall of 2020 to the spring of 2021), and they reference C.J.B.'s continued problems, with speech and language, along with the allegation of a chronic encephalopathy beginning on October 6, 2020. Ex. 13 at 3. There is also a note that C.J.B.'s mother stated the speech therapy and occupational therapy are progressing. Ex. 13 at 6. I do not find that any of these more recently-filed records provide any basis for altering my conclusion herein.

III. Parties' Arguments

Petitioners' response to the Order to Show Cause begins with a recitation of the facts largely consistent with what is set forth above, highlighting in particular the difference between C.J.B.'s language and speech development pre- versus post-vaccination. Br. at 1-3. They also emphasize Dr. Falchek's embrace of encephalopathy "in the context of immunizations" as a diagnostic explanation for this developmental loss. *Id.* at 4; Ex. 5 at 9, 11.

To support the continuation of this claim, Petitioners cite two cases that they maintain underscore that C.J.B. likely experienced a vaccine-induced encephalopathy. Br. at 6; *Midland Trust Co. v. Sec'y of Health & Hum. Servs.,* No 14-1186V, 2020 WL 5887547 (Fed. Cl. Spec. Mstr. Sept. 15, 2020); *Cook v. Sec'y of Health & Hum. Servs.,* No. 99-538V, 2004 WL 3049764, at *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004). *Midland Trust*, the Petitioners argue, was a case where encephalopathy was deemed to explain developmental delay along with seizures, but they do not provide more than a sentence's description of the holding therein or why it establishes a basis for allowing this matter to go on. Br. at 6. *Cook*, they propose, reached a similar result in the context of a non-Table claim, finding that the injured child had experienced a chronic encephalopathy. *Id.* (This case was incorrectly cited, and is in fact captioned as *Noel v. Sec'y of Health & Hum. Servs.,* No. 99-538V, 2004 WL 3049764, at *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004)). Allowing Petitioners to obtain an expert, they argue, would permit them the opportunity of establishing how the records corroborate their favored conclusion herein.

Respondent asks for dismissal of the claim, arguing that the medical history evidence would not permit a reasonable conclusion, under the preponderance evidentiary test applicable to non-Table claims, that C.J.B. suffered a vaccine-caused encephalopathy. Opp. at 15. First, he observes that Petitioner has not made a demonstration consistent with my Order to Show Cause that the record supports their contentions. In particular, there is little to no contemporaneous evidence from around the time of the vaccinations to suggest C.J.B. experienced the immediate and direct symptoms reflecting an encephalopathy. *Id.* at 16. He highlights in particular the fact that Petitioners "had a pattern of seeking care and advice for a number of issues" before vaccination, thus allowing the inference they would also have done so after vaccination had C.J.B.'s condition truly appeared alarming or in need of medical evaluation. *Id.* at 16-17. Respondent also notes that Petitioners' onset reporting varied in the record – from late July to early September 2017. *Id.* at 18-19. And the only treater support for an encephalopathy diagnosis comes from 2019 or 2020 (largely Dr. Falchek's evaluation) – and the substantiation for that opinion is lacking in the record. *Id.* at 19.

Second, Respondent denies that either of the cases cited in Petitioners' brief are on point or otherwise supportive of the continued maintenance of this claim. Opp. at 22-24. *Midland Trust*, for example, (which was miscited) is a damages determination resulting from a prior ruling on

entitlement in a differently captioned case. *Id.* at 22-23; *Morales v. Sec'y of Health & Hum. Servs.,* No. 14-1186V, 2019 WL 4047627 (Fed. Cl. Spec. Mstr. July 30, 2019). But the injured child in that case developed a post-vaccination fever plus seizures within a day of vaccination, with more seizures thereafter and subsequent associated developmental delay. *Morales,* 2019 WL 4047627, at *1, 7. Thus, *Morales/Midland Trust* involved strong evidence of an acute reaction wholly absent from this case. *Cook*, Respondent argues, is similarly distinguishable, since it too involved proof of a post-vaccination fever resulting in a series of seizures and associated acute evidence directly establishing an encephalopathy. *Noel,* 2004 WL 3049764, at *17. Respondent otherwise observes that the cases I referenced in my Order to Show Cause (which are discussed again below) provide more useful guidance supporting the dismissal of this matter. Opp. at 21-22.

Petitioners filed a brief reply, reiterating points in the medical record (such as the treatment C.J.B. obtained at CHOP in October 2017) that they argued underscored the temporal association between vaccination and C.J.B.'s language loss. Reply at 1-2. They noted more recent medical records supporting the chronic encephalopathy diagnosis. *Id.* at 2. And they underscored that because they do not assert a Table claim, cases involving the standards relevant to such a claim, like *Wright v. Sec'y of Health & Hum. Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015) (petitioner met the requirements of an acute encephalopathy as set forth in the Vaccine Injury Table), are irrelevant. Otherwise, Petitioners maintained that Respondent could show no alternative cause for C.J.B.'s developmental losses. Reply at 2-3.

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, Petitioners do not 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[5]

Although this is a non-Table case, 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 in this context. *See* 42 C.F.R. § 100.3(a)(II)(B) (2018). Petitioners herein are not obligated to meet these requirements, but some brief review of them helps illuminate the kinds of symptoms that would be associated with an encephalopathy resulting in developmental deficits.

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.

[5] 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.

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). My Order to Show Cause cited the *Wright* case as an example of the rare circumstances in which such elements have been met (and even despite the fact that it involved a child diagnosed with autism – a kind of claim that has *never* succeeded in the Program). *Wright*, 2015 WL 6665600, at *30-31.

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. 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*, 2004 WL 3049764, at *17.

I have decided many non-Table cases in which a claimant alleged a child 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., *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).[6]

Such petitioners have frequently pointed to the temporal relationship between evidence of developmental decline and vaccination, and often over-relied on witness testimony a child experienced a concerning reaction right before showing regression, but without being able to corroborate their contentions in any medical records. In addition, and more importantly, in such cases petitioners could point to *no* medical evidence that the child had ever been suspected by medical treaters of suffering any kind of neurologic brain injury. *See, e.g.*, *Austin*, 2018 WL 3238608, at * 277. The claimants simply maintained that the evidence of post-vaccination

[6] Some of these cases also involved the direct allegation that a child's autism was vaccine-caused -- although, when confronted with the tenuous legal merit of such a claim, the relevant petitioners often have backed away from or renounced the allegation. *See,* e.g., *Kreizenbeck*, 2018 WL 3679843, at *26-27. Here, by contrast, the record does not establish that C.J.B. received that diagnosis, nor do the Petitioners so allege.

developmental regression *meant* the child had likely experienced a vaccine-related injury – despite an absence of evidence establishing that injury.

II. Petitioners Cannot Show C.J.B. Experienced an Encephalopathy

Identifying whether the alleged injury actually occurred is critical to this claim's resolution. *Broekelschen*, 618 F.3d at 1346. In this case, Petitioners argue C.J.B. experienced a vaccine-induced encephalopathy that later caused his language regression, plus a number of other follow-on symptoms (although the "through-line" symptom primarily at issue herein is speech loss). The vaccines C.J.B. 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.

But insufficient preponderant evidence exists in this case that would support a determination that C.J.B. suffered an encephalopathy in any reasonable post-vaccination timeframe. The medical records filed in this case do not establish anything close to suggesting a brain injury sufficient to lead to any form of developmental delay or regression, with no instances in which C.J.B. received emergency care from June to the fall of 2017 not prompted by Petitioners' personal concerns about vaccine metal toxicity or language loss. Certainly, this record establishes that Petitioners regularly demonstrated their concern for C.J.B.'s health by seeking out treatment for him, both before and after the vaccinations in question, so it is reasonable to conclude they might have done so had he displayed any concerning symptoms directly suggestive of a brain injury. Opp. at 4-5 (setting forth numerous instances in which Petitioners obtained treatment of C.J.B.). There is also no evidence he ever had any change in consciousness in this period that might have reflected the existence of an encephalopathic event, and no treaters who saw him in the six months after vaccination proposed otherwise. And unlike some of the cases Petitioners reference, such as *Morales* or *Noel*, there is no evidence herein at all that C.J.B. has ever had seizures or any kind of seizure disorder – and thus determinations that seizure activity harmed the brain sufficient to cause developmental regression or plateauing have no bearing at all on this case.

In addition, treater evidence supporting the claimed encephalopathy is fairly weak, and certainly not preponderant. The best Petitioners can offer is Dr. Falchek's diagnosis, but it was arrived at more than *two years* after vaccination, and seems also to rely on Petitioners' reported history rather than the record filed in this case, which are inconsistent with what he was told. Otherwise, as Respondent has noted, the substantiation for this diagnosis is weak. And the evidence filed in this case contemporaneous with vaccination would not corroborate an after-the-fact assertion by a treater that, despite the lack of contemporaneous evidence that the vaccines harmed C.J.B., the records were in error. Prior MRIs that might bulwark the encephalopathy contention were not consistent with that conclusion – Dr. Falchek even acknowledged "normal myelination patterns per reports." Ex. 5 at 10. At bottom, the critical timeframe for looking for evidence of encephalopathy in this case is within the first month of vaccination – and that record

does not preponderantly support the conclusion that an encephalopathy occurred.

Although it is not clear whether Petitioners ever obtained proper medical confirmation of their claim that C.J.B. began manifesting language loss in July or August 2017, their general claim of it having happened is not rebutted by the record. But this makes no difference for purposes of my determination, since these symptoms cannot persuasively be pointed to as proof of "encephalopathy"—they are at most *sequelae* of an alleged encephalopathy, and therefore it is circular reasoning to propose that they prove C.J.B. experienced an encephalopathy in the first place merely by pointing to the fact of language loss. *See R.V. v. Sec'y of Health & Hum. Servs.*, No. 08-504V, 2016 WL 3882519, at *34, n.80 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review denied*, 127 Fed. Cl. 136 (2016) (discussing the limited value of evidence of developmental loss in confirming or substantiating a mitochondrial disorder). The language loss cannot be attributed to vaccination without preponderant proof of a vaccine-caused brain injury.

My decision herein admittedly gives more weight to medical records - which show no immediate efforts from late June to even the fall of 2017 to treat C.J.B. for suspicious symptoms that would directly corroborate their allegations of a brain injury – than to Petitioners' witness statement claims that they observed C.J.B. act differently after vaccination in this timeframe (beyond the documented instances in which they reported language loss). I acknowledge that (as the Federal Circuit has recently stressed in *Kirby*) petitioners can "prove" a variety of fact matters pertaining to symptoms or onset even where records are silent on the contention at issue. Records do not automatically trump witness testimony.

Nevertheless, records still have evidentiary value, and must be weighed against witness statements. And it remains the case that claimants cannot prevail *solely* on the basis of their own claims. Section 13(a)(1). Rather (and especially when a record alone does not memorialize a contention) petitioners need to offer a mix of proof, and show how records corroborate witness statements and vice versa, based upon the totality of proof. Here, the records *do* corroborate Petitioners' claims that C.J.B. began to experience post-vaccination language regression – but they do *not* reflect or confirm the contention that this was due to encephalopathy. Since the regression is a symptom of a vaccine-induced brain injury, the inability to prove that injury is fatal to the claim.[7]

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[7] Because Petitioners cannot show that C.J.B. actually experienced the kind of encephalopathy that might arguably lead to developmental harm, the vaccines he received could not be found causal, and therefore there is no need to conduct a full *Althen* analysis. *Dillon v. Sec'y of Health & Hum. Servs.*, 114 Fed. Cl. 236, 244 (2014) (citing *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (2011)).

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 Petitioners' arguments have convinced me that they cannot preponderantly establish that C.J.B. suffered a vaccine-induced encephalopathy responsible for his developmental problems. It is admittedly the case that 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 (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 Hannah Poling, a successful Vaccine Program claimant who alleged a Table encephalopathy claim for her autism-type symptoms; noting that Hannah 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). And the cases Petitioners cite in response to this Order to Show Cause, like *Noel* or *Morales,* show mainly that injuries *well understood* to lead later to developmental issues, like seizure disorders (which do damage to the brain every time a seizure is experienced), have been proven to be vaccine-associated – but *no* such kind of seizure disorder occurred under the undisputed facts of this case.

Otherwise, 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.

Austin, 2018 WL 3238608 at *4-6; *A.S.*, 2019 WL 5098964 at *3-4. The relevant records filed in this case do not support the conclusion that the onset of C.J.B.'s condition occurred within a reasonable timeframe following receipt of the June 23, 2017 vaccines, and it does not appear that C.J.B. has ever received an encephalopathy diagnosis from a contemporaneous treater.

I also note that the record reveals some concern by Petitioners that metal toxicity, due to aluminum included as an adjuvant[8] in some of the vaccines C.J.B. received, could have prompted injury. But this kind of theory has also uniformly been rejected in the Program as an explanation for developmental issues due to a brain injury. *A.S.*, 2019 WL 5098964, at *8; *Morris v. Sec'y of Health & Hum. Servs.*¸No. 12-415V, 2016 WL 3022141, at *12 (Fed. Cl. Spec. Mstr. Apr. 1, 2016) (discussing lack of reliability of theory of autoimmune/inflammatory syndrome induced by adjuvants ("ASIA"), which involves purported propensity of aluminum adjuvant to cause autoimmune diseases).

Because of the foregoing, it would be an unnecessary expenditure of judicial resources to continue the case (no matter how admittedly heartfelt Petitioners' 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 obligates them to steer cases in the most sensible and legally-proper direction, based on the facts presented as well as the special master's experience with comparable claims. Just as cases that appear meritorious should be pushed in the direction of settlement or a swift resolution, so too should cases that plainly are lacking in evidentiary basis be pushed in the direction of termination. Because my preliminary review of the filings did not suggest to me this case should continue to exist, I asked Petitioner to establish whether, and how, I might be wrong. And despite due opportunity, Petitioner has not succeeded in doing so.

The fact that Petitioners have not yet offered an expert opinion does not alter my conclusions, or establish a reason for allowing the matter to persist. Petitioners could no doubt find an expert willing to advocate for them – but such efforts would run head-on into an absence of persuasive, contemporary medical support for the conclusion that C.J.B. likely experienced any kind of vaccine-induced injury sufficient to cause developmental problems. Thus, allowing that process to occur (which would also entail Respondent likely seeking to offer a rebuttal expert of

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[8] There are many cases that have tried to prove claims of toxicity from the aluminum included in vaccines, theorizing that it produces toxicity or harms due to ASIA. *See generally Rogero v. Sec'y of Health & Hum. Servs.*, No. 11-770V, 2017 WL 4277580 (Fed. Cl. Spec. Mstr. Sept. 1, 2017), *aff'd*, 748 F. App'x 996 (Fed. Cir. 2018); *Bushenell v. Sec'y of Health & Hum. Servs.*, No. 02-1648V, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. June 12, 2015). Specifically, in *Bushnell* the Special Master quoted the expert in the case stating, "[t]here are no cases published in the peer-reviewed medical literature that report aluminum toxicity, including neurotoxicity, due [to] the doses of aluminum found in vaccines." (Ex. G, p. 6.) 2015 WL 4099824, at *14.

his own) would waste time and Program resources.[9]

Finally, my determination does *not* turn on the supposition or suspicion that this case actually seeks to litigate the oft-rejected claim that C.J.B. experienced vaccine-caused autism. *Anderson v. Sec'y of Health & Hum. Servs.*, 131 Fed. Cl. 735 (2017), *aff'd*, 717 F. App'x 1009 (Fed. Cir. 2018). Petitioners have gone out of their way to note that C.J.B. was never diagnosed with autism, and I concur the record does not directly say otherwise.[10] Rather, my determination to dismiss flows directly from the fact that the medical record does not establish encephalopathy as an injury that could in turn have caused developmental problems. Many petitioners have hoped to show a child's developmental issues were vaccine-caused, but they cannot succeed in doing so *solely* by relying on the evidence of the developmental problem. Where the record does not allow the conclusion that a true brain injury occurred in the first place, developmental symptoms that manifest post-vaccination cannot be linked to the vaccine – and there is no reason to allow the matter to proceed.

CONCLUSION

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.[11]

IT IS SO ORDERED.

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

[9] In addition, any expert opinion that C.J.B. suffered metal toxicity, due to the miniscule amounts of aluminum contained in the vaccines he received (as an adjuvant, to encourage immunogenicity), would utterly fail the preponderant test. The Program has uniformly rejected causation theories relying on this theoretical contention as scientifically unreliable. *Rogero*, 2017 WL 4277580, at *64-65.

[10] Autism is, however, mentioned in some diagnostic differentials. *See,* e.g., Ex. 7 at 4, 9, 13; Ex. 8 at 5, 25. And it is not clear whether Petitioners ever have ever attempted to rule it out or have C.J.B. screened formally for it.

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