In the United States Court of Federal Claims

(Filed Under Seal: March 3, 2022 | Reissued for Publication: March 23, 2022)*

JEFFREY BELLO and OKSANA Y. OGANESOV, Parents of C.J.B., A Minor,	
Petitioners,	No. 20-739V
v.)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	
)

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

Benjamin Warder, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, with whom were Alexis B. Babcock, Assistant Director, Heather L. Pearlman, Deputy Director, C. Salvatore D'Alessio, Acting Director, and Brian M. Boynton, Acting Assistant Attorney General, for Respondent.

OPINION AND ORDER

KAPLAN, Chief Judge.

This case arises under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "the Act"). It is currently before the Court on a motion for review filed by Petitioners Jeffrey Bello and Oksana Oganesov on behalf of their son, C.J.B. Petitioners challenge Chief Special Master Brian Corcoran's Decision on Entitlement dismissing their case without holding an evidentiary hearing based on his determination that the medical records did not demonstrate that C.J.B. had experienced a compensable injury.

For the reasons set forth below, the Court concludes that the Chief Special Master's decision is neither arbitrary, capricious, nor contrary to law. Petitioners' motion for review must therefore be **DENIED**.

^{*} Pursuant to Vaccine Rule 18(b), this opinion was initially filed on March 3, 2022, and the parties were afforded fourteen days to propose redactions. The parties did not propose any redactions and, accordingly, this Opinion is reissued in its original form for publication.

BACKGROUND

I. C.J.B.'s Birth and Health History

C.J.B. was born on March 21, 2016, weighing seven pounds and twelve ounces. Pet'rs' Ex. 3, at 1, 11–12, ECF No. 7-3. At his first well-child visit on March 25, 2016, C.J.B.'s physical exam was normal. <u>Id.</u> at 11–14. On April 1, 2016, C.J.B. returned for a weight check and to receive his first Hepatitis B vaccination. <u>Id.</u> at 14–16.

C.J.B. received well-child checkups at the age of one, two, four, six, nine, and twelve months. Pet'rs' Ex. 3, at 23–25, 31–35, 37–43, 46–52, 59–62, 64–69. Medical records from these visits reflect that C.J.B. was a healthy baby whose physical exams were normal. See id. They also reflect that he received a series of vaccinations during the visits, with no negative reactions reported other than crankiness or fussiness the day the vaccination was administered. Id. at 36, 71–72.

Beginning in the first month of C.J.B.'s life, Petitioners sought the advice of his pediatrician on a regular basis. <u>See id.</u> at 17–18, 20–21 (April 4, 2016 call seeking advice about upset stomach; April 9, 2016 call to report coughing, wheezing, and congestion; April 10, 2016 call and visit about congestion). Over the next fourteen months, C.J.B.'s mother called his pediatrician, made medical appointments for him, or took him to the emergency room at least fourteen more times. During these calls and visits she sought advice and care for a wide range of concerns, including fussiness, fever, feeding issues, irritability, congestion, rashes, and falls and head injuries. <u>See id.</u> at 26–30, 36, 43–46, 55–56, 63–64, 71–80; Pet'rs' Ex. 4, at 47, ECF No. 7-4.

II. C.J.B.'s Health and Development Between His June 23, 2017 Vaccinations and the August 28, 2017 Call His Mother Made to the Pediatrician

On June 23, 2017, during his fifteen-month well-child visit, C.J.B. received the Pentacel and pneumococcal conjugate vaccines. Pet'rs' Ex. 3, at 81–87. The affidavit Petitioners submitted to the Chief Special Master states that C.J.B.'s health and development "rapidly declined" after he received these vaccinations. Pet'rs' Ex. 2, ¶ 4, ECF No. 7-2. They describe C.J.B. as "crying constantly after coming home from the doctor's office," and further assert that he was "having 'fits' every [three to five] minutes." <u>Id.</u> ¶ 5. Petitioners also stated that C.J.B.

¹ During this period, C.J.B. received hepatitis B vaccines; Pentacel (which includes the diphtheria-tetanus toxoid-acellular pertussis, poliovirus, and haemophilus B conjugate vaccines); pneumococcal conjugate vaccines; and rotavirus vaccines at two, four, and sixth months of age; as well as measles, mumps, and rubella and varicella vaccines. Pet'rs' Ex. 3, at 23–25, 31–35, 37–43, 46–52, 59–62, 64–69. The record reflects that on June 3, 2016, and April 19, 2017, C.J.B.'s mother called his pediatrician to inquire if crankiness was a normal reaction to the vaccinations he had received that day and two weeks prior, respectively. <u>Id.</u> at 36 (June 3, 2016 call); <u>id.</u> at 71–72 (April 19, 2017 call reporting that C.J.B. was cranky and had a rash). The record reflects that C.J.B.'s providers reassured his mother that fussiness on the day an infant receives a vaccine is normal. Id. at 36.

"very rapidly began to lose his ability to say many of the words that he had been saying daily for weeks," ultimately "los[ing] his entire ability to speak" within three weeks of vaccination. <u>Id.</u> ¶ 6; see also id. ¶ 7 (stating that C.J.B.'s "condition worsened daily until . . . September 2017"). They also allege that they "called the pediatrician for help, but did not receive any guidance or an appointment." Br. in Support of Pet'r's Claim and in Resp. to Order to Show Cause ("Pet'rs' Resp. to Show Cause Order") at 2, ECF No. 33.

The medical records before the Chief Special Master do not reflect the rapid decline in C.J.B.'s health and development that his parents described in their affidavit. Among other things, there is no record of any call to the pediatrician the day of the vaccination when his parents stated C.J.B. was "crying constantly" and having "fits" every few minutes. Nor do the records reflect that they sought medical assistance in the ensuing three weeks to address what they state in their affidavit was his complete loss of the ability to speak.

The first call to the pediatrician that is reflected in the medical records occurred on June 28, 2017, five days after vaccination. Pet'rs' Ex. 3, at 88. During the call, C.J.B.'s mother asked for advice about weaning him from breastfeeding. <u>Id.</u> She reported that she had stopped breastfeeding him during the day and wanted to stop doing so at night as well. <u>Id.</u> The record of that call includes no mention of any unrelated health or behavioral issues. <u>See id.</u>

Some five weeks later, on August 2, 2017, C.J.B.'s mother called the pediatrician again, this time for advice on C.J.B.'s sleep issues. <u>Id.</u> at 88–89. She reported that, in the past "few weeks," since she had weaned him from breastfeeding, he had been "wak[ing] up at night screaming" and kicking and biting her. <u>Id.</u> at 89. The pediatrician provided C.J.B.'s mother with advice on "sleep training/sleep hygiene" and noted that this behavior corresponded with C.J.B. being weaned from nighttime breastfeeding. <u>Id.</u>

C.J.B.'s mother called the pediatrician two weeks later, on August 16, 2017, after he fell down some steps. <u>Id.</u> at 89–90. During the call, she reported that he had a "large bump" on his head, but that his behavior was otherwise normal and that he had been easily consoled after his fall. <u>Id.</u> at 89. She was told to monitor C.J.B. for signs of a concussion, and to call again if his symptoms changed. <u>Id.</u> at 90.

III. C.J.B.'s Parents Pursue Medical Treatment for His Loss of Speech and Related Symptoms (August 28, 2017–December 29, 2018)

The first mention of any concern about C.J.B.'s language or development skills appears in a medical record dated August 28, 2017. Pet'rs' Ex. 3, at 90. On that day, C.J.B.'s mother called the pediatrician and reported that he "ha[d] less words than [one] month ago" (i.e., the end of July, which was approximately four to five weeks post vaccination). <u>Id.</u> She was told that C.J.B.'s skills, including his speech, would be checked at his eighteen-month well-child visit, presumably in September. <u>Id.</u>

Four days later, on Friday, September 1, 2017, both of C.J.B.'s parents—first his father and, a few hours later, his mother—placed more urgent calls to their son's pediatrician. <u>Id.</u> at 90–

91. The notes of the pediatrician's office reflect that Petitioners had called several times and wanted to "discuss [C.J.B.'s] speech" "as soon as possible." <u>Id.</u> at 91.

Having not received a call back from the pediatrician on Friday, Petitioners took their son to the emergency room at the Virtua Memorial Hospital the next day (Saturday, September 2, 2017). Pet'rs' Ex. 4, at 25. They told the emergency room doctor that C.J.B. had begun to experience language regression three weeks earlier (i.e., mid-August, approximately seven weeks post vaccination). Id.; see also Pet'rs' Ex. 3, at 92 (documenting toxicology department doctor's call to C.J.B.'s pediatrician seeking his vaccination history). They expressed concern that C.J.B. may have experienced "heavy metal poisoning" from his June 23, 2017 vaccinations, Pet'rs' Ex. 4, at 25, and requested "aluminum and lead testing," id. at 27.

During this visit, emergency room providers noted that C.J.B. was "awake, alert, and comfortable during evaluation." <u>Id.</u> at 25. After obtaining C.J.B.'s medical records from his pediatrician, Pet'rs' Ex. 3, at 92, the doctor noted that he had not had a reaction to the vaccines he had received on April 3, 2017, and that the vaccines he had received on June 23, 2017, "did not contain mercury or other metals," Pet'rs' Ex. 4, at 27. Nevertheless, they conducted urine and blood aluminum testing. <u>Id.</u> (noting that C.J.B.'s parents told the doctor his "lead level [had been] obtained previously," and that the results were "normal").

The next day, on Sunday, September 3, 2017, C.J.B.'s pediatrician returned the calls Petitioners had placed to him on September 1. Pet'rs' Ex. 3, at 91. C.J.B.'s father expressed his concern about "aluminum toxicity from the [June] vaccines," in light of the fact that his son's vocabulary of twenty-plus words had disappeared. <u>Id.</u> He requested "immediate blood testing," to which the pediatrician responded that he "would like to get a neurology and developmental evaluation . . . first." <u>Id.</u> The pediatrician explained that he would call back in two days (i.e., the Tuesday after the Labor Day holiday). <u>Id.</u> C.J.B.'s pediatrician then made an appointment for him to see developmental pediatrician Dr. Theresa McSween on September 19, 2017. <u>Id.</u> at 92–93.

In the meantime, C.J.B.'s mother called the pediatrician again on September 8, 2017, concerned that her son's symptoms were worsening. <u>Id.</u> at 93. The following day, he called to assure her that he would "check on [the] heavy metal screening" and confirm their appointment with the developmental pediatrician. Id. at 93, 98.

On September 11, 2017, C.J.B.'s mother brought him to the Virtua Memorial Emergency Room following a fall. <u>Id.</u> at 98, 135–36; <u>see also Pet'rs' Ex. 4</u>, at 6–9. He was evaluated and, because he was not exhibiting any symptoms of a concussion, discharged. Pet'rs' Ex. 4, at 9.

On September 19, 2017—the day C.J.B. was to be seen by the developmental pediatrician—Petitioners took him instead to the Emergency Department at the Children's Hospital of Philadelphia. See Pet'rs' Ex. 8, at 3–7, ECF No. 7-8; id. at 6 (explaining that C.J.B.'s "pediatrician was able to get [an] appointment scheduled for 1pm today with [a] neurologist," but that the "family did not go to this appointment as [they] did not believe that child needed developmental pediatrician"). The emergency department intake notes state that Petitioners had "started noticing decreased speech [and] mood swing[s]" "[a]round [L]abor [D]ay" (i.e.,

September 4, 2017), and were concerned that their son had experienced "aluminum toxicity" following his vaccination. <u>Id.</u> at 3.

Petitioners told Dr. Sage Myers, who treated C.J.B. during this visit, that his language skills had been regressing "over the last few weeks," which his father "believe[d] [was] due to toxic encephalopathy from aluminum." <u>Id.</u> at 4 (noting that C.J.B.'s "[f]ather reports that he has done extensive research and read many periodicals on this topic and is certain of this diagnosis"). Dr. Myers, however, saw "[n]o signs of encephalitis or encephalopathy" following a "[n]ormal . . . full neuro[logical] exam." <u>Id.</u> at 6–7. She opined that C.J.B.'s "[s]peech regression [was] more likely due to [a] genetic or developmental disorder," given that "[a]luminum toxicity in [an] otherwise normal child [would be] extremely unlikely." <u>Id.</u> at 6. Dr. Myers encouraged Petitioners "to continue to [follow up] with developmental pediatrics to help aid in diagnosis." <u>Id.</u> at 7.

On October 5, 2017, C.J.B. returned to the Children's Hospital of Philadelphia for a follow-up appointment with Dr. Mark Magnusson. Pet'rs' Ex. 10, at 9, ECF No. 14-2. Dr. Magnusson noted that C.J.B.'s parents were "concerned and convinced that he has aluminum toxicity," <u>id.</u> at 3, and "aluminum encephalopathy," and that they "reported loss of language and onset of temper tantrums," <u>id.</u> at 9; <u>see also id.</u> at 3 (reiterating Petitioners' concern that their son had experienced "significant developmental regression" following his June 2017 vaccinations). He observed that C.J.B. was "apparently developmentally normal," <u>id.</u> at 9, and ordered blood tests to check C.J.B.'s liver and kidney function, <u>id.</u> at 6. Dr. Magnusson also recommended that Petitioners take their son to see a developmental pediatrician. <u>Id.</u> at 9.

The record reflects that Dr. Magnusson called Petitioners to follow up a few days later, leaving a voicemail on October 9, 2017, and speaking with C.J.B.'s father the following day. See id. at 25–42. Petitioners told Dr. Magnusson that C.J.B.'s mood had improved, and he reiterated his recommendation that they take C.J.B. to a developmental pediatrician. Id. at 35. He noted that C.J.B.'s father "disagree[d] with [the Children's Hospital of Philadelphia] info and resources." Id. at 35 (noting Petitioner's belief that C.J.B.'s "[t]ooth grinding [was] symptomatic of heavy metal poisoning" and that "[l]ow zinc [is] associated with aluminum"). Dr. Magnusson recommended a multivitamin and that some of C.J.B.'s blood laboratory tests be repeated in two or three months. Id.

Two weeks later, at his eighteen-month well-child visit on October 23, 2017, C.J.B.'s pediatrician noted that Petitioners were concerned that he had "stopped talking" since his vaccinations. Pet'rs' Ex. 3, at 108. Specifically, Petitioners told the pediatrician that C.J.B. currently had a vocabulary of two or three words, although he had initially gone "down to only saying [one] word" the week following his vaccination. <u>Id.</u> (noting that "mom states ever since [his June] immunizations he has stopped talking" and began "having tantrums, biting, hitting, throwing toys and high pitched screaming"). The pediatrician observed that C.J.B.'s physical exam was normal. <u>Id.</u> at 110. C.J.B.'s mother requested that his mineral and vitamin levels be tested and expressed her concerns about aluminum. <u>Id.</u> at 111. Noting that providers at the Children's Hospital of Philadelphia had opined that C.J.B.'s "toxicology levels are not a problem," the pediatrician reiterated to Petitioners the recommendation that they follow up with a developmental pediatrician. <u>Id.</u>

A month later, on November 24, 2017, C.J.B.'s parents sought treatment with a new pediatrician, Dr. David Bruner. Pet'rs' Ex. 11, at 7, ECF No. 17-1; id. at 9 (noting that C.J.B. was there to "follow up [on] other office and [emergency department] visits [regarding] developmental regression presenting primarily as loss of most of his regressive language [and the] new onset of aggressive behavior"). According to Dr. Bruner's notes, Petitioners told him that C.J.B. "was very fussy and irritable after his [six] month shots," and that he "began to grind [his] teeth which he subsequently ground through enamel now to point of needing [a] root canal." Id. at 9. They explained that C.J.B. "began to lose language milestones" around fifteen months of age. <u>Id.</u> Dr. Bruner recorded Petitioners' "concerns [about] possible aluminum toxicity" and their belief that the results of C.J.B.'s aluminum blood tests were unusual. Id. (noting that "serum and urine aluminum levels . . . do not have known agreed upon standards"). He noted that C.J.B. "ha[d] not had a neurological evaluation or speech evaluation to date," but stated that the child was "[o]bservationally" normal. <u>Id.</u> at 9–10. He explained to Petitioners that C.J.B. "[n]eed[ed] to begin speech therapy," because, "regardless of [the] cause" of his speech regression, he "likely has frustration over this which may lead to his outbursts." Id. at 11. He scheduled a follow-up exam with C.J.B. in six months. Id.

Although not memorialized directly in the record, C.J.B. was apparently seen by developmental pediatrician Dr. McSween on December 29, 2017. See Pet'rs' Ex. 9, at 2 (Dr. McSween's diagnosis of "speech abnormality" on that date), ECF No. 14-1; id. at 21 (noting a diagnosis of "speech abnormality" on that date); id. at 7 (noting C.J.B.'s height and weight on that date); id. at 12 (Dr. McSween's order of that date scheduling an MRI on January 18, 2018, for "encephalopathy" and diagnosing C.J.B. with "speech disturbance").

IV. 2018 Medical Records

On January 18, 2018, Petitioners brought C.J.B. to Cooper University Hospital for the MRI that Dr. McSween had ordered on December 29, 2017. Pet'rs' Ex. 9, at 2–38. Dr. Christopher Plymire recorded Petitioners' concerns about vaccine-related "aluminum toxicity" as allegedly demonstrated by C.J.B.'s "[d]evelopmental delay and regression." <u>Id.</u> at 8, 23. The results of the MRI were normal except for the discovery of a "thin-walled pineal gland cyst," which prompted the radiologist to recommend "[a] three to six-month follow-up MRI of the brain with thin sections through the pineal gland." Id. at 13.³

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² This observation is unaddressed by the parties and is the first and only time that a provider suggested that C.J.B. had a reaction to any vaccine other than his June 23, 2017 fifteen-month vaccinations.

³ The pineal gland is "a small, flattened cone-shaped body in the epithalamus, lying above the superior colliculi and below the splenium of the corpus callosum." <u>Dorland's Illustrated Medical Dictionary</u> (30th ed. 2003) at 774. A pineal cyst is a benign and rarely symptomatic growth commonly found in the pineal region of the brain in both children and adults. Michael D. Jenkinson, Samantha Mills, Conor L. Mallucci, & Thomas Santarius, <u>Management of pineal and colloid cysts</u>, 21 Prac. Neurology 292, 292–93 (2021).

On February 28, 2018, C.J.B. was seen by Dr. Jaya Ganesh at Cooper University Hospital for an "initial genetic consultation . . . due to developmental regression presenting primarily as loss of most of his expressive language and onset of aggressive behavior." Pet'rs' Ex. 7, at 4, ECF No. 7-7. Petitioners told Dr. Ganesh they were concerned that C.J.B.'s developmental regression was attributable to methylenetetrahydrofolate reductase ("MTHFR") gene polymorphisms. <u>Id.</u> She observed that C.J.B. met "normal growth parameters," and that, "[w]hile [his] expressive language is definitely behind for [his] age, he demonstrates age appropriate to advanced gross and fine motor skills and interactive play." <u>Id.</u> at 8 (concluding that "[a] genetic etiology is not readily apparent"). She ordered a "[c]hromosomal micro array," "MTHFR polymorphism screening," and "metabolic studies." <u>Id.</u>; <u>see also id.</u> at 13–18 (lab orders and results).

The next medical record is from May 24, 2018, when C.J.B. saw Dr. Bruner again for his two-year well-child visit. Pet'rs' Ex. 11, at 28–43. Dr. Bruner noted that C.J.B.'s "family reports he had a brief language regression that improved after glutathione (managed by outside provider)." <u>Id.</u> at 30. He also noted that C.J.B. was "due for a repeat MRI due to pineal cyst," and further that C.J.B.'s "family belie[ves] he has increase flare on MRI," which was "noted in [a] report from [pediatric] radiology as age appropriate," although C.J.B.'s parents "d[idn't] necessarily agree with this" assessment. <u>Id.</u>

On July 24, 2018, C.J.B. was seen at Cooper University Hospital for the follow-up MRI to observe the pineal gland cyst discovered in January. Pet'rs' Ex. 9, at 39–74. The next medical record is from December 26, 2018, when C.J.B.'s pediatrician treated him for a cough and runny nose. Pet'rs' Ex. 11, at 44–54.

V. Pertinent Medical Records for 2019, 2020, and 2021

C.J.B. saw Dr. Bruner again on April 29, 2019, for his three-year well-child visit. Pet'rs' Ex. 11, at 55–66. Dr. Bruner noted that C.J.B.'s parents "ha[d] not contacted [his] school for [evaluation]," even "though multiple speech concerns persist." <u>Id.</u> at 57. He further noted that Petitioners believed that the MRIs demonstrated an encephalopathy, but that, in his opinion, those tests "read as normal other than a small stable pineal cyst [observed] by our Pediatric Radiology department." <u>Id.</u> at 57; <u>id.</u> at 60 (noting that Petitioners were "also looking for a neurologist to look at the MRI's"). He advised C.J.B.'s parents to get an evaluation from his school because he was "concerned that a gap in therapies is not good for him." <u>Id.</u> at 60.

On July 8, 2019, Petitioners again brought C.J.B. to see Dr. Bruner, reporting that he was experiencing "daily" headaches and "gets motor tics like head shake when tired." <u>Id.</u> at 79–84; see <u>id.</u> at 80 (C.J.B. "told his family his head hurts during these episodes" which "occur daily and will awaken him at night"). Dr. Bruner noted that the third MRI he had ordered to monitor the pineal gland cyst had not been performed, and that he would work on getting it authorized in light of these "new [findings] of headache awakening him from sleep." <u>Id.</u> at 80, 83.

C.J.B. underwent a third MRI on July 30, 2019. Pet'rs' Ex. 9, at 75–124. His providers noted that the pineal gland cyst which had been discovered in January 2018 was "stable," and

there were no other abnormalities noted. <u>Id.</u> at 87 (noting that "myelination is within range for age").

On December 3, 2019, C.J.B. was seen by pediatric neurologist Dr. Stephen Falchek, who documented the family's concerns and C.J.B.'s medical history. Pet'rs' Ex. 5, at 5–7, ECF No. 7-5. Petitioners told Dr. Falchek that C.J.B. had been "very vocal . . . until about [twenty-four] hours after his [fifteen-]month immunizations," at which point "he began to display [behavior] consistent with pain and temper tantrums." <u>Id.</u> at 5. C.J.B.'s father also told Dr. Falchek that the first 2018 MRI showed "FLAIR abnormality all over." Id.

Dr. Falchek "discuss[ed] with [the] family the fact that FLAIR images in [the MRI scans of very] young children show the areas of ongoing myelination as bright areas," and accordingly "can be mistaken as abnormal." <u>Id.</u> at 7. Nevertheless, he noted that he would "try to have our neuroradiologists review [the MRIs]." <u>Id.</u> He also noted that the blood and urine tests conducted by the Children's Hospital of Philadelphia showed that C.J.B.'s "total aluminum level was 3, well within the normal range," and that his "aluminum/creatinine ratio was 33 mcg/gr creatinine," which "is also within normal limits." <u>Id.</u> (noting that this test result "has caused some confusion as it was being interpreted as a total aluminum level, which it isn't"). Dr. Falchek reiterated the recommendation made by C.J.B.'s other providers that his parents consult with a speech therapist. <u>Id.</u>

On February 6, 2020, C.J.B. began treatment with Samantha Dommermuth, a speech-language pathologist. <u>Id.</u> at 12–20. She observed that C.J.B. displayed "mild receptive and expressive language delay in combination with mild speech sound delay," but found "little to no evidence of dyspraxia." <u>Id.</u> at 18. She recommended that C.J.B. receive speech and language therapy weekly for thirteen weeks, <u>id.</u>, and the record demonstrates that she saw him at least two more times, <u>id.</u> at 21–27 (medical records of speech and language therapy with Ms. Dommermuth on March 2 and March 9).

Dr. Falchek saw C.J.B. via video on April 14, 2020. <u>Id.</u> at 9–11. The report notes the purpose of the appointment was "for follow-up of chronic encephalopathy." <u>Id.</u> at 9 (noting C.J.B.'s "rather complex and confusing medical history"). Dr. Falchek noted that the results of C.J.B.'s blood and urine tests were all normal and that, although he had only been able to obtain one of C.J.B.'s three MRIs, he "concur[red]" that it "was probably normal." Id. at 10.

During this visit, Petitioners told Dr. Falchek that C.J.B. had experienced "[r]ecent regression in counting skills," as well as "cognitive and behavioral regression," and that his "speech [was] increasingly slurred." <u>Id.</u> Dr. Falchek's notes conclude with a recitation of his "[i]mpression" of C.J.B.'s condition, which he characterized as "complex encephalopathy with history of developmental regression in the context of immunizations and febrile illness." <u>Id.</u> at 11.

On October 6, 2020, Dr. Bruner saw C.J.B. for his four-year well-child visit. Pet'rs' Ex. 13, at 3–22, ECF No. 36-1. He noted that C.J.B. had begun "speech therapy and now occupational therapy," and his mother "report[ed] he has made very good progress of late." <u>Id.</u> at 6 (noting that his mother "is thrilled with his progress"). She told Dr. Bruner that C.J.B.'s

"speech is coming along," as were his "[f]ine motor and gross motor skills . . . [and] sensory issues." Id.

The most recent medical record provided by Petitioners is a one-paragraph letter signed by Dr. Bruner, addressed "[t]o whom it may concern" and dated March 13, 2021. Pet'rs' Ex. 12, at 2, ECF No. 34-1. In it, Dr. Bruner states that when he first met C.J.B. in 2017, the child "was experiencing a significant developmental regression." <u>Id.</u> He further states that a "broad based medical and neurological evaluation" was conducted and that the neurological evaluation "raise[d]... concerns about the developmental regression occurring probably as a result of intense immune reactions he had to his vaccinations." <u>Id.</u> "[D]ue to these reactions," Dr. Bruner stated, C.J.B. should be treated as "medically exempt from further vaccination." <u>Id.</u>

VI. The Vaccine Claim

In the meantime, on June 22, 2020, C.J.B.'s parents filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 to -34. Pet. for Comp. at 1, ECF No. 1. In their petition, Mr. Bello and Ms. Oganesov alleged, among other things, that the vaccines C.J.B. received on June 23, 2017, caused him to experience encephalopathy, speech abnormality, and language regression. Id. 4

The case was assigned to Chief Special Master Brian H. Corcoran on June 22, 2020. ECF No. 4. After having received several extensions of time to do so, Petitioners filed their affidavit as well as medical records on August 26, 2020, and on November 13, 2020. ECF Nos. 7, 14. They filed their Statement of Completion on November 13, 2020, in accordance with Vaccine Rule 2(f). ECF No. 16.⁵

VII. The Show Cause Order

On February 24, 2021, over three months after Petitioners filed their Statement of Completion, Chief Special Master Corcoran held a status conference in the case. During the conference he expressed concerns regarding whether the medical record supported Petitioners' claims that the vaccines C.J.B. received on June 23, 2017, caused him to develop encephalopathy, speech abnormality, language regression and/or significant aggravation of an underlying condition. See Order to Show Cause at 1, ECF No. 29.

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⁴ The Petition also alleged that the vaccines had "aggravat[ed] . . . an underlying condition [caused by] the genetic mutation MTHFR," Pet. for Comp. at 1, but Petitioners did not pursue that claim before the Chief Special Master.

⁵ Vaccine Rule 2(f) provides that a "[p]etitioner should file a 'Statement of Completion,' indicating that a certified copy of all medical and other records relevant to the petition has been filed, as soon as possible after the petition is filed," and that "[i]f additional medical records or other documents are necessary to complete the record, petitioner should delay filing the Statement of Completion until all necessary and relevant records have been filed."

He followed up the next day with an Order directing Petitioners to show cause why their claim should not be dismissed. <u>Id.</u> at 2. The Chief Special Master acknowledged that "in rare circumstances, claimants have successfully demonstrated that a vaccine could precipitate an encephalopathy in an infant, leading to similar kinds of injuries." <u>Id.</u> at 1. He observed, however, that such claims are "far more often than not <u>unsuccessful</u>" because claimants are usually unable to produce medical evidence that the infant experienced an acute injury in the days immediately after they were vaccinated. <u>Id.</u> at 2. Instead, he stated, they rely on parents' recollection of behavioral changes that are not corroborated by medical records. <u>Id.</u>

The Chief Special Master's "initial and admittedly cursory review of the medical records filed in this case" suggested to him that the Petitioners' claims were not likely to succeed for two reasons: (1) because the records "do not seem to 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 (2) because it did not appear that C.J.B. "ever received an encephalopathy diagnosis from a contemporaneous treater." <u>Id.</u>

In light of these concerns, the Chief Special Master directed Petitioners to file written briefs explaining how the evidence in the record supported their claim that C.J.B. suffered an injury as a result of the vaccine he received on June 23, 2017. <u>Id.</u> In doing so, he directed, they should identify decisions under the Vaccine Act that found entitlement under facts consistent with those supporting their claim. <u>Id.</u> If the Petitioners were unable to support their claims with sufficient facts, he warned, he might find it appropriate to dismiss their claims on the existing record. Id.

VIII. Petitioners' Response to the Show Cause Order

Over two months later, on April 30, 2021, Petitioners filed their response to the Chief Special Master's Order. <u>See</u> Br. in Support of Pet'r's Claim and in Resp. to Order to Show Cause ("Pet'rs' Resp. to Show Cause Order"), ECF No. 33. In it, they asserted (without citation to any evidence in the record) that C.J.B. began to lose his speech "[w]ithin hours of receiving the vaccines," and that, "[f]or several days thereafter, [C.J.B.'s] number of words decreased each day." <u>Id.</u> at 2.

Petitioners' Response also included brief quotes or excerpts from a number of the medical records they had submitted. Those records reflected that, as described above, Petitioners first reported concerns about C.J.B.'s loss of language in an August 28, 2017 call to his pediatrician. <u>Id.</u>⁶ The Response also asserts that Petitioners were awaiting "updated medical records." <u>Id.</u> at 4. In addition, the Response emphasized that it was "[o]f utmost importance" that "not one Emergency room doctor, pediatrician, or specialist ever diagnosed C.J.B. with Autism." <u>Id.</u> at 5.

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⁶ The Response also states that C.J.B. made an earlier visit to Children's Hospital of Philadelphia on July 19, 2017, during which Petitioners reported decreased speech by C.J.B., as well as other issues (biting mother, throwing toys). <u>See</u> Pet'rs' Resp. to Show Cause Order at 2. That visit, however, took place on September 19, 2017, not July 19, as was misstated in the Response. Pet'rs' Ex. 8, at 7.

In their Response, Petitioners also advised the Chief Special Master that C.J.B.'s case was under "preliminary review" by Dr. Yuval Shafrir, a pediatric neurologist. <u>Id.</u> at 6. They stated that Dr. Shafrir had not yet been retained, and that his "initial opinion [was] that C.J.B.'s diagnoses are not autism." <u>Id.</u> at 6–7.

Petitioners asserted that, as of the time they filed their Response, "there is a temporal relationship and a clear diagnosis." <u>Id.</u> at 7. They requested that they "be given the opportunity to further consult with Dr. Shafrir," whom they represented would "assist in establishing the causation-in-fact prong, set forth in <u>Althen</u>, that the vaccines caused C.J.B.'s encephalopathy, initial complete loss of speech, and current extremely slurred version of speech." <u>Id.</u>

Petitioners filed the additional updated medical records they referenced in their Response on May 5 and 7, 2021. See ECF Nos. 34, 36. On June 28, 2021, the Secretary of Health and Human Services ("the Secretary") filed a reply to Petitioners' Response to the Show Cause Order. Resp't's Br. in Reply to Pet'rs' Resp. to Order to Show Cause ("Resp't's Reply to Show Cause Order"), ECF No. 39. The Secretary argued that Petitioners failed to address the concerns set forth in the Chief Special Master's Order, and that their claim should be dismissed because they had failed to provide any evidence to support it. Id. at 1, 15. Petitioners filed their reply on August 12, 2021. Reply Br. in Support of Pet'rs' Claim and in Resp. to Order to Show Cause, ECF No. 42.

IX. Ruling on Entitlement

The Chief Special Master issued his entitlement decision on September 10, 2021. Entitlement Dec. at 1, ECF No. 43. He ordered the case dismissed because he found that "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." <u>Id.</u> at 2. He explained that "[t]he 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." <u>Id.</u> at 15. He concluded that there did not exist preponderant evidence showing that C.J.B. "suffered an encephalopathy in any reasonable post-vaccination timeframe." <u>Id.</u>

The Chief Special Master explained that, in his view, the medical records "do not establish anything close to suggesting a brain injury sufficient to lead to any form of developmental delay or regression," and noted that there were "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." <u>Id.</u> He further found that there was no evidence that C.J.B. experienced either a loss of consciousness or seizures "in this period [which] might have reflected the existence of an encephalopathic event, and no treaters who saw him in the six months after vaccination proposed otherwise." <u>Id.</u>

The Chief Special Master also explained that he was exercising his discretion to decide the case on the basis of the existing record and without holding a hearing, as permitted by Section 12(d)(2)(D) of the Vaccine Act and Vaccine Rule 8(d). <u>Id.</u> at 13, 17–19. He observed

that a review of the cases showed that no claimant had successfully demonstrated vaccination-precipitated encephalopathy absent a showing of evidence of a seizure or medical reports of the emergence of symptoms of acute encephalopathy in the forty-eight hours after vaccination. Id. at 17. Further, he observed that the record revealed that Petitioners were concerned "that metal toxicity, due to aluminum included as an adjuvant in some of the vaccines C.J.B. received, could have prompted injury." Id. at 18 (footnote omitted). But this theory, he noted, "has also uniformly been rejected in the [Vaccine] Program as an explanation for developmental issues due to a brain injury." Id.; see also id. n.8 (citing 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)).

Finally, the Chief Special Master advised that he saw no reason to allow Petitioners to provide the testimony of an expert witness, as they requested in their response to the Show Cause Order. <u>Id.</u> at 18. While he acknowledged that Petitioners "could no doubt find an expert willing to advocate for them . . . 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." <u>Id.</u> "Thus," he reasoned, "allowing that process to occur (which would also entail Respondent likely seeking to offer a rebuttal expert of his own) would waste time and Program resources." <u>Id.</u> at 18–19.

X. Motion for Review

Petitioners filed their motion for review of the Chief Special Master's Decision on October 9, 2021. See Mot. for Review, ECF No. 46; Pet'r's Mem. in Support of his Mot. for Review ("Pet'rs' Mot."), ECF No. 46-1. In their motion, they contend that the Chief Special Master abused his discretion by dismissing the case without holding an evidentiary hearing or giving them an opportunity to submit an expert report. Id. at 5–6, 12–13. They also argue that the Chief Special Master gave insufficient weight to evidence in the record that they say supports a diagnosis of an encephalopathy that was caused by the vaccinations C.J.B. received in June 2017. Id. at 14–15.

The Secretary filed his response on November 8, 2021. Resp't's Resp. to Pet'rs' Mot. for Review ("Sec'y's Resp."), ECF No. 49. On February 22, 2022, three days before oral argument on their motion for review, Petitioners filed a motion for leave to file "telephone records indicating phone calls made by the parents to the pediatrician during the initial time frame of Petitioner's injury." Mot. for Leave to File Add'l Docs. at 1, ECF No. 51. Oral argument was held on both motions via videoconference on February 25, 2022.

DISCUSSION

I. The Vaccine Act

A. **Proving Entitlement**

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. <u>Figueroa v. Sec'y of Health & Hum. Servs.</u>, 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). There are two routes by which a petitioner may establish entitlement to compensation under the Vaccine Act.

First, in a so-called "Table" case, a petitioner may secure compensation by showing that—within specified time periods after receiving one of the vaccines identified in the Vaccine Injury Table—he "sustained" or "significantly aggravated" an "illness, disability, injury, or condition" identified in the Table. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1341–42 (Fed. Cir. 2010); 42 U.S.C. § 300aa-11(c)(1)(C)(i). If a petitioner makes this showing, it is presumed that the vaccine caused his injury. Broekelschen, 618 F.3d at 1341–42 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i)); Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009)).

In an off-Table case, on the other hand, a petitioner establishes his entitlement to benefits by first identifying and establishing the injury that he claims he has suffered as a consequence of the vaccine, and then proving by preponderant evidence that the vaccine caused the injury. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)(A); see also Andreu, 569 F.3d at 1374; Broekelschen, 618 F.3d at 1346. "[A] petitioner must show that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quotations omitted).

The three-pronged test that the Federal Circuit announced in <u>Althen v. Secretary of Health & Human Services</u>, 418 F.3d 1274 (Fed. Cir. 2005), guides the causation determination in an off-Table case. It requires a petitioner to demonstrate: (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 proximate temporal relationship between vaccination and injury." <u>Id.</u> at 1278. "Once the petitioner has demonstrated causation [under <u>Althen</u>], she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." <u>Broekelschen</u>, 618 F.3d at 1342 (citing <u>Doe v. Sec'y of Health & Hum. Servs.</u>, 601 F.3d 1349, 1351 (Fed. Cir. 2010)); <u>see also</u> 42 U.S.C. § 300aa-13(a)(1)(B).

B. Jurisdiction and Standards of Review

A petition seeking compensation under the Vaccine Act must be filed in the Court of Federal Claims, after which it will be forwarded to the Office of Special Masters for assignment. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned is responsible for deciding whether the petitioner is entitled to compensation, and, if so, the amount of compensation due. <u>Id.</u> § 300aa-12(d)(3)(A).

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the decisions of special masters (subject to further review in the Federal Circuit). 42 U.S.C. §§ 300aa-12(e), (f); see also Mahaffey v. Sec'y of Health & Hum. Servs., 368 F.3d 1378, 1383 (Fed. Cir. 2004) (citing 42 U.S.C. § 300aa-12(d)(3)(A)). On review, the Court has several options. It may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Vaccine Rule 27.

The Court applies the "not in accordance with law" standard when reviewing a special master's legal determinations. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). Such review is de novo. Althen, 418 F.3d at 1278–79. The reviewing court "give[s] no deference to the . . . Special Master's determinations of law." Carson v. Sec'y of Health & Hum. Servs., 727 F.3d 1365, 1368 (Fed. Cir. 2013).

By contrast, review of a special master's factual determinations is to decide whether they are arbitrary, capricious, and/or reflect an abuse of discretion. Moberly, 592 F.3d at 1321. The Court applies a "uniquely deferential" standard to those determinations. Milik v. Sec'y of Health & Hum. Servs., 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). It does not reweigh the evidence; nor does it or examine its probative value or the credibility of the witnesses, because those "are all matters within the purview of the fact finder." Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen, 618 F.3d at 1349). Therefore, if a special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,' then reversible error is 'extremely difficult to demonstrate." Milik, 822 F.3d at 1376 (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Petitioners' Motion for Review

In their motion for review, the Petitioners assert that—contrary to the Chief Special Master's findings—the medical record contains persuasive evidence that C.J.B. suffered from a chronic encephalopathy caused by his immunizations. Pet'rs' Mot. at 8. Moreover, they contend, the Chief Special Master abused his discretion by dismissing their claims without holding an evidentiary hearing or receiving an expert report. <u>Id.</u> at 7–8. Had the Chief Special Master not dismissed the case on the existing record, they say, they might have been able to fill the gaps in proof that concerned him. <u>Id.</u> at 9, 11.

Petitioners' arguments are unpersuasive. First, the Chief Special Master's determination that Petitioners did not prove C.J.B. suffered a vaccine-related encephalopathy was supported by the evidence before him. As he observed, to prove that the vaccines C.J.B. received on June 23, 2017, caused him to lose speech capabilities, Petitioners would first have to show an injury to C.J.B.'s brain. Entitlement Dec. at 15. In addition, he noted—and Petitioners do not disagree—"the critical timeframe" to establish a causal relationship between the vaccine and any brain injury was "within the first month of vaccination." <u>Id.</u>

The Chief Special Master reviewed the medical records Petitioners supplied and found that they "do not establish anything close to suggesting a brain injury sufficient to lead to any form of developmental delay or regression," observing that there were "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." <u>Id.</u> Further, he found, there was no evidence that C.J.B. "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." <u>Id.</u> There was also no evidence C.J.B. had ever suffered seizures which could have caused brain injury sufficient to cause the speech regression his parents had observed. <u>Id.</u> at 15, 17.

The Chief Special Master gave no weight to the allegations in Petitioners' affidavit that C.J.B.'s health "rapidly declined" after he received the June 23, 2017 vaccination and that he was "crying constantly" and "began having 'fits' every 3-5 minutes" after coming home from the doctor's office that day. Pet'rs' Ex. 2. ¶¶ 4–5; see Entitlement Dec. at 16. Nor did he credit their assertion that C.J.B. lost his ability to speak entirely within three weeks of receiving the vaccines. See Pet'rs' Ex. 2 ¶ 6; Entitlement Dec. at 16. Those assertions were not credited because they were not reflected in the many medical records documenting C.J.B.'s speech difficulties in the months that followed his vaccinations. Entitlement Dec. at 16.

As the court of appeals has observed, medical records "warrant consideration as trustworthy evidence" because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," and are "generally contemporaneous to the medical events." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). They are prepared when the patient's "proper treatment [is] hanging in the balance" and "accuracy has an extra premium." Id.

In this case, Petitioners routinely called the pediatrician or sought treatment for C.J.B. for a broad range of health concerns, both before and after he received the June 23, 2017 vaccines. The Chief Special Master's decision to accord more weight to contemporaneous medical records was therefore appropriate, and reflects the "familiar and reasonable assessment that contemporaneous documentary evidence of the sort at issue here, prepared by professionals doing their jobs independently of litigation, can be (though is not necessarily) more reliable than testimony of interested parties." Rogero v. Sec'y of Health & Hum. Servs., 748 F. App'x 996, 1001 (Fed. Cir. 2018) (citing Reusser v. Sec'y of Health & Hum. Servs., 28 Fed. Cl. 516, 523 (1993) (stating that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later")); Skinner v. Sec'y of Health & Hum. Servs., 30 Fed. Cl. 402, 410 (1994) ("In

general, contemporaneous written records are to be given more weight than testimony adduced years later.").

The Chief Special Master also found it significant that none of the medical professionals who treated C.J.B. in the months following his vaccinations diagnosed him as suffering from an encephalopathy. Entitlement Dec. at 15. Petitioners fault the Chief Special Master for not giving greater weight to Dr. Falchek's report (which provided his "impression" that C.J.B. had experienced "complex encephalopathy with history of developmental regression in the context of immunizations and febrile illness."). Pet'rs' Mot. at 14 (quoting Pet'rs' Ex. 5, at 11). But the Chief Special Master reasonably found this evidence not especially helpful to Petitioners. To begin with, Dr. Falchek saw C.J.B. more than two years after he received the vaccinations in question. Entitlement Dec. at 15. In addition, his impression regarding the existence of a "complex encephalopathy" does not appear to be supported by objective evidence. Id. (explaining that this impression "rel[ies] on Petitioners' reported history rather than the record filed in this case, which are inconsistent with what he was told").

Petitioners' reliance upon Dr. Falchek's reported impression is also undermined by the two pages of notes that preceded it. See Pet'rs' Ex. 5, at 9–10. In those notes, Dr. Falchek characterized C.J.B.'s medical history as "complex and confusing," and stated that his medical records demonstrated that the three MRIs he underwent were normal. Id. It appears, therefore, that the sole bases for Dr. Falchek's impression regarding the "complex encephalopathy" were Petitioners' assertions. See id.; see also Entitlement Dec. at 15.7

Perhaps recognizing the weakness of their case on the existing record, Petitioners focus most of their motion for review on the Chief Special Master's decision to dismiss the case without holding an evidentiary hearing. They contend that had he held such a hearing, they could have testified as to the "onset of encephalopathy" and "phone calls to the pediatrician's office that were unfortunately omitted from the medical record, as well as information that was incorrectly set forth in the medical record." Pet'rs' Mot. at 6, 9. They also argue that the Chief Special Master should have granted their request for additional time to submit an expert report by Dr. Yuval Shafrir. Id. at 6, 13. These contentions are unavailing.

Special masters have broad discretion to determine how best to manage the cases before them. Vaccine Rule 3(b) states that "[t]he special master is responsible for conducting all proceedings" and "shall determine the nature of the proceedings, with the goal of mak[ing] the proceedings expeditious, flexible, and less adversarial." Further, under Vaccine Rule 8(a), the special master has discretion to "determine the format for taking evidence and hearing argument

⁷ In their motion, Petitioners contend that C.J.B.'s MRIs "showed significant 'brain flare'" and argue that if Dr. Shafrir had been retained, he could have provided an expert opinion "whether brain flares are consistent with Encephalopathy of the brain" as well as potentially its onset. Pet'rs' Mot. at 14. They provide no citation to the record that supports their assertion regarding evidence of "significant 'brain flare'" in the MRIs. Dr. Falchek's report states that C.J.B. was evaluated at Children's Hospital of Philadelphia and that in his father's opinion the MRI "showed 'FLAIR abnormality all over" but that "the final report was normal." Pet'rs' Ex. 5, at 9–10 (Dr. Falchek's notes apparently quoting C.J.B.'s father).

based on the specific circumstances of each case and after consultation with the parties." And Vaccine Rule 8(d) expressly states that "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing."

To be sure, special masters are obligated to "consider all relevant and reliable evidence" and the proceedings must be "governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b). Special masters also "must determine that the record is comprehensive and fully developed before ruling on the record." Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2020). But so long as the special master follows these general principles, decisions regarding the management of a case are left to his discretion and subject to reversal only under the highly deferential abuse of discretion standard. Id. at 1364.

In this case, the Chief Special Master gave Petitioners a full and fair opportunity to present written evidence and argument. Petitioners were afforded several extensions of time to submit their affidavits and medical records, and they ultimately filed a Statement of Completion, signaling that all supporting records had been submitted. See ECF Nos. 16, 19. The record before the Chief Special Master contained reports from all of the medical providers who saw C.J.B. about his speech regression and other health issues in the months and years after his vaccination.

In addition, the Chief Special Master expressly gave Petitioners a chance to address the difficulties that are commonly presented when claimants attempt to prove that vaccines have caused developmental issues like those C.J.B. experienced. He warned them that, in his experience, "this kind of case is far more often than not <u>unsuccessful</u>," and explained that "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 not corroborated by contemporaneous medical records." Show Cause Order at 2. He therefore invited Petitioners to identify medical evidence that C.J.B. had suffered an encephalopathy and that it had caused the developmental problems they had observed.

Instead, in their response to his Order, Petitioners took precisely the approach the Chief Special Master warned them against. They relied almost exclusively on their own observations of C.J.B.'s language regression, and their efforts to secure treatment, as set forth in the medical evidence of record. See Pet'rs' Resp. to Show Cause Order. They also emphasized the fact that none of the medical evidence showed an autism diagnosis. Id. at 5, 7. What they did not do was point to medical evidence that reflected that C.J.B. suffered a brain injury that might have cause his speech regression.

The Court finds unpersuasive Petitioners' contentions that the Chief Special Master should have held an evidentiary hearing at which they could have provided testimony about the onset of C.J.B.'s injuries and what they now claim were errors or omissions in the medical records. See Pet'rs' Mot. at 9, 11, 13. For one thing, Petitioners had the opportunity but never advised the Chief Special Master that there were errors in the medical records either in the affidavit they originally filed in their case, or in response to the Chief Special Master's Show Cause Order. Moreover, and in any event, the flaw that the Chief Special Master identified in their case was the absence of medical evidence showing an encephalopathy. Petitioners'

testimony regarding their observations would not fill that gap, and would likely not be found persuasive in any event to the extent that they differed from those provided contemporaneously to C.J.B.'s medical providers.

Nor did the Chief Special Master abuse his discretion when he determined that it was not necessary to permit Petitioners to retain and submit testimony from an expert. The Chief Special Master concluded that expert testimony would not be sufficient to overcome "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." Entitlement Dec. at 18.

The Chief Special Master, in short, found that the record did not support a finding that C.J.B. suffered a brain injury. Therefore, Petitioners could not link the developmental symptoms that manifested themselves after vaccination to the vaccines he received. The Chief Special Master's factual findings were reasonable and supported by the record before him. His decision not to hold an evidentiary hearing or consider expert testimony represents a reasonable exercise of his discretion to decide how to manage the case and did not deprive Petitioners of a full and fair opportunity to have their claims heard. Petitioners' motion for review must therefore be denied.

III. Motion to Submit Additional Phone Records

Finally, on February 22, 2022, three days before oral argument on their motion for review, Petitioners filed a motion for leave to file "telephone records indicating phone calls made by the parents to the pediatrician during the initial time frame of [C.J.B.'s] injury." Mot. for Leave to File Add'l Docs. at 1. As explained above, the Court's review in Vaccine cases is based on the record before the Chief Special Master. Moreover, Vaccine Rule 8(f)(1) provides that "[a]ny fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision." The Court cannot, therefore, grant Petitioners' request that it consider additional material not presented to the Chief Special Master.

To be sure, while the Court itself cannot consider new evidence, it has the discretion to remand the case to the Chief Special Master with directions that he do so. 42 U.S.C. § 300aa-12(e)(2)(C) (providing that the Court "shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter remand the petition to the special master for further action in accordance with the court's direction"); Shaw v. Sec'y of Health and Hum. Servs., 91 Fed. Cl. 715, 716 (2010) (remanding to the special master for the limited purpose of considering previously available but newly presented evidence); Plavin v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 609, 621 (1998) (noting the court's authority to direct the special master to consider additional evidence). For several reasons, however, the Court believes that such a remand is not warranted.

First, Petitioners have supplied no reasonable justification for not supplying the Chief Special Master with the telephone records they would like the Court to admit into the record. According to counsel, C.J.B.'s father recently obtained the records from his cell phone provider.

<u>See</u> Oral Arg. at 1:58–3:58. They contain a list of the phone calls placed from the cell phone beginning on July 26, 2017. <u>Id.</u> at 3:30–58. Because the records could have been secured from the cell phone provider at any point before or while the claim was before the Chief Special Master, in the Court's view, Petitioners should not be permitted to submit them at this late stage.⁸

Further, the relevance of the records to Petitioners' claim is unclear at best. At oral argument on Petitioners' motions, Petitioners' counsel stated that the cell phone provider's records reflect that C.J.B.'s father made calls to the pediatrician that the office did not record. <u>Id.</u> at 4:03–20, 6:38–7:01. Specifically, counsel referenced four calls C.J.B.'s father made to the pediatrician on September 1, 2017. <u>Id.</u> at 4:21–52. But two of those calls were only two minutes long and so may well have represented calls answered by a receptionist and not medical providers. <u>Id.</u> at 5:01–14. The other two calls were eleven and eighteen minutes long. <u>Id.</u> The pediatrician's records reflect those two calls and describe their substance. <u>See</u> Pet'rs' Ex. 3, at 90–91.

Moreover, and in any event, records of phone calls placed but not recorded in medical records starting on July 26, 2017, have no bearing on the Chief Special Master's causation determination because they do not cover the critical thirty-day time period that followed the vaccinations. See Entitlement Dec. at 15. In addition, the central reason the Chief Special Master found Petitioners' case unpersuasive was because of the absence of an objectively supported medical opinion showing C.J.B. suffered a brain injury within a reasonable time frame after he received his vaccination. The phone records do not help Petitioners address this flaw. The Court therefore will not remand this case to the Chief Special Master to consider the records Petitioners seek to introduce.

CONCLUSION

On the basis of the foregoing, Petitioners' motion for leave to file additional documents, ECF No. 51, is **DENIED**. Petitioners' motion for review, ECF No. 46, is also **DENIED** and the Decision of the Chief Special Master is **SUSTAINED**. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Chief Judge

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⁸ During oral argument on Petitioners' motions, counsel for the Petitioners stated that she had not provided the records to the Chief Special Master because of the supposedly fast pace of the proceedings before him. Oral Arg. at 1:58–2:38, 10:29–43. The Court does not find counsel's justification for not supplying the records to the Chief Special Master especially persuasive. The Chief Special Master issued his Show Cause Order on February 25, 2021, and did not dismiss the case until September 10, 2021. There was ample time in that six- or seven-month period for Petitioners to secure the records which are the subject of their motion.