In the United States Court of Federal Claims

GARY GIANNANTONIO, Parent of C.G., a minor, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 18-497V (Filed: August 3, 2023)

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Sarah B. Rifkin, Trial Attorney, Torts Branch, Civil Division, Department of Justice, Washington, DC, for Respondent, with whom were Brian M. Boynton, Principal Deputy Assistant Attorney General, C. Salvatore D'Allessio, Director, Torts Branch, Civil Division, Heather L. Perlman, Deputy Director, Torts Branch, Civil Division, and Darryl R. Wishard, Assistant Director, Torts Branch, Civil Division.

OPINION AND ORDER[*]

KAPLAN, Chief Judge.

This case arises under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–34 ("Vaccine Act" or "the Act"). It is currently before the Court on a motion for review filed by Petitioner, Gary Giannantonio, on behalf of his daughter, C.G. Mr. Giannantonio challenges Special Master Christian J. Moran's decision rejecting his claim that a varicella vaccine caused C.G. to contract acute disseminated encephalomyelitis ("ADEM"). Pet., ECF No. 1.[1]

[*] This Opinion was originally issued under seal and the parties were given the opportunity to propose redactions of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Neither party proposed any redactions. Therefore, the Court now issues its Opinion publicly and in full.

[1] ADEM is a neurological disorder that causes inflammation in the brain, which can result in "confusion, excessive irritability, or altered level of consciousness (encephalopathy)," among

The special master denied compensation on two grounds. First, he held that Mr. Giannantonio had not proven by preponderant evidence that C.G. suffered from ADEM. Decision of Special Master (hereinafter the "Decision") at 13–18, ECF No. 120. Second, the special master concluded that Petitioner had not, in any event, met his burden of providing a persuasive medical theory causally connecting the varicella vaccine to ADEM, as required under Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Decision at 22.

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

BACKGROUND

I. Facts

C.G. was born on February 22, 2007. Ex. 1 at 1, ECF No. 7-1. On April 8, 2015, C.G., then eight years old, had an unremarkable well-child exam performed by her pediatrician, Dr. Melissa Davidson. See Ex. 4 at 1, 40, ECF No. 7-4. During the exam, C.G. received her second dose of the varicella vaccine. See Ex. 1 at 1.

On April 27, 2015, C.G. returned to Dr. Davidson's office with a fever (recorded at 102 degrees) and a sore throat that had started the previous day. Ex. 4 at 1. Dr. Davidson administered a rapid strep test, which was negative, and took a throat culture, which was reported positive to Mr. Giannantonio two days later on April 29. See Ex. 4 at 40; Ex. 7 at 4, ECF No. 7-7.

On Saturday, April 30, at approximately 10 PM, C.G.'s parents took her to the emergency room at Holy Name Medical Center ("Holy Name") in Teaneck, New Jersey. See Ex. 7 at 4. In addition to her sore throat and fever, she presented with "vision disturbance, gait disturbance, poorly tolerating [oral intake]," and "very dilated" pupils. Id. On exam, the doctor reported that C.G. was "ill-appearing," "irritable," had "mild slurred speech," and was "slow to respond, [with] wide based ataxic gait." Id. A throat culture was obtained, and the results were negative. Id. at 2. The doctor prescribed two antibiotics for C.G., ceftriaxone and vancomycin. Id.

The progress notes from Holy Name indicate that the attending physician that evening consulted with Dr. Shira Gertz at the pediatric intensive care unit at Hackensack University Medical Center ("HUMC") to discuss starting C.G. on steroids "for [the] possibility of ADEM." Ex. 7 at 5. The notes reflect that Dr. Gertz wanted to postpone initiating steroid treatment until a

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other similar symptoms; in the most extreme circumstances, ADEM can cause serious motor and sensory defects or even coma. See Ex. 68 (Siegel Rare Neuroimmune Association, Acute Disseminated Encephalomyelitis, https://wearesrna.org/living-with-myelitis/disease-information/acute-disseminated-encephalomyelitis/diagnosis/ (last visited July 18, 2023)) at 3, ECF No. 100-1; see also Ex. 51 (Arayamparambil C. Anilkumar et al, Acute Disseminated Encephalomyelitis, https://www.ncbi.nlm.nih.gov/books/NBK430934/?report=printable (last updated July 17, 2020)) at 2, ECF No. 77-2.

spinal tap (which had so far been deferred because of C.G.'s "unstable condition") could be performed. Id.

Later that night, C.G. was transferred to HUMC for "further management." Id. The transfer form reflects discharge diagnoses that included "AMS [altered mental state], ataxia, [and] ADEM." Ex. 3 at 7, ECF No. 7-3.

C.G. arrived at HUMC at around 1:15 AM, on May 1. Ex. 3 at 31. Dr. Gertz saw her shortly after her arrival and reported that she presented with "altered mental status" and "strep pharyngitis." Id. at 16. Among other things, Dr. Gertz ordered an MRI and a video EEG. Id. at 19.

At around 10 AM the next morning, the chief of pediatric infectious diseases, Dr. Julia Piwoz, visited C.G. Dr. Piwoz reported that C.G.'s symptoms were not consistent with strep throat, observing that she had not improved with treatment. Id. at 24. "Given the progression of her symptom[s]," Dr. Piwoz wrote, she "agree[d] that there is significant concern for ADEM," and that "as such, [she did] not see a contraindication for giving steroids pending results." Id. Like Dr. Gertz, Dr. Piwoz recommended an MRI. Id. at 32. She also recommended that a pediatric neurologist be consulted. Id.

Dr. Felicia Gliksman, a pediatric neurologist, saw C.G. shortly thereafter on the morning of May 1. Id. at 25. In addition to a fever, Dr. Gliksman reported that C.G. had a headache, issues with eye movement, and other central nervous system abnormalities. Id. at 25–26, 29. These symptoms, Dr. Gliksman reported, were "highly suspicious for ADEM, though rarely seen with strep infections." Id. at 29. Dr. Gliksman directed that C.G. should continue taking the antibiotics she prescribed and also ordered an EEG and an MRI, as Drs. Gertz and Piwoz had recommended. Id.

The EEG, which was performed the morning of May 1, was "abnormal" "due to the presence of diffuse slowing," which was "indicative of a diffuse cerebral dysfunction." Id. at 10. An MRI of C.G.'s brain, both with and without contrast, was performed the afternoon of May 1. Id. at 94. The radiologist who read the results, Dr. Sudha Ramachandran, reported that they were "unremarkable." Id.

On May 2, Dr. Gliksman again examined C.G. Id. at 42. Based on her examinations and the results of the MRI and EEG, she now identified C.G.'s diagnosis as "likely viral encephalitis." Id. at 45. Dr. Gliksman also reviewed the MRI again with a neuroradiologist (Dr. Patel). Id. at 46. Dr. Gliksman stated that there was "[n]o evidence of abnormality seen in orbits on this study," but cautioned that it was "obviously not a dedicated study." Id.

On May 3, a team of HUMC doctors reviewed C.G.'s case. Dr. Martha Kutko, an attending physician in the pediatric intensive care unit, opined that C.G. suffered from encephalitis that was "likely post-infectious." Id. at 53. Dr. Kutko reported that C.G. had received the varicella vaccine three weeks earlier but noted that an "[a]dverse vaccine reaction would have occurred within 1–2 weeks as discussed with Dr. Piwoz." Id. at 54.

Dr. Piwoz, for her part, wrote in progress notes that same day that C.G. had "symptoms suggestive of ADEM, responding well to steroids." Id. at 51. Dr. Piwoz directed that acyclovir be discontinued because, she opined, C.G.'s symptoms were "not a result of direct viral invasion but likely an immune-mediated response." Id.

That same day, after learning that C.G. had received the varicella vaccine three weeks earlier, Dr. Gliksman modified her earlier assessment that C.G. suffered from viral encephalitis. She now expressed the opinion that it was "most likely that [C.G.] has an immune mediated polyneuropathy and less likely viral encephalitis," although she could not "fully discount" the latter. Id. at 71. Dr. Gliksman discontinued steroid treatment because C.G. was not improving and was experiencing hallucinations. Id. She started C.G. on intravenous immunoglobulin because of her "lack of substantial neurological improvement." Id.

HUMC's discharge report, written on May 3, 2015, identifies C.G.'s final diagnosis as "altered mental status." Id. at 60.[2] Consistent with Dr. Gliksman's modified view, the report states that her course "seemed more consistent with [an] immune mediated response, and less likely viral encephalitis." Id. at 62.

On May 4, C.G. was transferred to New York-Presbyterian Morgan Stanley Children's Hospital ("Children's Hospital") "for further management and work up." See Ex. 5 at 11, ECF No. 7-5. Dr. James Riviello, a pediatric neurologist at the Children's Hospital, stated that C.G.'s potential diagnoses included "ADEM due to acute onset of mental status changes" but that ADEM was "less likely given a negative MRI." Id. He further stated that an "immune-mediated process is possible given the fact that she received Varivax 3 weeks prior to presentation." Id. Also "still in the differential," he noted, was "a viral encephalitis or post-infectious syndrome."

The Hospital notes summarized C.G.'s recent medical history as involving an "acute onset of an apparent streptococcal illness with then irritability, visual complaints, and ataxia, initially diagnosed as ADEM but with a normal MRI, LP negative for infection but had been pre-treated with antibiotics, then received steroid[s] and [intravenous immune globulin] because she was not improving as quickly as everyone wanted." Id.

On May 6, an audiologist who examined C.G. found "[m]ild to moderately severe sensorineural hearing loss" in both ears. Id. at 27. On May 7, another pediatric neurologist, Dr. Lauren Dunn, evaluated C.G. with Dr. Riviello. Id. at 39. The report of the examination indicated that C.G. was "improving slowly." Id. On May 8, Dr. Riviello reported that he had spent fifteen minutes counseling C.G.'s mother "regarding the diagnosis of likely Miller-Fisher Syndrome, the therapeutic options[,] and that we shall not give any subsequent immune mediated therapy if she continues to improve." Id. at 43.

On May 11, C.G. was discharged from Children's Hospital. Id. at 50. In the discharge report, Dr. Riviello noted that C.G. had improved and was ready to transfer for rehabilitation. Id. at 53. He observed that her "gait remains ataxic with upper extremity dysmetria, with improving ophthalmoplegia." Id. Dr. Riviello also recorded that he had discussed with her mother a

[2] "Altered mental status" is not a specific diagnosis; it is a broad term that encompasses a variety of neurological symptoms. See What Is an Altered Mental Status?, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/diseases/23159-altered-mental-status-ams#:~:text=What%20is%20an%20altered%20mental,in%20awareness%2C%20movement%20and%20behaviors (last visited July 18, 2023); Hai-yu Xiao et al., Evaluation and Treatment of Altered Mental Status Patients in the Emergency Department: Life in the Fast Lane, 3 WORLD J. EMERG. MED. 270, 271 (2012).

"tentative diagnosis of post-infectious disorder, likely Bickerstaff encephalitis versus Miller Fisher syndrome." Id.

After her discharge from Children's Hospital, C.G. received rehabilitation treatment. Ex. 22, ECF No. 12-2. In September 2015, C.G. visited Dr. Steven A. Kane, a pediatric neuro-ophthalmologist, to whom she had been referred by Dr. Riviello. See Ex. 11, ECF No. 8-1. Dr. Kane reported that "[d]eficits involving vision, audition, and cognition persist since [C.G.'s] discharge home." Id. at 2. He opined that "[e]xcept for a lack of neuroimaging evidence the clinical course suggests [ADEM] with demyelination of the optic nerves." Id. at 3. Contrary to Dr. Riviello, Dr. Kane stated that he considered both Miller-Fisher syndrome and Bickerstaff encephalitis unlikely, due to a lack of antibodies suggesting a viral response that would have caused those conditions. Id. at 4. He also stated that it might be "instructive to review the MRI data and even obtain new data to clarify remaining questions about the cause of her condition and the possibility of recurrence, if a normal MRI of the brain during the early phase of ADEM is felt possible." Id.

On November 17, 2015, C.G. visited another pediatric neurologist, Dr. Wendy Vargas. Ex. 36 at 11–13, ECF No. 55-1. Dr. Vargas observed that C.G.'s "story is typical of postinfectious encephalitis, with development of neurologic symptoms days after febrile illness." Id. at 13. "However," Dr. Vargas stated, "her MRI is not typical of ADEM." Id. Dr. Vargas indicated that she wished to review the original MRI of C.G.'s brain and see her for a follow-up appointment in six months. Id.

At the follow-up appointment in May 2016, Dr. Vargas reported that she personally reviewed C.G.'s May 2015 MRI and determined that it was normal. Id. at 10. She stated that she found it "odd" that the MRI was "completely normal" and that C.G. "ha[d] not recovered her vision or hearing more significantly." Id. Her assessment was that C.G. suffered from post-infectious encephalitis. Id.

Dr. Vargas ordered another MRI, with and without contrast, which was performed on June 20, 2016. See id. at 19–20. The attending radiologist, Dr. Utukuri, reported that the MRI of the brain and orbit was "[u]nremarkable." Id. at 20.

Dr. Vargas continued to treat C.G. over the next several years. Ex. 66, ECF No. 92-1. In a report covering an October 29, 2019 visit, Dr. Vargas observed that C.G.'s "stability over the last 4 years and lack of new symptoms suggest that she had a monophasic course and her current vision and hearing issues are residual from her initial event." Id. at 16.

On November 24, 2020, Dr. Vargas reported that C.G. had a "history of post-infectious autoimmune encephalitis, now with residual left vision loss and hearing impairment." Id. at 12. Dr. Vargas noted that C.G.'s headaches, as well as her mood, had improved. Id. She also noted that she had discussed the novel COVID-19 vaccines, and that "given her profound neurological impairment in the setting of Varivax, [C.G.] should not receive further vaccinations." Id.

C.G. saw Dr. Vargas again a year later, on November 23, 2021. Ex. 73, ECF No. 113-4. Dr. Vargas reported that C.G.'s vision and hearing were stable since her last visit. Id. at 17. Now 14 years old, C.G. was interested in getting a COVID vaccine. Id. Dr. Vargas advised her that a recent study had shown that "mRNA vaccines are safe even in those with previous neurological

autoimmune diseases," and noted that she "would be happy to support [C.G.] in either decision (to vaccinate or not)." Id. at 21.

II. Proceedings Before the Special Master

On April 4, 2018, Mr. Giannantonio filed a petition seeking compensation for C.G. pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1–34. Pet. In that petition, Mr. Giannantonio sought compensation for injuries C.G. allegedly sustained "after receiving the Varicella vaccine on April 8, 2015, specifically: hearing loss, vision loss, encephalopathy, ADEM, Miller Fisher Syndrome variant of GBS, encephalitis, emotional/psychological distress, and/or a significant aggravation of an underlying condition/symptom(s)." Pet. at 1.

The case was assigned to Special Master Moran on April 4, 2018. ECF No. 4. Mr. Giannantonio filed affidavits and medical records on April 25, 2018, ECF Nos. 7–8; June 18, 2018, ECF No. 11; and July 6, 2018, ECF No. 12. He filed a Statement of Completion on July 6, 2018, ECF No. 13, in accordance with Rule 2(f) of the Vaccine Rules of the United States Court of Federal Claims (the "Vaccine Rules").

The Secretary filed his report under Vaccine Rule 4(c) on September 17, 2018, opposing the petition for compensation and contending that many of C.G.'s medical records had not been provided. Resp't's Report, ECF No. 16. Over the next four-plus years the Petitioner continued to file additional medical records as well as medical literature. See Ex. 24, ECF No. 18; Ex. 25, ECF No. 23; Ex. 26–27, ECF No. 28; Ex. 29, ECF No. 34; Ex. 30–31, ECF No. 37; Ex. 32, ECF No. 41; Ex. 33–34, ECF No. 45; Ex. 35, ECF No. 50; Ex. 36–38, ECF No. 55; Ex. 39, ECF No. 56; Ex. 63–65, ECF No. 88; Ex. 66, ECF No. 92; Ex. 70–74, ECF No. 113. In addition, the parties submitted two sets of expert reports each in 2020 and 2021. Ex. 40, ECF No. 62; Ex. A, ECF No. 70; Ex. 49, ECF No. 74; Ex. C, ECF No. 84.

III. The Special Master's Decision

On February 1, 2023, the special master issued an opinion denying compensation. He supplied two independent grounds for his decision. First, he found that Mr. Giannantonio failed to show by preponderant evidence that C.G. suffered from ADEM. Decision at 13–18. Second, he concluded that Mr. Giannantonio had failed to present a persuasive theory to show how the varicella vaccine could cause ADEM, as required to establish entitlement to compensation under prong 1 of the three-part test set forth in Althen, 418 F.3d at 1278. Id. at 18–22.

The special master relied on the so-called "Krupp" diagnostic criteria for ADEM in determining that Mr. Giannantonio had not established that C.G. suffered from that condition. Id. at 14–15 (citing Ex. A-1 (Krupp et al., International Pediatric Multiple Sclerosis Study Group Criteria for Pediatric Multiple Sclerosis and Immune-Mediated Central Nervous System Demyelinating Disorders: Revisions to the 2007 Definitions, 19(10) MULTIPLE SCLEROSIS J. 1261, (2013)) at 1262, ECF No. 71-1 ("Krupp Criteria")). Under those criteria, which other special masters have endorsed and employed,[3] an ADEM diagnosis requires the presence of the

[3] See O.M.V. v. Sec'y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *1 (Fed. Cl. Spec. Mstr. June 16, 2021), mot. for rev. denied, 157 Fed. Cl. 376 (2021); Orloski v. Sec'y of Health & Hum. Servs., No. 17-936V, 2019 WL 7565495, at *9 (Fed. Cl. Spec. Mstr. Oct. 31,

following: 1) "[a] first polyfocal, clinical CNS event with presumed inflammatory demyelinating cause;" 2) "[e]ncephalopathy that cannot be explained by fever;" 3) "[n]o new clinical and MRI findings [that] emerge three months or more after the onset;" and 4) a "[b]rain MRI [that] is abnormal during the acute (three-month) phase" typically showing "[d]iffuse, poorly demarcated, large (>1-2 cm) lesions involving predominantly the cerebral white matter." Id.

The Special Master credited the opinion of the government's expert, Dr. Michael Kruer, that—applying the Krupp criteria—C.G.'s unremarkable MRIs were "incompatible with [a diagnosis of] ADEM." Id. at 15 (citing Expert Report of Michael C. Kruer, MD ("Expert Report of Dr. Kruer"), ECF No. 70-1). He was not persuaded by the contrary view of Petitioner's expert, Dr. Georges Ghacibeh, who opined that at the time C.G. underwent her first MRI, it was too early in the disease process for an MRI to identify the lesions that are typically found on an individual suffering from ADEM. Instead, the special master credited Dr. Kruer's critique of Dr. Ghacibeh's reasoning, finding that Dr. Kruer had "persuasively shown" that the study on which Dr. Ghacibeh had relied (Jari Honkaniemi et al., Delayed MR Imaging Changes in Acute Disseminated Encephalomyelitis, 22 AM. J. NEURORADIOL. 1117 (2001)) was outdated because in the ensuing years "the magnets used in MRIs have gotten stronger, increasing the ability to detect lesions." Id. at 16 (citing Ex. A-2 to Expert Report of Dr. Kruer (Birgit Simon et al., Improved in vivo detection of cortical lesions in multiple sclerosis using double inversion recovery MR imaging at 3 Tesla, 20 EUR. RADIOL. 1675 (2010)), ECF No. 71-2).

The special master also cited Mr. Giannantonio's failure to present direct evidence of central nervous system inflammation. See Decision at 16. As noted, the Krupp criteria state that an ADEM diagnosis requires the patient to experience a "polyfocal, clinical CNS event with presumed inflammatory demyelinating cause." See Krupp Criteria at 1262. The special master found that while Mr. Giannantonio had argued that certain of C.G.'s symptoms were consistent with neuroinflammation, he did not rebut the government's argument that her symptoms could have also been consistent with other conditions. See Decision at 16 (citing Resp.'s Mem. at 30, ECF No. 109).

The special master also noted the lack of clarity and consensus on the part of C.G.'s treating physicians as to the cause of her symptoms and the proper diagnosis. Id. at 17 (observing that "whether [C.G.'s] symptoms amounted to ADEM befuddled her doctors," and that other possible diagnoses included viral encephalitis, Miller-Fisher Syndrome, and an unspecified polyneuropathy). "The lack of clarity from the treating doctors does not help Mr. Giannantonio," the special master reasoned, "because, ultimately, he bears a burden of demonstrating, by preponderant evidence, that C.G. suffered from the disease a vaccine allegedly caused." Id.

Finally, the special master found that even if Mr. Giannantonio had proven that C.G. suffered from ADEM, he had failed to provide a persuasive medical theory that causally connected the varicella vaccine to ADEM. Id. at 18 (citing Althen, 418 F.3d at 1278). Mr. Giannantonio's expert, the special master found, did not provide any evidence or explanation of the precise biological mechanisms that would result in a patient suffering an autoimmune reaction to a varicella vaccine that would lead to ADEM. See id. at 21. Therefore, he concluded,

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2019), mot. for rev. denied, 147 Fed. Cl. 713 (2020), aff'd, 839 F. App'x 538 (Fed. Cir. 2021); Spracklen v. Sec'y of Health & Hum. Servs., No. 16-559V, 2019 WL 4201572, at *4-5 (Fed. Cl. Spec. Mstr. July 31, 2019).

"the evidence in this case is not sufficiently robust to meet Mr. Giannantonio's burden under Althen prong 1." Id.

III. The Motion for Review

Mr. Giannantonio filed a motion for review of the special master's Decision on March 3, 2023. Mot. for Review, ECF No. 118. In that motion, Mr. Giannantonio argues that the special master's decision that preponderant evidence did not show that C.G. suffered from ADEM is arbitrary and capricious. He contends that the special master: 1) overemphasized the import of the fact that C.G.'s May 1, 2015 MRI did not reveal lesions as required under the diagnostic criteria for ADEM, and 2) failed to give proper weight to the opinion of his expert, Dr. Ghacibeh, "a well-respected and highly accredited neurologist" whose "conclusion that C.G. had a clear ADEM diagnosis," he claims, "was supported by both the medical records and the medical literature." Id. at 12.

The government takes issue with Mr. Giannantonio's argument that the special master focused excessively on C.G.'s MRI results and argues that the special master acted within his discretion when he credited the opinion of the government's expert over that of Petitioner's. See Resp. at 8–12, ECF No. 121. The motion for review and supporting brief, the government contends, constitute "nothing more than a request for this Court to reweigh the evidence, which is impermissible." Id. at 7.

This case is now fully briefed. The Court has determined that oral argument is unnecessary.

DISCUSSION

I. Standard of Review

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. Figueroa v. Sec'y of Health & Hum. Servs., 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). The Act is "[r]emedial legislation" which "should be construed in a manner that effectuates its underlying spirit and purpose." Id. at 1317 (alteration in original) (citing Cloer v. Sec'y of Health & Hum. Servs., 675 F.3d 1358, 1362 (Fed. Cir. 2012)).

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. Id. § 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. Further, 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).

The motion for review in this case does not challenge a legal determination. Rather, it challenges the special master's factual determination that Mr. Giannantonio did not prove that C.G. suffered from ADEM. The Court has the authority to set such determinations aside only where they are arbitrary, capricious, and/or reflect an abuse of discretion. Moberly, 592 F.3d at 1321. This standard of review is "uniquely deferential." 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)). The Court may not reweigh the evidence nor examine its probative value or the credibility of the witnesses, for 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 v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010)). Therefore, if a special master "'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,' 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. Failure to Seek Review of Special Master's Ruling that the Petitioner Did Not Meet Burden Under Althen Prong 1

Mr. Giannantonio's motion for review is focused entirely on the reasonableness of the special master's finding that he failed to prove that C.G. suffered from ADEM, the injury he alleges was caused by the varicella vaccine. He does not challenge the special master's alternative finding that—even had he proven that C.G. did, in fact, suffer from ADEM—his claim for compensation would nonetheless fail because he did not satisfy the requirement of Althen prong 1. See Decision at 21.[4]

[4] Under prong 1 of the Althen causation-in-fact standard Mr. Giannantonio had the burden of supplying a "reputable medical or scientific explanation" linking the receipt of a varicella vaccine to the development of ADEM. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Moberly, 592 F.3d at 1322). Prong 2 requires a petitioner to prove by preponderant evidence a logical sequence of cause and effect showing that the vaccination was the reason for the injury. And prong 3 requires him to establish a proximate temporal relationship between the vaccination and the alleged injury. 418 F.3d at 1278. Because

In its response brief, the government contends that, in light of the special master's alternative holding, even were the Court to disagree with the special master's finding that Petitioner failed to prove that C.G. suffered from ADEM, the error would be a "harmless" one. Resp. at 10 n.4. Mr. Giannantonio, for his part, takes the position that the special master only "briefly discussed the first prong of Althen, [and] he did not complete a full analysis of the Althen standard, since he declared the matter irrelevant based solely on the lack of MRI findings." Pet'r's Reply at 10 (citing Decision at 22), ECF No. 122. According to Mr. Giannantonio, "the Decision does not contain a true analysis of anything beyond the incorrect analysis that led to the conclusion that C.G. did not establish a diagnosis of ADEM." Id.

Mr. Giannantonio's characterization of the special master's analysis of Althen prong 1 as "incomplete" is inaccurate. The special master devoted an entire section of his opinion to an analysis of whether Dr. Ghacibeh had supplied a sound theory regarding how a varicella vaccine might cause ADEM. Decision 18–22. He discussed both experts' written statements in some depth, as well as the medical literature that Mr. Giannantonio cited, and the Secretary's arguments regarding his failure to meet his burden of proof. Id. at 18–21. And finally, he closed his discussion by expressly finding, as noted above, that "the evidence in this case is not sufficiently robust to meet Mr. Giannantonio's burden on Althen prong 1." Id. at 21. He observed that some of the medical literature "could supply a foundation for the presentation of a more developed and more persuasive theory." Id. at 22. Nonetheless, he concluded that Mr. Giannantonio had not only failed to present preponderant evidence that C.G. suffered from ADEM; he had also "fail[ed] to present a persuasive theory to show how the varicella vaccine could cause ADEM (assuming C.G. had ADEM)." Id. at 21–22; see also id. at 22 (stating in conclusion that "even if ADEM had been established as an appropriate diagnosis, the evidence explaining how a varicella vaccine could cause ADEM was unpersuasive").

Mr. Giannantonio asserts in his reply brief that if the special master had "afforded the proper weight to the evidence on the record and particularly to Dr. Ghacibeh's credibility, the conclusions drawn in his analysis of the first Althen prong may differ." Pet'r's Reply at 10. Similarly, he asserts that had the special master heard live testimony, his analysis of Althen prong 1 "may have differed significantly." Id. But these barebones assertions appear for the first time in Petitioner's reply brief; they were not so much as mentioned in his motion for review, which included two numbered objections: 1) that the Special Master erred in concluding that Mr. Giannantonio did not establish a diagnosis of ADEM and 2) that he also erred in not assigning sufficient weight to Dr. Ghacibeh's opinion regarding that diagnosis. See Mot. for Review at 8.

Under Vaccine Rule 24, a petitioner moving for review of a special master's decision must include a "statement of objections" with his motion, which must "fully and specifically state and support each objection to the decision, including specific citations to the record created by the special master (e.g., to specific page numbers of the transcript, exhibits, or other papers)." Further, it is well established that "[r]aising [an] issue for the first time in a reply brief does not suffice; reply briefs reply to arguments made in the response brief—they do not provide the moving party with a new opportunity to present yet another issue for the court's consideration."

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the special master found that C.G. did not have ADEM and that prong 1 had not been satisfied, he found it unnecessary to address whether prongs 2 and 3 were met. Decision at 22.

Novosteel SA v. U.S., Bethlehem Steel Corp., 284 F.3d 1261, 1274 (Fed. Cir. 2002). And even if an objection could be raised for the first time in a reply, Mr. Giannantonio did not develop any arguments he might have regarding Althen prong 1 in his reply brief.

For those reasons, the Court is of the view that Mr. Giannantonio has waived any objection to the special master's adverse finding as to Althen prong 1. Because that finding, on its own, is sufficient to justify a denial of compensation, the Court must sustain the special master's decision. Cf. Sapuppo v. Allstate Floridian Ins. Co., 739 F.3d 678, 680 (11th Cir. 2014) ("When an appellant fails to challenge properly on appeal one of the grounds on which the district court based its judgment, he is deemed to have abandoned any challenge of that ground, and it follows that the judgment is due to be affirmed."); In re Zantac (Ranitidine) Prod. Liab. Litig., No. 21-10335, 2022 WL 16729170, at *7 (11th Cir. Nov. 7, 2022) (holding that "to obtain reversal of a district court judgment that is based on multiple, independent grounds, an appellant must convince us that every stated ground for the judgment against him is incorrect," and that "[w]hen an appellant fails to challenge properly on appeal one of the grounds on which the district court based its judgment, he is deemed to have abandoned any challenge of that ground, and it follows that the judgment is due to be affirmed"); Nagle v. Alspach, 8 F.3d 141, 143 (3d Cir. 1993) (where the plaintiffs/appellants did not contest "two of the four independent grounds upon which the district court based its grant of summary judgment, each of which is individually sufficient to support that judgment, we must affirm").

III. The Special Master's Finding that Petitioner Failed to Prove By Preponderant Evidence that C.G. Suffered from ADEM

As noted, in his motion for review, Mr. Giannantonio argues that it was arbitrary and capricious for the special master to find: 1) that preponderant evidence did not show that C.G. suffered from ADEM and 2) that the testimony of the government's expert, Dr. Kruer, was more persuasive than that of the petitioner's expert, Dr. Ghacibeh. Mot. for Review at 9–12. Specifically, he argues that the special master assigned too much importance to the fact that C.G.'s MRIs did not reveal the presence of lesions on her brain. Id. at 10–11. He further contends that the special master did not assign sufficient weight to the opinion of Dr. Ghacibeh that—despite the results of C.G.'s MRI—C.G.'s clinical presentation was sufficient to support an ADEM diagnosis. Id. at 12.

Assuming that the Court were to reach these arguments (notwithstanding that Mr. Giannantonio noted no objection to the special master's finding regarding his failure of proof with respect to prong 1 of Althen), they are unavailing because they involve the type of determinations regarding the weight to be assigned to evidence that are committed to the discretion of the special master. See Lozano v. Sec'y of Health & Hum. Servs., 958 F.3d 1363, 1370 (Fed. Cir. 2020) ("Where both sides offer expert testimony, a special master's decision may be 'based on the credibility of the experts and the relative persuasiveness of their competing theories.'") (quoting Broekelschen, 618 F.3d at 1347). Indeed, the court of appeals has observed that where a special master's decision is based on his resolution of conflicting expert testimony, his "credibility findings 'are virtually unchallengeable on appeal.'" Id.

As noted, in contesting the special master's determination that C.G. did not suffer from ADEM, Mr. Giannantonio primarily argues that the special master "over-emphasiz[ed] the importance of both the May 1, 2015, MRI and the overall importance of an abnormal MRI in confirming a diagnosis of ADEM." Mot. For Review at 10 (citing Decision at 12–17). He further

contends that "[w]hile the appearance of lesions on an MRI may help to support a diagnosis of ADEM, it is not necessarily dispositive." Id.

The special master, however, did not find the negative MRI "dispositive" as to whether C.G. suffered from ADEM. What he found was that the absence of lesions on the MRI made an ADEM diagnosis more unlikely. That finding was consistent with the diagnostic criteria for ADEM, which require a "[b]rain MRI [that] is abnormal during the acute (three-month) phase" typically showing "[d]iffuse, poorly demarcated, large (>1-2 cm) lesions involving predominantly the cerebral white matter." Krupp Criteria at 1262. It was also consistent with the views of the government's expert, Dr. Kruer, who went further, characterizing C.G.'s MRI results as "incompatible" with an ADEM diagnosis. See Expert Report of Dr. Kruer at 4.[5]

To be sure, petitioner's expert, Dr. Ghacibeh, was of the view that the initial MRI was taken "too early in the course of the illness, probably before lesions typically develop." Suppl. Expert Report of Georges A. Ghacibeh, MD, Ex. 49, at 2, ECF No. 74-1.[6] He further stated that it was "[o]f note [that] the images were degraded by motion artifact, and therefore, subtle lesions could have been missed." Id. But Dr. Ghacibeh based his opinion in large part on a study performed in 2001, which the special master found Dr. Kruer had "persuasively shown provides little helpful information." Decision at 16. Specifically, Dr. Kruer was of the view that the study was outdated given improvements in MRI imaging since 2001. See Expert Report of Dr. Kruer, Ex. C, at 4 (citing id. Ex. A-2 (Birgit Simon et al., Improved in vivo Detection of Cortical Lesions in Multiple Sclerosis Using Double Inversion Recovery MR Imaging at 3 Tesla)); see also Suppl. Expert Report of Michael C. Kruer, MD at 3, ECF No. 84-1 (critiquing Dr. Ghacibeh's reliance on Khurana, et al. (2005)).

Moreover, the special master's determination that the negative MRI results made it less likely that C.G. suffered from ADEM is consistent with the effect those results had on the interpretation of her symptoms by her treating physicians. Before C.G. underwent an MRI on May 1, several of her treating physicians raised the possibility that C.G. was suffering from ADEM. Ex. 7 at 5 (attending physician at Holy Name consulting with Dr. Gertz at HUMC pediatric intensive care unit regarding steroid treatment based on the "possibility of ADEM"); Ex. 3 at 24 (Dr. Piwoz recording "significant concern for ADEM"); id. at 25–26, 29 (Dr. Gliksman, pediatric neurologist, stating that symptoms were "highly suspicious for ADEM").

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[5] Dr. Kruer is a board-certified pediatric neurologist and fellowship-trained neuroimmunologist. He is a member of the pediatric neuroimmunology section within the Barrow Neurological Institute at Phoenix Children's Hospital. Ex. B (Curriculum Vitae of Michael C. Kruer, MD), ECF No. 70-2.

[6] Dr. Ghacibeh is a board-certified neurologist. Ex. 63 (Curriculum Vitae of Georges A. Ghacibeh, MD), ECF No. 88-1. His C.V. does not reflect any certification or special training in pediatric neurology or neuroimmunology. In his brief, Mr. Giannantonio characterizes Dr. Ghacibeh as "a well-respected and highly accredited neurologist, both within the VICP and the larger medical community." Mot. for Review at 12 (citing Ex. 63). He further asserts (without supporting citation) that Dr. Ghacibeh's "opinions have been regarded as credible and persuasive on many occasions." Id. That may be the case, but the Court has been unable to confirm the assertions as a Westlaw search does not reveal any mention of Dr. Ghacibeh's participation in any case arising under the Vaccine Act.

But when the May 1 MRI came back negative, they acknowledged that an ADEM diagnosis was less likely, and floated other possible causes for C.G.'s symptoms. See Ex. 3 at 45 (Dr. Gliksman's May 2 observation that C.G.'s symptoms likely indicated "viral encephalitis"); id. at 62 (May 4 Hackensack discharge summary stating that C.G.'s symptoms "seemed more consistent with immune mediated response, and less likely viral encephalitis); Ex. 5 at 11 (Dr. Riviello's May 4 report that ADEM "is less likely given a negative MRI"); id. at 19 (Dr. Sebrow's May 5 conclusion that C.G. likely suffered from "miller-fisher variant or viral-post infectious encephalitis"); id. at 35 (Doctors Riviello and Dunn's May 6 notation that the symptoms were "highly suspicious for autoimmune etiology," but "also concerning for Miller Fisher variant"); Ex. 11 at 2 (discounting Miller-Fisher syndrome based on absence of antibodies); Ex. 36 at 13 (Dr. Vargas' October 2015 statement that C.G.'s "MRI is not typical of ADEM.").

While the doctors at Holy Name, not having the benefit of any MRI results, included ADEM among the diagnoses on the form memorializing C.G.'s transfer to HUMC, neither HUMC nor Children's Hospital mentioned ADEM in C.G.'s discharge reports. The doctors who treated C.G. at these facilities reached no consensus regarding the root cause of her symptoms and while some believed that they "suggested" or were "suspicious" for ADEM; only Dr. Ghacibeh, Mr. Giannantonio's expert, committed to the diagnosis of ADEM. But the special master rejected his reasoning, finding Dr. Kruer's critiques more persuasive.

Finally, the Court notes that—in addition to the MRI result that was inconsistent with the diagnostic criteria for ADEM—the special master also found that Mr. Giannantonio had not shown by preponderant evidence that C.G. had experienced inflammation of her central nervous system, another of the four diagnostic criteria for ADEM. Dr. Kruer, for his part, opined that there was "no evidence" of such inflammation. Expert Report of Dr. Kruer at 4. Dr. Ghacibeh, on other hand, asserted that "[n]euroinflammation was indisputably demonstrated in CG's case, based on her clinical presentation of ataxia, altered mental status, and optic neuritis, all signs of severe involvement of the CNS." Suppl. Expert Report of Georges A. Ghacibeh, MD at 2. But Dr. Kruer responded that Dr. Ghacibeh's statement is "quite simply incorrect" because "ADEM is not the only possible diagnosis that may lead to such symptoms," and because "a number of neurogenetic disorders (that do not involve neuroinflammation) may present in a similar manner." Suppl. Expert Report of Michael C. Kruer, MD at 2.

The special master found that "[o]n the specific point regarding whether C.G.'s presentation was consistent with inflammation in the central nervous system, each expert offers a plausible interpretation of C.G.'s medical records." Decision at 16. Ultimately, however, he found "little persuasive evidence that C.G. experienced inflammation in her central nervous system." Id. at 18.

In short, the special master relied on the accepted diagnostic criteria for ADEM in reaching his decision. He fully considered C.G.'s medical records, the medical literature, and the opinions of the parties' experts. The inferences he drew from the evidence were reasonable, and he acted within his discretion in finding that the government's expert was more credible than Mr. Giannantonio's. The Court therefore lacks any basis for setting the special master's decision aside.

CONCLUSION

For the foregoing reasons, the Motion for Review, ECF No. 118, is **DENIED**. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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