In the United States Court of Federal Claims

CRISTIAN GARCIA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 21-1601V (Filed Under Seal: June 12, 2025 Reissued for Publication: June 27, 2025)[*]

Ronald C. Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Felicia D. Langel, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, with whom were Julia M. Collison, Assistant Director, Heather L. Pearlman, Deputy Director, C. Salvatore D'Alessio, Director, and Yaakov M. Roth, Acting Assistant Attorney General, for Respondent.

OPINION AND ORDER

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"). Petitioner, Cristian Garcia, alleges that he developed anti-N-methyl-D-aspartate receptor ("anti-NMDAR" or "anti-NMDA receptor") encephalitis as a result of receiving the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine. See Decision of Spec. Mstr., ECF No. 64 [hereinafter "Dec."]; see also Garcia v. Sec'y of Health & Hum. Servs., 2025 WL 1544677, 2025 U.S. Claims LEXIS 1412 (Fed. Cl. Spec. Mstr. Jan. 3, 2025). Chief Special Master Brian Corcoran denied entitlement on the grounds that Mr. Garcia failed to satisfy prongs one and two of the three-pronged test of causation set forth in Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274 (Fed. Cir. 2005). The Chief Special Master held that: 1) Petitioner did not provide a medical theory based on a "sound and reliable medical or scientific explanation" supporting his assertion that the Tdap vaccine can cause anti-NMDAR encephalitis (prong one), see Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355–56 (Fed. Cir. 2006); and 2) Petitioner did not provide a logical sequence of cause and effect showing that the vaccination did cause his injury (prong two).

[*] Pursuant to Vaccine Rule 18(b), this opinion was initially filed on June 12, 2025, 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.

The case is currently before the Court on Petitioner's motion for review. Pet'r's Mot. for Rev., ECF No. 65. In his motion, Petitioner alleges that the Chief Special Master's findings were not based on the record as a whole, as required by statute, because the Chief Special Master allegedly failed to take into consideration two reports that the Petitioner's expert prepared in response to the reports of the Secretary's experts.

For the reasons set forth below, the Court finds that Petitioner has not established that the Chief Special Master failed to consider the two reports at issue and that, even if he did, such error was harmless. Petitioner's motion for review is therefore **DENIED**.

BACKGROUND

I. Mr. Garcia Is Diagnosed with Anti-NMDAR Encephalitis

The factual background of this case is set forth in the Chief Special Master's decision. Dec. at 2–5. To summarize, Mr. Garcia received the Tdap vaccine on October 2, 2020. Pet'r's Ex. 1, at 4, ECF No. 13-1. He was then twenty-six years old, had no history of neurological problems, and had never before experienced any adverse reaction to a vaccine. See Pet'r's Ex. 7, at 7–14, ECF No. 13-7.

On October 20, 2020, eighteen days after he received the vaccine, Mr. Garcia had a seizure while driving, marking the onset of his disease. See Pet'r's Ex. 4, at 31–33, ECF No. 13-4; Pet'r's Ex. 3, at 5–6, ECF No. 13-5; Pet'r's Ex. 7, at 16, 21. After experiencing worsening symptoms and undergoing a series of tests, see, e.g., Pet'r's Ex. 4, at 11, 16, 18; Pet'r's Ex. 3, at 8; Pet'r's Ex. 6, at 22, 27, 31–34, 37–39, 44–45, ECF No. 13-6; Pet'r's Ex. 15, at 64–67, ECF No. 21-3; Pet'r's Ex. 5, at 2, 70, ECF No. 13-5, Mr. Garcia was diagnosed with anti-NMDAR encephalitis, Pet'r's Ex. 8, at 135, 162, ECF No. 13-8.

Anti-NMDAR encephalitis is an autoimmune, neuroinflammatory disease. Its exact etiology is in many cases unknown. It results when specific antibodies, known as NMDA receptor antibodies, bind to a certain subunit of NMDA receptors found in the central nervous system and block their proper functioning. Dec. at 6–7, 11. Symptoms of anti-NMDAR encephalitis include seizures, confusion, agitation, speech disturbances, depressed consciousness, and autonomic instability. Hr'g Tr. 16:7–11, ECF No. 63.

After his diagnosis, Mr. Garcia received a variety of treatments. Although he had shown signs of "significant recovery," as of 2022, he continued to suffer from lingering neurological symptoms. See Pet'r's Ex. 8, at 18–41, 79, 84; Pet'r's Ex. 13, at 4–5, 8–9, 101, 104, ECF No. 21-1.

II. Petitioner's Theory of Causation

Petitioner's expert in this case was Kristen Babinski, MD, PhD.[1] Dr. Babinski prepared an expert report in support of Petitioner's claim. Pet'r's Ex. 18, ECF No. 32-1. She also prepared

[1] Dr. Babinski received a bachelor's degree in biochemistry from Colgate University, a PhD in biochemistry from Duke University, and an MD from the University of North Carolina School of Medicine. Pet'r's Ex. 19, at 1, ECF No. 32-2. She was a Neurology Resident, Neurology Chief

written responses to the opinions of the government's two experts, Jagannadha Avasarala, MD, PhD, and Stephen Hedrick, PhD. Pet'r's Ex. 45, ECF No. 38-1; Pet'r's Ex. 50, ECF No. 60-1. In addition, she testified at the entitlement hearing.

In her expert report, Dr. Babinski discussed the prevalence of anti-NMDAR encephalitis following vaccination as reflected in the medical literature[2] and the Vaccine Adverse Events Reporting System ("VAERS") database.[3] She acknowledged that "the mechanism for vaccine induced anti-NMDAR encephalitis is unclear," but identified three possible theories to support the existence of such a mechanism. Pet'r's Ex. 18, at 6–7.

Resident, and Multiple Sclerosis (Neurology) Fellow at the New York University School of Medicine. Id. She currently serves as the Assistant Professor of Neurology and Director of Multiple Sclerosis at Tufts Medical Center. Id.

[2] The medical literature cited reported the cases of: 1) a 15-year-old girl who showed symptoms of the illness five weeks after administration of a booster vaccination against tetanus/diphtheria/pertussis and polio (Tdap-IPV), Pet'r's Ex. 18, at 5 (citing Pet'r's Ex. 33, ECF No. 32-16 (Hofmann et al. (2011))); 2) a 22-year-old woman whose symptoms developed three days after receiving a Tdap-IPV booster, id. (citing Pet'r's Ex. 27, ECF No. 32-10 (Endres et al. (2019))); 3) two patients who developed the disorder after vaccination against H1N1 influenza, id. at 6 (citing Pet'r's Ex. 25, ECF No. 32-8 (Dalmau et al. (2011))); and 4) a two-year-old child who developed anti-NMDAR encephalitis 17 days after receiving the second dose of the Japanese encephalitis vaccination, id. (citing Pet'r's Ex. 40, ECF No. 32-23 (Wang (2017))). In addition, Dr. Babinski cited a case report published in 2017 which "describe[d] a patient who developed postural orthostatic tachycardia syndrome (POTS) with a positive serum anti-NMDA receptor antibody, without evidence of encephalitis, after vaccination with a bivalent human papilloma-virus (HPV) vaccine, Cervarix." Id. (citing Pet'r's Ex. 21, ECF No. 32-4 (Blitshteyn & Brook (2017))). She also cited literature which reported "four cases of autoimmune encephalitis after vaccination against yellow fever," three of whom developed anti-NMDAR encephalitis." Id. (citing Pet'r's Ex. 24, ECF No. 32-7 (Coeckelbergh & Reynders (2021)); Pet'r's Ex. 32, ECF No. 32-15 (Guedes et al. (2021))). Finally, Dr. Babinski observed "anti-NMDAR encephalitis was also reported following administration of the Pfizer-BioNTech and BNT162b2 COVID-19 vaccines in 2021 and 2022, respectively." Id. (citing Pet'r's Ex. 29, ECF No. 32-12 (Flannery et al. (2021)); Pet'r's Ex. 35, ECF No. 32-18 (Lee et al. (2022))).

[3] VAERS "is a national early warning system to detect possible safety problems in U.S.-licensed vaccines," and it "accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination." Dec. at 7 n.10 (quoting About VAERS, Vaccine Adverse Event Reporting System, https://vaers.hhs.gov/about.html (last visited April 16, 2025)). According to Dr. Babinski, the VAERS database for autoimmune encephalitis and vaccines produced 74 reports, three of which were associated with the Tdap vaccine, one with the DTaP (diphtheria and tetanus toxoids and acellular pertussis) vaccine, one with the DTaP-IPV (DTaP plus inactivated poliovirus vaccine), and one with the DTaP-IPV-HIB (DTaP, inactivated poliovirus, and Haemophilus B conjugate vaccine). Pet'r's Ex. 18, at 6.

The first theory, she said, "suggests that there may be an exacerbation of an underlying systemic autoimmune disease with central nervous system activity following vaccination." Pet'r's Ex. 18, at 6; see also Hr'g Tr. 22:14–16. She observed that "[i]t has been shown that the influenza vaccination can transiently increase anti-nuclear antibodies (ANA) and anti-double-stranded DNA titers in patients with systemic lupus erythematosus." Pet'r's Ex. 18, at 6 (citing Pet'r's Ex. 42, ECF No. 32-25 (Wiesik-Szewczyk et al. (2010))). In addition, "[i]t has also been reported that patients with relapsing-remitting multiple sclerosis develop relapses and new MRI lesions after YF (yellow fever) 17D-204 immunization." Id. (citing Pet'r's Ex. 28, ECF No. 32-11 (Farez & Correale (2011))).

A second hypothesis, according to Dr. Babinski, "suggests that some individuals have pre-existing specific T- and B-cell lymphocyte clones that are re-stimulated by vaccination," which "causes them to proliferate and synthesize excess antibodies." Id. (citing Pet'r's Ex. 27, ECF No. 32-10 (Endres et al. (2019))). Dr. Babinski observed that "[r]esearch has shown that antibody-secreting cells releasing functional NMDA receptor antibodies are part of the human naïve B-cell repertoire and might be much more common than previously assumed." Id. (citing Pet'r's Ex. 41, ECF No. 32-24 (Wenke (2019)))." She theorized that "[a] vaccine's effect of boosting antibody production may lead to a transient increase in the NMDA receptor antibody levels, thereby causing clinical symptoms and detectable antibodies." Id. (citing Pet'r's Ex. 27 (Endres et al. (2019))).

At the hearing, Dr. Babinski further explained that—to become pathogenic—the circulating NMDA receptor antibodies would need to cross the blood-brain barrier. Hr'g. Tr. 26:6–27:1. She posited that cytokines generated by a vaccination can alter the permeability of the blood-brain barrier, allowing antibodies to cross into the central nervous system. See Hr'g Tr. 27:4–15, 28:14–16. There, the antibodies bind to the NMDA receptors in the brain causing the symptoms associated with anti-NMDAR encephalitis.

As a final theory, Dr. Babinski noted that "the association between anti-NMDA receptor encephalitis and vaccination" had been investigated "by analyzing the phylogenetic relationship of microRNAs (miRNAs) and the phylogenetic relationship of certain viruses and bacteria." Pet'r's Ex. 18, at 6 (citing Pet'r's Ex. 40, ECF No. 32-23 (Wang (2017))). She explained that "miRNAs are small RNA molecules approximately 22 nucleotides long that can upregulate or downregulate their target gene expression post-transcriptionally." Id. (citing Pet'r's Ex. 23, ECF No. 32-6 (Chuang & Jones (2007))). Dr. Babinski postulated that "[r]esults of [the Wang] study showed that from a phylogenetic perspective, anti-NMDAR encephalitis could be caused by Japanese encephalitis virus vaccination, H1N1 influenza vaccination and DPT-polio vaccination." Id. at 6–7 (citing Pet'r's Ex. 40 (Wang (2017))).

III. The Secretary's Response

The Secretary's expert was Steven M. Hedrick, PhD.[4] Dr. Hedrick prepared an expert report. Resp't's Ex. B, ECF No. 41-1. He also testified at the entitlement hearing.[5]

In his report, Dr. Hedrick opined on the statistical probability that the Tdap vaccine causes anti-NMDAR encephalitis. Id. at 5. He observed that the VAERS database covering 1990 to 2023 revealed only two clear cases of anti-NMDAR encephalitis following a Tdap or DTaP vaccination, out of what he estimated were at least 300 million vaccinations administered. Id. He explained that—assuming anti-NMDAR encephalitis occurs at a rate of 1 per million per year, for 40 million people over 30 years (1991–2023)—the expected number of cases of Tdap or DTaP-caused anti-NMDAR encephalitis would be approximately 1200. Id. However, he noted, this number "is orders of magnitude more than the number of reported vaccine-related adverse events specific for anti-NMDAR encephalitis." Id. "Combined with safety studies showing no increased risk for medically attended neurologic or allergic reactions," he wrote, "there is no evidence that Tdap or DTaP vaccinations increase the probability of anti-NMDAR encephalitis." Id. (citing Resp't's Ex. B-16, ECF No. 41-17 (Klein et al. (2010))).

Dr. Hedrick also rejected the notion that molecular mimicry could be at play. He pointed out that "[t]he case studies of anti-NMDAR encephalitis cited by Dr. Babinski include the spectrum of vaccines: Tdap-IPV, H1N1 influenza vaccination, Japanese encephalitis vaccine, human papillomavirus (HPV) vaccine, yellow fever vaccine, and COVID-19 vaccines." Id. "If these rare case studies are to be taken as evidence," he said, "the conclusion is that there is no proposed vaccine specificity, meaning there must not be any form of molecular mimicry where an immune response to the vaccine components cross-react with NMDAR." Id. "Since these cited vaccines are all very different in composition," he wrote, Dr. Babinski's "theory must be that any immune provoking entity is capable of causing this disease." Id.

Dr. Hedrick also criticized Dr. Babinski's reliance on the theory that "a vaccine may exacerbate an underlying autoimmune disease, i.e., some individuals have pre-existing specific T- and B-cell lymphocyte clones that are re-stimulated by vaccination." Id. Dr. Hedrick noted that "there is no evidence in the lab tests that 26-year-old Mr. Garcia harbored autoimmunity, cryptic or otherwise—for example, he had no anti-nuclear antibodies (ANA), a common characteristic of autoimmunity." Id.

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[4] Dr. Hedrick received his undergraduate degree in biology and his PhD in molecular biology and biochemistry from the University of California, Irvine. Resp't's Ex. B-1, at 1, ECF No. 41-2. Dr. Hedrick was a postdoctoral fellow at the National Institutes of Health. Resp't's Ex. B, at 1. He currently serves as a Distinguished Professor, Emeritus at the University of California, San Diego, having retired from the University in 2021. Id.

[5] The Secretary also submitted a report written by Jagannadha Avasarala, MD, PhD, a Professor of Neurology and Director of MS and Neuroimmunology Program at the University of Kentucky Medical Center. Resp't's Ex. A, ECF No. 35-1. That report is discussed below.

Dr. Hedrick rejected Dr. Babinski's theory "that some individuals have pre-existing autoreactive T- and B-cell lymphocyte clones that are re-stimulated by vaccination." Id. He observed that "[t]his does not explain how such cells are activated by toxoids in aluminum salts, and signaled to migrate and gain access to the central nervous system via a breakdown in the [blood-brain barrier]." Id.

Dr. Hedrick further observed that "[m]ost autoimmune encephalitides, that is autoantibody-mediated encephalitis diseases, occur in patients with no apparent immunologic triggers—neither viral infections, teratoma allografts, nor vaccinations." Id. at 6. Moreover, he said, "[o]ur understanding of Tdap and its immunogenicity does not include activity that would cause the breakdown of the [blood-brain barrier] and the incitement of an autoimmune encephalitis." Id.; see also Hr'g Tr. 84:22–25 (stating that there is no evidence "that a routine vaccine, such as Tdap[,] will cause a breakdown of the blood-brain barrier"). "Importantly," Dr. Hedrick noted, "there is no evidence for increased encephalitis in Tdap vaccinees compared with the general population." Resp't's Ex. B, at 6.

Dr. Hedrick concluded that,

> Hearing the story of the petitioner falling victim to a debilitating disease in the weeks following vaccination, the very human reaction is to assume that one caused the other. However, a dispassionate evaluation of the biology and epidemiology considering the hundreds of millions of vaccinations that have been given, along with the lack of biological evidence to support a cause and effect, there is a high probably that the two events were coincidental. In my opinion, more likely than not, this very unfortunate disease process experienced by Mr. Garcia occurred independently from the Tdap vaccination.

Id.

IV. The Chief Special Master's Decision

Mr. Garcia filed his petition for compensation on July 22, 2021. Pet., ECF No. 1. The Secretary filed his Rule 4(c) report on November 25, 2022. ECF No. 30. An entitlement hearing was held on August 26, 2024. See Hr'g Tr., ECF No. 63.

On January 3, 2025, the Chief Special Master issued an opinion finding Petitioner not entitled to compensation. He found that Petitioner had failed to satisfy prongs one and two of the three-prong test for establishing causation set forth in Althen. Dec. at 23–24.[6]

With respect to prong one, the Chief Special Master found that the Petitioner failed to provide a reputable medical theory causally connecting the vaccination and the injury. He concluded that "[i]t simply has not been preponderantly demonstrated that the Tdap vaccine can

[6] Because a petitioner must satisfy all three prongs of the Althen test, it was not necessary for the Chief Special Master to consider the third prong after deciding that Petitioner failed at prongs one and two. See Dec. at 23 n.21 (citing Dobrydnev v. Sec'y of Health & Hum. Servs., 566 Fed. Appx. 976, 980 (Fed. Cir. 2014)).

likely produce the specific anti-NMDAR antibodies thought to cause this form of encephalitis." Id. at 23. He noted that while Dr. Babinski "displayed good command of the subject of anti-NMDAR encephalitis, her expertise did not extend to matters involving purportedly pathogenic immunologic responses that would result in such an injury." Id. He dismissed her "reliance on case report associations" which he characterized as "a weak form of causation proof," that "was not enough to show the specific vaccine at issue could result in production of the relevant autoantibodies." Id.

In addition, he found that "overall, testimony from both experts about the nature of this form of encephalitis (which seems in some cases to more likely begin within the [central nervous system] is not consistent with systemically-driven creation of autoantibodies finding their way to the relevant receptors." Id. "[E]ven if the Tdap vaccine could cause the production of the relevant antibodies in the periphery—i.e., outside the central nervous system (due to the locus of vaccine administration in Petitioner's arm)," he observed, "it has not been preponderantly established that cytokines upregulated by vaccination would also likely breach the [blood-brain barrier] in the same way cytokines attributable to an active infection or tumor could." Id. He concluded that "Dr. Hedrick persuasively established that the type of cytokines likely to increase [blood-brain barrier] permeability were not likely vaccine-associated—and that in fact, vaccination generally was not the kind of immune stimulative event sufficient at all to raise this as an actual risk." Id. (citing Hr'g Tr. 75–76, 84–85, 125).

The Chief Special Master made it clear that his decision was based on what he viewed as the generality and lack of precision in Petitioner's medical theory. He observed that "[t]his is not a case where Respondent's expert strongly rebutted the entirety of Petitioner's evidentiary showing." Id. at 24. "[F]or example," he explained, Dr. Hedrick "offered a number of arguments about predicted incidence of vaccine-caused anti-NMDAR encephalitis that were not particularly robust, or relied on statistical comparisons that did not in turn derive from sound epidemiologic evidence." Id. But regardless of these flaws in Dr. Hedrick's analysis, he emphasized, "it is a petitioner's initial burden to make a prima facie showing of causation—and that showing must be preponderant and scientifically-medically reliable." Id. "Petitioner's showing," he found, "was simply too general and vague to succeed." Id. "Indeed," he explained, that showing "would arguably apply to any vaccination that preceded manifestation of encephalitic symptoms." Id.

Finally, the Chief Special Master stated that he also could not find that the Tdap vaccine "likely 'did cause'" Petitioner's anti-NMDAR encephalitis, as required to satisfy Althen prong 2. Id. He noted that "[t]here is little preponderant record evidence that Petitioner experienced any unusual levels of inflammation after his early October vaccination that would be consistent with the alleged [blood-brain barrier]-breaching cytokine reaction, with over two weeks passing before Petitioner's October 20, 2020 seizure while driving." Id. And "[t]hen," he observed, "Petitioner did not even immediately test positive for the relevant autoantibodies (based on blood testing—which would have picked up the existence of these antibodies had they been systemically generated) when he first sought hospitalization on October 28, 2020—now more than three weeks post-vaccination." Id. "If the Tdap vaccine had in fact been instigating the production of harmful autoantibodies," he posited, "why were they not then detected—and after Petitioner had manifested a number of concerning symptoms?" Id. He concluded that "Dr. Babinski did not credibly explain these findings away." Id.

V. Motion for Review

Petitioner filed his motion for review of the Chief Special Master's decision and a supporting memorandum on February 3, 2025. Pet'r's Mot. for Rev.; Pet'r's Mem. Supp. Mot. for Rev., ECF No. 66 [hereinafter Pet'r's Mem.]. In his motion, Petitioner argues that in rendering his opinion, the Chief Special Master did not take into consideration Petitioner's Exhibit 45 (Dr. Babinski's report in response to Dr. Avasarala's expert report) or Petitioner's Exhibit 50 (Dr. Babinski's report in response to Dr. Hedrick's expert report). In doing so, Petitioner contends, the Chief Special Master violated his statutory obligation to render a decision that takes into account all relevant evidence.

The Secretary filed a response to the motion for review on March 3, 2025. Resp't's Resp. to Pet'r's Mot. for Rev., ECF No. 68. The Secretary contends that Petitioner has not established that the Chief Special Master did not consider the two exhibits in question. He also argues that even if the Chief Special Master failed to do so, the error was harmless and does not supply a basis for reversing the Chief Special Master's finding on entitlement.

DISCUSSION

I. Jurisdiction

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 Vaccine Act is remedial legislation that "should be construed in a manner that effectuates its underlying spirit and purpose." Id. (quoting Cloer v. Sec'y of Health & Hum. Servs., 675 F.3d 1358, 1362 (Fed. Cir. 2012) (en banc)).

A petition seeking compensation under the Vaccine Act is filed in the Court of Federal Claims, after which the Clerk of the Court forwards it to the Chief Special Master for assignment to a special master. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned "issue[s] a decision on such petition with respect to whether compensation is to be provided under the [Vaccine Act] and the amount of such compensation." Id. § 300aa-12(d)(3)(A).

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the decisions of special masters with authority to:

> (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 RCFC App. B, Vaccine Rule 27.

II. Standard of Review

The court reviews a special master's legal determinations de novo, applying the "not in accordance with law" standard. Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Althen, 418 F.3d at 1278–79. Judicial review of a special master's factual determinations, on the other hand, is circumscribed and "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 only set aside a special master's factual determinations where they are arbitrary, capricious, and/or reflect an abuse of discretion. Moberly, 592 F.3d at 1321. In conducting judicial review, the court does not reweigh the evidence, examine its probative value, or judge 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, 1254 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010)). Thus, 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)).

III. Petitioner Has Not Established that the Chief Special Master Failed to Consider Dr. Babinski's Responses to the Reports of the Government's Experts

The Vaccine Act provides that "'[c]ompensation shall be awarded . . . to a petitioner if the special master or court finds on the record as a whole' that the petitioner has met his evidentiary burdens." Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1327 (Fed. Cir. 2016) (quoting 42 U.S.C. § 300aa-13(a)(1)). The evidence the special master is required to consider includes medical records or reports "contained in the record regarding the nature, causation, and aggravation of the petitioner's . . . injury" as well as "all other relevant medical and scientific evidence contained in the record." 42 U.S.C. § 300aa-13(b).

As the court of appeals has observed, this statutory language "indicates that a special master, reviewing the entire record of the case before him, must consider all relevant medical and scientific evidence contained in the record, which includes any relevant medical records or reports. The language also instructs that the special master 'shall' consider the entire record, which includes this relevant evidence, when assigning the weight given to particular evidence." Moriarty, 844 F.3d at 1327–28.

In this case, as noted, Petitioner argues that the Chief Special Master failed to consider Petitioner's Exhibit 45 (Dr. Babinski's November 26, 2023 supplemental report in response to Dr. Avasarala's review of petitioner's case) or Petitioner's Exhibit 50 (Dr. Babinski's July 10, 2024 supplemental report responding to the opinions of Dr. Hedrick). He bases these assertions on: 1) the fact that the Chief Special Master did not specifically cite the reports in his decision; and 2) the Chief Special Master's statement that Dr. Babinski had "prepared a single written report." Pet'r's Mem. at 2 (quoting Dec. at 6).

Petitioner's argument lacks merit. In cases arising under the Vaccine Act, the Court "generally presume[s] that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." Moriarty, 844 F.3d at 1328 (citing Hazlehurst v. Sec'y of Health & Hum. Servs., 604 F.3d 1343, 1352 (Fed. Cir. 2010)). A special master is not required to discuss "every piece of medical literature a petitioner files or references in his or her final decision." K.L. v. Sec'y of Health & Hum. Servs., 134 Fed. Cl. 579, 609 (2017). And "failing to discuss every piece of evidence will not alter the presumption that a Special Master has considered the entire record in his or her decision to grant or deny compensation." Id. (citing Moriarty, 844 F.3d at 1328). Therefore, the fact that the Chief Special Master did not cite Dr. Babinski's rebuttal reports in response to the government's experts does not establish that he failed to consider them.

To be sure, the presumption that a special master has considered all of the relevant evidence of record must give way where a special master expressly states that they have not done so. In Moriarty, for example, the special master expressly stated that he had not considered certain relevant reports because they were not discussed at the hearing. The court of appeals held that, in the face of this express statement, the presumption was not applicable. 844 F.3d at 1328; see also Medtronic, Inc. v. Daig Corp., 789 F.2d 903, 906 (Fed. Cir. 1986) ("We presume that a fact finder reviews all the evidence presented unless he explicitly expresses otherwise.").

In this case, the Chief Special Master did not state, expressly or otherwise, that he did not consider Dr. Babinski's supplemental reports. To the contrary, the Chief Special Master stated that he had conducted a review "of the complete medical record as filed, expert reports, medical/ scientific literature, and the parties' briefs." Dec. at 1. He also stated that he would discuss only the medical literature and records that were most relevant to his determination and/or were central to Petitioner's case. Dec. at 21 (citing Moriarty, 844 F.3d at 1328).

Petitioner's argument that the Chief Special Master did not consider Dr. Babinski's supplemental reports is thus based almost entirely on the Chief Special Master's passing observation when introducing Dr. Babinski's opinion that she had "prepared a single written report and testified at hearing." See Pet'r's Mem. at 2 (quoting Dec. at 6). As Petitioner recognizes, when the Chief Special Master stated that Dr. Babinski had prepared a "single written report," he was referring to her April 9, 2023 expert report, which provided the bases for her opinion that the Tdap vaccine that Mr. Garcia received was the cause of his anti-NMDAR encephalitis. Pet'r's Ex. 18. The other two reports she prepared were not for the purposes of presenting Mr. Garcia's affirmative case, but rather to respond to the submissions of the government's experts. See generally Pet'r's Exs. 45, 50.

It is conceivable, therefore, that the Chief Special Master referred to "a single written report" because, in fact, there was only a single written report that presented Petitioner's affirmative case. Or perhaps it is the case that this observation merely reflects a lack of care or precision of language when describing Dr. Babinski's contributions to Petitioner's case. Either way, the Chief Special Master's passing observation that Dr. Babinski prepared a single written report hardly represents the kind of express statement Moriarty and Medtronic require to rebut the presumption that all relevant evidence was taken into consideration.

IV. Even Assuming that the Chief Special Master Did Not Consider Petitioner's Exhibits 45 and 50, the Error Was Harmless

For the reasons set forth above, the Court has concluded that Petitioner failed to rebut the presumption that the Chief Special Master considered all relevant evidence, including Petitioner's Exhibits 45 and 50, when he rendered his decision. But even if he did not consider those exhibits, that error would be harmless and does not provide a basis for reversing his entitlement decision. See SolarWorld Americas, Inc. v. United States, 962 F.3d 1351, 1359 (Fed. Cir. 2020) ("The party that 'seeks to have a judgment set aside because of an erroneous ruling carries the burden of showing that prejudice resulted.'" (quoting Shinseki v. Sanders, 556 U.S. 396, 409 (2009))).

For example, Petitioner alleges that the Chief Special Master did not consider Petitioner's Exhibit 45 (Dr. Babinski's response to the report prepared by Dr. Avasarala). Even if true, the error would have no effect on the outcome of the case. The Chief Special Master did not rely on Dr. Avasarala's opinion when he ruled that Petitioner had failed to meet his burden under Althen prongs one and two. To the contrary, he expressly stated that it was unnecessary to discuss Dr. Avasarala's report because he believed it largely concerned the accuracy of Petitioner's diagnosis, a matter that was not in dispute. Dec. at 10 n.10.

To be sure, Dr. Avasarala's report also discussed the World Health Organization's criteria for assessing the probability that a vaccination was responsible for an adverse event. See Resp't's Ex. A, at 4–7. But the Secretary did not cite or rely on this aspect of Dr. Avasarala's opinion in his prehearing brief. See Resp't's Prehearing Brief, ECF No. 45. And the Chief Special Master did not cite or rely upon it either when he found that Petitioner failed to demonstrate causation. Therefore, Petitioner was not prejudiced by the Chief Special Master's alleged failure to consider Dr. Babinski's critiques of Dr. Avasarala's report.

There is similarly no merit to Petitioner's argument that he was prejudiced by the Chief Special Master's alleged failure to consider Petitioner's Exhibit 50 (Dr. Babinski's written response to Dr. Hedrick's report). Petitioner notes that the Chief Special Master stated in his opinion that "[i]t simply has not been preponderantly demonstrated that the Tdap vaccine can produce the specific anti-NMDAR antibodies thought to cause this form of encephalitis." Pet'r's Mem. at 9, 11 (quoting Dec. at 23). According to Petitioner, had the Chief Special Master considered Petitioner's Exhibit 50, he would have understood that Dr. Babinski's theory was not that the vaccine can produce NMDAR antibodies, but that "vaccination can trigger the process by which circulating, pre-existing, NMDAR antibodies in the periphery can reach the NMDA receptors in the brain." Pet'r's Mem. at 11 (citing Pet'r's Ex. 50, at 4).

But the record makes clear the Chief Special Master was aware of—and considered—this theory. Dr. Babinski discussed her theory involving pre-existing NMDAR antibodies at some length during the entitlement hearing. See Hr'g Tr. 23–28, 46–51, 55–57. The Chief Special Master described her testimony in his opinion. See Dec. at 8–9. The theory was also put before the Chief Special Master in Petitioner's prehearing brief at pages 42–44, ECF No. 43, and in Petitioner's prehearing reply brief at pages 6–7, ECF No. 61. The latter, in turn, cited Petitioner's Exhibit 50. See Pet'r's Prehearing Reply Br. at 4–7. The Chief Special Master also reviewed and cited the medical literature Dr. Babinski referenced in support of this theory in her report. See

Dec. at 13 (citing Pet'r's Ex. 53, ECF No. 55-4; Pet'r's Ex. 67, ECF No. 55-18). The Chief Special Master thus did not "fail[] to consider the medical expert opinion proffered by Dr. Babinski," Pet'r's Mem. at 11; he simply found the theory unpersuasive, Dec. at 23.

Petitioner also contends that the Chief Special Master's alleged failure to consider Petitioner's Exhibit 50 caused him to erroneously state that Dr. Babinski had "invoked molecular mimicry as a mechanism." Pet'r's Mem. at 9, 11 (quoting Dec. at 23). As Petitioner observes, Dr. Babinski explicitly stated in her response to Dr. Hedrick's report that "[m]olecular mimicry was not proposed as a potential biological mechanism." Pet'r's Ex. 50, at 3. Petitioner contends that he was prejudiced by the Chief Special Master's failure to consider Dr. Babinski's disclaimer, claiming that "the Chief Special Master denied entitlement on the basis that petitioner did not provide enough evidence to support molecular mimicry as a mechanism." Pet'r's Mem. at 12 n.11; id. at 13 n.12.

Petitioner's argument regarding molecular mimicry is a red herring. Although the Chief Special Master briefly and mistakenly referenced molecular mimicry, his decision was not based on the absence of evidence for that mechanism. Instead, the decision rests on the conclusion that Petitioner failed to present persuasive evidence for any of the theories Dr. Babinski did advance. Dec. at 7–8, 23–24. As the Chief Special Master explained, "testimony from both experts about the nature and form of [anti-NMDAR] encephalitis . . . is not consistent with systemically-driven creation of autoantibodies finding their way to the relevant receptors." Id. at 23 (emphasis added). The core issue here was not how the autoimmunity developed, but whether Petitioner showed that the Tdap vaccine could initiate or facilitate the crossing of the blood-brain barrier in a way that would allow any antibodies, whether pre-existing or produced by the Tdap vaccine, to reach NMDA receptors within the central nervous system. The Chief Special Master found no persuasive evidence that it could. See id. at 24 (explaining that Dr. Babinski "attempts to leverage what is known about vaccine-induced cytokine production [to explain the breakdown of the blood-brain barrier] . . . without evidence suggesting that vaccination affirmatively is likely to promote [blood-brain barrier] weakening").

Similarly, Petitioner contends that—because the Chief Special Master allegedly never reviewed Petitioner's Exhibit 50—he did not understand why Dr. Babinski rejected as unreliable Dr. Hedrick's calculation of the predicted incidence of Tdap-caused anti-NMDAR encephalitis. As noted above, Dr. Hedrick opined that the number of cases of Tdap-caused anti-NMDAR encephalitis that could be predicted were many times higher than the number of incidents reported in VAERS. In her response to Dr. Hedrick's report, Dr. Babinski identified a number of flaws in Dr. Hedrick's calculations. See Pet'r's Ex. 50, at 2–3. But the Chief Special Master did not credit Dr. Hedrick's calculations or give them any weight. To the contrary, he stated that "[t]his is not a case where Respondent's expert strongly rebutted the entirety of Petitioner's evidentiary showing," noting that "Dr. Hedrick, for example, offered a number of arguments about predicted incidence of vaccine-caused anti-NMDAR encephalitis that were not particularly robust, or relied on statistical comparisons that did not in turn derive from sound epidemiologic evidence." Dec. at 24.

Finally, the Court notes that Petitioner's motion for review does not address the Chief Special Master's ruling that Althen prong 2 was also not satisfied because Petitioner had failed to show that the Tdap vaccine likely did cause him to develop anti-NMDAR encephalitis.

Specifically, the Chief Special Master found, the evidence did not show "that Petitioner experienced any unusual levels of inflammation after his early October vaccination that would be consistent with the alleged [blood-brain barrier]-breaching cytokine reaction." Id.

To show causation, a petitioner must satisfy all three Althen prongs. So far as the Court can tell, there is nothing in Dr. Babinski's responses to the Secretary's experts that undermines, or even affects, the Chief Special Master's conclusion that prong two was not satisfied. For that reason alone, even assuming that the Chief Special Master did not consider Petitioner's Exhibits 45 and 50, the error did not affect the Chief Special Master's ruling regarding prong two and therefore had no effect on the ultimate outcome of the case.

CONCLUSION

For the foregoing reasons, Petitioner's motion for review is **DENIED** and the decision of the special master is **SUSTAINED**. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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