In the United States Court of Federal Claims

No. 15-1016V
Filed Under Seal: July 27, 2020
Reissued: August 11, 2020*
NOT FOR PUBLICATION

MARYELLEN KOTTENSTETTE and NICHOLAS KOTTENSTETTE, as best friends of their daughter (CK),

***Petitioners*,**

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

***Respondent*.**

Keywords: Vaccine; Motion for Review; *Althen* Test; Infantile Spasms; DTaP Vaccine; DPT Vaccine

John F. McHugh, Law Office of John McHugh, New York, New York, for the petitioners.

Camille Michelle Collett with *Voris Edward Johnson*, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C., for the defendant.

MEMORANDUM OPINION AND ORDER

***HERTLING*, Judge**

For vaccine injuries not already recognized in the Department of Health and Human Service's Vaccine Injury Table, a petitioner must prove that the vaccine (1) "can" cause and (2) "did" cause the injury. *See Pafford v. Sec'y of Health & Human Servs.,* 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). The petitioners' daughter, C.K., suffers from severe psychomotor regression attributed to a seizure disorder called "infantile spasms." The petitioners observed C.K.'s first seizure ten hours after C.K. had received the combined vaccine for diphtheria, tetanus and pertussis (the "DTaP" vaccine) at her four-month wellness exam. The petitioners argue that the

* Pursuant to Vaccine Rule 18(b), this opinion was initially filed under seal, and the parties were afforded 14 days after the filing of this opinion within which to notify the court of any information that should be redacted from this decision for reasons of privilege or confidentiality. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for posting on the Court's website.

DTaP vaccine "can" cause infantile spasms by lowering the threshold for a seizure to occur, and that it "did" trigger the early onset of C.K.'s infantile spasms at an age when the seizures would be most damaging to C.K.'s brain.

The most recent decision on the petitioners' claim, issued by Special Master Horner following remand by this Court, denied the petitioners compensation, finding insufficient evidence that the DTaP vaccine caused the onset of C.K.'s infantile spasms.[1] *Kottenstette v. HHS*, No. 15-1016 (Fed. Cl. Spec. Mstr. June 2, 2020) [hereinafter *Decision on Remand*], https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2015vv1016-142-0. The petitioners move for review of that decision. The Court denies the motion for review and sustains the Special Master's decision.

I. BACKGROUND

The Court reviews first the details of C.K.'s injury and then the history of this case.

A. DTaP Vaccination and Seizure Disorder

C.K. received the DTaP vaccine, along with other vaccines, at her four-month wellness visit in October 2012. That same day, and again four days later, C.K.'s parents observed her moving her arms, legs, and shoulders in a manner that a treating neurologist consulted by the petitioners determined was consistent with the "infantile spasms" seizure disorder. The neurologist treated C.K. with a standard treatment for the disorder, adrenocorticotropic hormone ("ACTH").

At a follow-up visit three weeks later, the petitioners reported some improvement while C.K. was treated with ACTH, reporting that the seizures were more frequent (three to five per day) but of shorter duration (one to two minutes). (ECF 9-1 at 10-11.) They reported no regression in C.K.'s development since the onset of the seizures. (*Id.* at 11.) During another follow-up visit, two weeks later, they noted less frequent and less severe seizures, along with normal development.

Three-and-a-half months after C.K.'s vaccination and first observed seizure, C.K. appeared to be suffering progressive brain damage with "less movements and arrested development with some elements concerning for regression, particularly her head control and level of interaction." (ECF 9-2 at 4.) C.K.'s ACTH treatment lasted through early December. Ms. Kottenstette later testified at the entitlement hearing that C.K. declined rapidly after the ACTH treatment was stopped. (*Id.* at 10.) C.K. started and continued having approximately 30 seizures per day lasting between 10 and30 seconds. These seizures did not respond to medication. (ECF 86-1 at 15.)

---

[1] The Court vacated and remanded an earlier decision in this case reached by another special master, holding that it had applied the wrong legal standard. *See Kottenstette v. HHS*, No. 15-1016, 2020 WL 953484 (Fed. Cl. Feb. 12, 2020).

As of June 2017, C.K. had "physical disabilities that impact her functional mobility, postural stability, eye-hand coordination, fine motor control, pre-writing skills, and self-care skills" and "a visual impairment that affects her performance on visually-based activities." *Decision on Remand* at 4 (summarizing medical records). Further, C.K. "can differentiate sounds and turn her head toward unfamiliar sounds, but she does not yet respond to her name." *Id.* C.K. "does not yet understand any words and does not yet use gestures to communicate." *Id.*

B. Initial Decision Granting Compensation

The petitioners filed a petition for compensation in 2015. (ECF 1.) Special Master Millman held a hearing on entitlement to compensation. At that hearing, petitioner Ms. Kottenstette, the petitioners' expert, and the respondent's expert testified. (*See* Transcript, ECF 66 [hereinafter cited as "Tr."] Special Master Millman granted compensation, finding that the DTaP vaccine was a "substantial cause" of C.K.'s developmental disabilities because the vaccine hastened the onset of the brain-damaging infantile spasms that C.K. otherwise might only have experienced later in her development. *Kottenstette v. HHS*, No. 15-1016, 2017 WL 6601878 (Fed. Cl. Spec. Mstr. Dec. 12, 2017). Special Master Millman thereafter awarded damages on the basis of her earlier finding of entitlement. *Kottenstette v. HHS*, 2019 WL 2587395 (Fed. Cl. Spec. Mstr. May 29, 2019).

After these decisions, Special Master Millman retired and the case was reassigned to Special Master Horner.

The respondent, the United States Department of Health and Human Services, moved for review of Special Master Millman's entitlement decision. (ECF 107.) This Court found the legal standard and evidentiary basis of Special Master Millman's decision unclear, vacated the decision, and remanded the case for further consideration of causation under the three-prong test established by *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005).[2] *See Kottenstette v. HHS*, No. 15-1016, 2020 WL 953484 (Fed. Cl. Feb. 12, 2020).

This Court summarized the *Althen* test as follows:

---

[2] Special Master Millman's decision was ambiguous as to whether she had applied the *Althen* causation standard or dispensed with *Althen* on account of a correlation between C.K.'s facts and an immunological study together with the short, 10-hour delay between vaccination and the onset of CK's first seizure. Special Master Millman relied on *Knudsen ex. rel. Knudsen v. Secretary of the Department of HHS*, 35 F.3d 543, 548-49 (Fed. Cir. 1994), and another special master's decision, *see H.J. v. Sec'y of HHS*, No. 11-301V, 2015 WL 6848357 (Fed. Cl. Spec. Mstr. Nov. 6, 2015), to conclude that "when a [vaccine recipient] would fit within an epidemiological study, that alone is sufficient proof of vaccine causation." *Kottenstette*, 2017 WL 6601878 at *13, *14. Special Master Millman then concluded that "because CK would have qualified to have been in the Bellman and Melchior studies [discussed below], the undersigned finds that her four-month vaccinations triggered the onset of her cryptogenic seizures." *Id.* at *14.

> The Vaccine Act requires preponderant evidence of causation. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner must show the harm was more likely than not caused by the vaccine. *Althen*'s three prongs, together, enumerate the facts that are relevant and essential to prove causation in cases such as this one, in which the possibility of injury is not already recognized in the Vaccine Table. *Althen* requires "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278.

Id. at *3.

C. Decision on Remand Denying Compensation

On remand, Special Master Horner reviewed the record, concluded that both parties had had a full and fair opportunity to present their cases, found no new, unaddressed issues, and issued a decision denying compensation. (ECF 131, *withdrawn by* ECF 134.) The petitioners moved to reopen the record and for reconsideration. (ECF 133.) They argued that this Court's decision remanding the case had heightened their burden of proof after the record had been closed. Special Master Horner withdrew his earlier decision in order to consider the petitioners' arguments. (ECF 134.) Special Master Horner ultimately denied the motion to reopen the record (ECF 141) and issued a superseding decision denying compensation. *See Decision on Remand* at 4.

In the decision on remand, Special Master Horner applied the *Althen* test to the two studies that Special Master Millman had found were dispositive in proving causation. *Id.* at 10-13 (discussing M.H. Bellman, E.M. Ross & D.L. Miller, *Infantile Spasms and Pertussis Immunisation*, 1 Lancet 1031 (1983) (ECF 54-1); J.C. Melchior, *Infantile Spasms and Early Immunization Against Whooping Cough*, 52 Archives of Disease in Childhood 134 (1977) (ECF 54-2). Special Master Horner found that these studies were insufficient as evidence that the DTaP vaccine could cause the onset of infantile spasms. *Id.* at 13. He then applied the *Althen* test to the specifics of the petitioners' theory of causation, which Special Master Millman's earlier decision had not addressed. *See id.* at 6, 14-20. Special Master Horner found that the petitioners had failed to establish by a preponderance of the evidence that vaccination, as opposed to infection, could start a seizure-triggering immune response. *Id.* at 20. Special Master Horner accepted that a vaccine can contribute to a seizure-triggering fever or other inflammation but nevertheless found insufficient evidence that C.K. had suffered from a fever or other inflammation when her first seizure occurred. *Id.* at 21-25. In Special Master Horner's view, the petitioners narrowly satisfied *Althen*'s first prong but failed to satisfy *Althen*'s second prong because they had failed to show that the facts of C.K.'s injury fit the only theory of causation that they had established.

1. The Melchior and Bellman Studies

In the decision on remand, Special Master Horner first analyzed what weight, if any, he should give to the Melchior and Bellman studies that Special Master Millman had found dispositive. *Decision on Remand* at 10-13 (discussing Melchior and Bellman, *supra*). The Melchior study examined whether giving children the then-dominant DPT formulation of the pertussis vaccine at an earlier age would affect the typical onset-age of infantile spasms. *Id.* at 10-11.

Special Master Horner gave no weight to the Melchior study. *Id.* at 13. The study's author rejected a causal connection between the pertussis vaccine and infantile spasms and, more significantly, the study's statistical observations of the safety of the DPT vaccine could not be reasonably applied to the DTaP vaccine, which had specifically been developed to be safer than the DPT vaccine. *Id.* at 12. Special Master Horner noted that previous vaccine-compensation decisions had persuasively concluded that the DPT vaccine's safety statistics could not reasonably be applied to the DTaP vaccine.[3] *Id.* at 11.

The petitioners' expert on neurology, Dr. Marcel Kinsbourne, M.D., opined that DPT's safety findings were applicable to the DTaP vaccine, but with a lower incidence of infantile spasms arising from the DTaP formulation. *Id.* at 12 (citing Tr. at 57, 92-93). The DTaP vaccine, Dr. Kinsbourne explained, contains less of the pertussis toxin present in the DPT vaccine (another pertussis vaccine formulation) but enough residual toxin to have the same effects with lower frequency. Special Master Horner rejected this opinion as speculation. *Id.* Special Master Horner explained that the Melchior study's conclusions were based solely on statistical observations, and that a difference in formulation between DPT and DTaP that implicates vaccine safety makes it unreasonable to apply statistical observations from the DPT vaccine to the DTaP vaccine. *Id.*

Special Master Horner gave minimal weight to the Bellman study as evidence that the onset-age of infantile spasms may respond to vaccines for diphtheria and tetanus, including DTaP, and not only DPT. *Id.* at 13. Unlike the Melchior study, the Bellman study tested a stand-alone diphtheria and tetanus ("DT") vaccine in addition to testing DPT. *Id.* The study compared recipients of the DT and DPT vaccine to control subjects of the same age and found a "small excess" in the number of cases of infantile spasms first observed within the seven days after vaccination, and a corresponding deficit in the cases observed within the next three weeks. *Id.* According to the Bellman study, "this suggests that, in some cases, immunization may

---

[3] As examples, Special Master Horner cited *Sharpe v. Secretary of HHS*, No. 14-65V, 2018 WL 7625360, at *31-32 (Fed. Cl. Spec. Mstr. Nov. 5, 2018); *Taylor v. Secretary of HHS*, No. 05-1133V, 2012 WL 4829293, at *30 (Fed. Cl. Spec. Mstr. Sept. 20, 2012); *Holmes v. Secretary of HHS*, No. 08-185V, 2011 WL 2600612, at *20 (Fed. Cl. Spec. Mstr. Apr. 26, 2011); *Simon v. Secretary of HHS*, No. 05-941V, 2007 WL 1772062, at *7 (Fed. Cl. Spec. Mstr. June 1, 2007); and *Grace v. Secretary of HHS*, No. 04-[redacted], 2006 WL 3499511, at *9 (Fed. Cl. Spec. Mstr. Nov. 30, 2006).

trigger the onset of spasms or attract attention to symptoms in children destined to show the condition overtly within a short time." Bellman, *supra*, at 1031. The fact that these results applied to the DT vaccine which, like DTaP and unlike DPT, did not contain whole-cell pertussis, meant that these results could not be dismissed for the same reason that Special Master Horner found the Melchior study's observations inapplicable. *Decision on Remand* at 13.

This finding of the Bellman study, Special Master Horner noted, was limited. Most of the study's "small excess" of post-DT-vaccine cases were the kind of infantile spasms caused by a known, pre-existing brain injury ("symptomatic"), unlike C.K.'s unexplained ("cryptogenic") infantile spasms. *Id.* (citing *Bellman*, *supra*, at 1033 tbl.III). Further, as the Bellman study's authors and the respondent's expert both suggested, some of the study's "small excess" of post-DT cases may be attributable to recall bias. *Id.* (citing Tr. at 161-62).

Because of these limitations, Special Master Horner found that the Bellman study, without more, was insufficient to establish by a preponderance of the evidence that the DTaP vaccine "can" cause infantile spasms under the first prong of the *Althen* test. *Id.*

2. Petitioners' Two-Hit Model of Infantile Spasms

Finding the evidence on which Special Master Millman had relied to be insufficient to satisfy the *Althen* test's preponderant-evidence standard, Special Master Horner then applied the *Althen* test to the petitioners' theory of causation that Special Master Millman had not reached in her earlier decision. *See Decision on Remand* at 6, 14-20.

Dr. Kinsbourne had proposed a "two-hit" model of causation in which a stressful event triggers infantile spasms in an already-susceptible individual. *See id.* at 15-16 (summarizing Dr. Kinsbourne's premises and scientific authorities). The model relies on various studies linking a release of corticotropin-releasing hormone ("CRH"), a stress hormone, to infantile spasms and identifying an immune response as a cause of CRH release. *Id.*

Based on this evidence, Special Master Horner found that infection could trigger an immune response that could contribute to the onset of infantile spasms. *Id.* at 20. He found no evidence, other than Dr. Kinsbourne's *ipse dixit*, that vaccination—as opposed to infection—could cause such a seizure-triggering immune response. *Id.* The cited studies, Special Master Horner found, implicated infection, not vaccination, as a second "hit" in the "two-hit" model that explained the onset of infantile spasms. *See id.* at 19-20.

The evidentiary gap between vaccination and a seizure-triggering immune response, Special Master Horner found, had been raised at the entitlement hearing before Special Master Millman. *Id.* at 17-18 (citing Tr. at 78). During the hearing, Special Master Millman asked Dr. Kinsbourne directly if any of the submitted studies on which he relied specifically implicated vaccination as the second "hit," and Dr. Kinsbourne responded that he did not recall. *Id.*

Dr. Kinsbourne had tried to close the gap in the petitioners' theory, explaining in his expert report how the body's immune response to vaccination could be the second (CRH-producing and ultimately seizure-triggering) "hit." *Id.* at 17 & n.34 (summarizing ECF 6 at 7).

Dr. Kinsbourne cited studies by Spinelli and Schmidt showing that an innate immune response could trigger CRH production and release inflammation-causing cytokines. *Id.* Dr. Kinsbourne, however, did not attribute discussion of vaccination as the cause of such an immune response to either study. Rather, Dr. Kinsbourne maintained that vaccination necessarily causes an innate immune response and thus could cause the same increase in CRH production that Spinelli and Schmidt attribute in their study to an innate immune response caused by infection. *See id.* at 18 n.35.

Special Master Horner found that Dr. Kinsbourne's attempt to implicate vaccination as a possible second "hit" lacked support. "[Dr. Kinsbourne's] insertion of vaccination as the 'in turn' vehicle for activation of proinflammatory cytokines, which he intimates are sufficient to bring about the cited findings by Spinelli and Schmidt, are his words alone." *Id.*

Special Master Horner rejected Dr. Kinsbourne's opinion that the findings in the Spinelli and Schmidt study of increased CRH production were necessarily applicable to the immune reaction caused by vaccination. *Id.* at 17 n.34. It was, Special Master Horner found, an "untested opinion deep-seated in advanced immunology." He noted that Dr. Kinsbourne was a practicing neurologist, not an immunologist. *Id.* at 19. Moreover, Special Master Horner provided multiple examples in which special masters had rejected similar reasoning.[4] *Id.* at 18

---

[4] Special Master Horner quoted *Inamdar v. Secretary of Health and Human Services*, which rejected reasoning similar to Dr. Kinsbourne's when applied sensorineural hearing loss following influenza vaccination:

> the argument that cytokine upregulation can be a pathogenic mechanism unsuccessfully attempts to leverage what is known about how vaccines generally affect the immune system into proof that these anticipated processes can also be pathogenic. To be sure, components of this theory are based on reliable science. Petitioner has referenced reliable literature establishing that certain proinflammatory cytokines (including IL-6 and TNFalpha) have been shown to be elevated following vaccine administration (*see, e.g.*, Christian at 1, 5), or that these same cytokines may play a role in the process of hearing loss (Kuemmerle-Deschner, Pathak). But the theory lacks similar support for its connecting proposition – that the cytokine upregulation *leads* to or causes hearing loss – as well as the concept that vaccination can instigate the entire disease process. It is not enough to note that increased numbers of inflammatory-associated cytokines have been measured in the context of certain injuries or illnesses (or are involved in the body's reaction to those illnesses). Dr. Axelrod does not personally have demonstrated expertise studying these unsupported elements of the

n.35. Special Master Horner explained, "[I]t cannot be enough for Dr. Kinsbourne to merely highlight cytokine production by innate immunity as a process that does occur and thereby claim it to be necessarily injurious." *Id.* Although Dr. Kinsbourne's report otherwise made use of scientifically reasonable propositions, the part of Dr. Kinsbourne's report implicating the body's immune response to vaccination as the CRH-related "second hit" that could cause an earlier

---

> theory, and no persuasive or reliable literature was offered on such points.

No. 15-1173V, 2019 WL 1160341, at *17 (Fed. Cl. Spec. Mstr. Feb. 8, 2019). Special Master Horner further cited three other decisions rejecting this reasoning:

> *Bender v. Sec'y of Health & Human Servs*., 141 Fed. Cl. 262, 266 (2019) (denying a motion for review where "[t]he Special Master found that Dr. Byers cited no evidence to explain how the mere presence of cytokines could instigate an autoimmune process that results in a demyelinating condition in the central nervous system ("CNS"), particularly when the vaccines were injected in the periphery."); *McKown v. Sec'y of Health & Human Servs*., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (finding with regard to eczema that "[t]he fact that cytokine upregulation is promoted by vaccination – a medically reliable assertion standing alone – does not mean that this cytokine increase is definitionally *harmful*, especially given (as observed by Dr. MacGinnitie) that it is difficult to establish whether certain proinflammatory cytokines are instigators or merely mediators of a disease process begun in some other way."); *Palattao v. Sec'y of Health Human Servs*., No. 13-591V, 2019 WL 989380, *36 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (explaining that "[p]etitioners argued that the immunologic stimulation that vaccinations generally provide (which inherently encourage cytokine production) could result in a demyelinating condition like TM. Petitioners' theory was rooted in the general proposition that virtually *any* vaccine could be pathogenic and result in TM. *See* Tr. at 160. But they have offered insufficient reliable scientific or medical evidence that addresses the specific pathogenicity of the vaccines in dispute herein, nor anything connecting vaccines to TM based merely on their recognized pro-inflammatory capacities.").

Decision on Remand at 18 n.35.

onset of infantile spasms was an "attempt[ ] to stitch together disparate areas of investigation in the field of immunology based only on his own say-so." *Id.* at 17 n.34.

Based on this record, Special Master Horner found that the only support in the record for the proposition that the DTaP vaccine could be the beginning of a second "hit," or an "inflammation and stress response leading to seizure," was the Bellman study. *Id.* at 18.

The respondent's expert argued that fever, not vaccination itself, lowers the seizure threshold. *See id*. at 16. Accordingly, Special Master Horner accepted the theory that "vaccines can in some contexts contribute to seizures as part of a larger immune/inflammatory process, namely where . . . the vaccine causes a seizure threshold-reducing fever and thereby results in febrile seizures." *Id.* at 20. Special Master Horner did "not find preponderant evidence on this record that the DTaP vaccine itself can cause seizures." *Id.*

3. *Althen*'s Second Prong

Next, Special Master Horner applied this narrow theory of how the DTaP vaccine "can" cause infantile spasms to the facts of C.K.'s case in order to determine whether C.K.'s vaccination "did" cause her first observed seizure.[5] *See Decision on Remand* at 21-25.

Special Master Horner noted that Dr. Kinsbourne's application of his theory to the facts of C.K.'s case was based "exclusively" on the short amount of time—ten hours—between C.K.'s vaccination and the first-observed seizure. *Id.* at 21. Dr. Kinsbourne testified:

> It is reasonable to suppose that when the onset of the seizure disorder is within hours of a vaccination that the – and when the vaccination is known to produce proinflammatory cytokines, which are known to have an excitatory or even repligenic property that the–that property of the cytokines was involved in the onset of the seizure disorder.

Id. (quoting Tr. at 73).

Relying on Federal Circuit precedent, Special Master Horner rejected this "mere suspicion of a temporal relationship" as insufficient to establish causation for C.K.'s off-table injury. *Decision on Remand* at 22. He explained that "'[w]hen a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury . . . A reputable medical

---

[5] Special Master Horner explained that infantile spasms, as a condition, consist of two elements: epilepsy (the condition of having seizures) and an encephalopathy (brain injury or infection). Finding that the petitioners had not argued that the DTaP vaccine somehow caused the encephalopathic element of C.K.'s infantile spasms, Special Master Horner narrowed the issue to whether DTaP caused both C.K.'s first seizure and thus the early onset of C.K.'s infantile spasms condition. See *Decision on Remand* at 14.

or scientific explanation must support this logical sequence of cause and effect.'" *Id.* (citing *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (ellipsis in original).

Special Master Horner rejected the effectiveness of ACTH in treating C.K.'s seizures as having case-dispositive evidentiary value. *See id.* at 22. He explained that even if he had accepted the effectiveness of C.K.'s ACTH treatments "as some limited evidence that C.K.'s initial seizures were triggered or mediated by a stress hormone," that conclusion "relates only to the broadest aspect of Dr. Kinsbourne's theory and, without more, does not implicate C.K.'s vaccination(s) as a relevant stress event." *Id*.

Special Master Horner found no other evidence in the record, including in the findings of C.K.'s treating physicians, that a vaccine caused C.K.'s infantile spasms. *Id.* at 22-23. Dr. Kinsbourne "suggested that evidence of inflammation, such as MRI findings or fever, would be expected if excessive or abnormal cytokine inflammation were the cause of C.K.'s condition." *Id.* at 22 (citing Tr. at 173-75). Dr. Kinsbourne also testified that fever is "'by far the most powerful component of the immune response that's related to a decrease in seizure threshold." *Id.* (quoting Tr. at 140.) Dr. Kinsbourne confirmed that there is no such evidence in C.K.'s records, explaining that it is "'not a routine investigation that's usually done.'" *Id.* (quoting Tr. at 99-100). Special Master Horner further noted that the petitioners had reported to C.K.'s treating physician that she did not have a fever during her first seizure, and there was no other evidence of seizure-triggering fever or other inflammation in the relevant records. *Id.*

Special Master Horner rejected Dr. Kinsbourne's opinion that the cytokine reaction he proposed would not necessarily manifest beyond the seizures themselves. *Id.* (citing Tr. at 99-100). Special Master Horner noted that fever was present in the case in which Dr. Kinsbourne's theory had been accepted. *Id.* at 23 (citing *Fuller v. Sec'y of Health & Human Servs.*, No. 15-1470V, 2019 WL 7576382 (Fed. Cl. Spec. Mstr. Dec. 17, 2019). Additionally, Special Master Horner explained that accepting the seizures—the effect—as the only evidence of underlying inflammation that caused the seizures was circular logic. *Id.*

Special Master Horner rejected Dr. Kinsbourne's further contention that without the vaccines, C.K. might have safely exited the age-related window for the onset of infantile spasms, and that it was "speculation" to conclude otherwise. *See id.* at 24. Special Master Horner noted that Dr. Kinsbourne's own report concluded that the question of whether C.K. could have exited the age-window without an onset of infantile spasms was unanswerable. *Id.* (citing Ex. 6 at 6, filed on compact disc as ECF 19). Yet Dr. Kinsbourne purported to shift the burden by answering the question and labeling the other side's answer "speculation." *See id.* The petitioners, Special Master Horner reminded, had the burden to show a logical sequence of cause and effect demonstrating that the vaccine caused C.K.'s infantile spasms. *Id.* He concluded that the petitioners had failed to do so under *Althen*'s second prong, and accordingly had failed to prove causation. *Id.* at 24-25.

The petitioners moved for review of Special Master Horner's decision, (ECF 140), and the motion is fully briefed. (ECF 140, 143.) The Court decides the motion without hearing oral argument, which, the Court finds, would not aid in resolving the motion.

II. ANALYSIS

Under the Vaccine Act, this Court reviews a special master's vaccine compensation decision to determine if it is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Althen*, 418 F.3d at 1277 (quoting 42 U.S.C. § 300aa–12(e)(2)(B)). More specifically, the Court considers a special master's interpretation of statutes and other legal rules anew, without deference to the special master. *Hines on Behalf of Sevier v. Sec'y of Dep't of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). The Court defers, however, to the special master's factual findings so long as the special master has (1) "considered the relevant evidence of record," (2) "drawn plausible inferences," and (3) "articulated a rational basis for the decision." *Id.*

Under the arbitrary and capricious standard, the Court does not "reweigh" or re-evaluate the probative value of the evidence or a witness's credibility. *Porter v. Sec'y of HHS*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). The Federal Circuit has explained:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of HHS, 717 F.3d at 1366-67 (Fed. Cir. 2003) (quoting *Hodges v. Sec'y of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993) (modification in original).

The petitioners argue that the special master erred by dismissing key "facts." (ECF 140 at 1.) The petitioners conclude that their explanation and evidence are well-established, and that the respondent's rejection of their theory amounts to the assertion of an idiopathic cause, grounded completely in speculation, for C.K.'s infantile spasms. The special master's decision to credit the respondents' arguments, the petitioners argue, is therefore arbitrary and capricious.

The Court finds that the petitioners' arguments were either waived or fail to address the dispositive parts of Special Master Horner's reasoning. Accordingly, the petitioners fail to show that Special Master Horner's decision on remand is arbitrary or capricious.

A. Waiver

The petitioners argue that it was arbitrary and capricious for Special Master Horner to dismiss the stress effects of C.K. having received four vaccinations. Vaccine Rule 8(f)(1) of the Rules of the Court of Federal Claims 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 petitioners' motion fails to develop this argument further, and they offer no explanation or citation of when or how the argument was raised before the special master. Accordingly, this argument is waived.

B. Implications of Rapid Onset

The petitioners argue, in passing, that the onset, within 10 hours of the receipt of the vaccination, of infantile spasms in the otherwise healthy, four-month-old C.K. distinguishes her case from those involving idiopathic, genetically-caused infantile spasms that manifest over several months. This rapid onset, the petitioners argue, means that C.K.'s infantile spasms must have had some other cause.

Special Master Horner addressed a similar argument regarding whether C.K. might have still developed infantile spasms without vaccination. *Decision on Remand* at 24. The special master did not reject the notion that C.K.'s infantile spasms might have had a non-genetic cause. Indeed, in his analysis of the petitioners' causal theory, Special Master Horner accepted that an inflammatory immune response triggered by infection can cause infantile spasms. *Id.* at 20. Special Master Horner rejected as insufficient the petitioners' evidence that C.K.'s DTaP vaccine caused a non-genetic, inflammatory immune response that the petitioners established could affect the onset of infantile spasms. The petitioners provide no rationale grounded in the record to support a conclusion that this finding of the special master is arbitrary or capricious.

C. Whether DTaP Causes Seizures

The petitioners argue that their evidence satisfies the *Althen* test's first prong because it is "well-accepted" that the DTaP vaccine causes seizures, albeit to a lesser extent than the DPT vaccine. It was arbitrary and capricious, they argue, for Special Master Horner to "hold that less adverse effects is none." (ECF 140 at 6.) The petitioners further argue that attenuated pertussis is a neuro-toxin. They argue that medical professionals agree that DTaP can cause the same neurological damage as DPT, but only about one-third as frequently. As a result, the DTaP vaccine can cause seizure-like disorders. They urge the Court to take judicial notice of the DTaP vaccine's labeling and additional studies that they first raised in their motion to supplement the record, which Special Master Horner denied.[6]

Special Master Horner held neither that the DTaP vaccine cannot cause seizures nor that the DTaP vaccine has no adverse effects. Instead, Special Master Horner found that the petitioners had failed to meet their burden with record evidence to establish that the DTaP vaccine can cause the onset of infantile spasms. In reaching that conclusion, the special master rejected the Melchior study as inapplicable because its findings on the effect of the DPT vaccine were statistical observations. He refused to use statistical observations of one vaccine's effects to extrapolate data on the effects of another vaccine that was designed to have significantly

[6] The petitioners make no argument that Special Master Horner's legal conclusions in his decision denying their motion to supplement the record were erroneous.

different (and safer) effects. This conclusion is reasonable and supported by precedent, which Special Master Horner cited.

The petitioners argue that the precedents Special Master Horner cited support their contention that the DTaP vaccine can cause seizures, albeit less often than the DPT vaccine does. The petitioners' argument quotes language from these precedents out of context and misses the point. The opinions Special Master Horner cited uniformly refuse to extrapolate statistical, immunological data from one context to a different context. Most of the cases cited dealt with the DPT and DTaP vaccines. The one decision that the petitioners criticize as not related to DPT and DTaP in fact calls out Dr. Kinsbourne for misapplying studies of children and infants to adolescents. *See Holmes v. Sec'y of HHS*, No. 08-185V, 2011 WL 2600612, at *20 (Fed. Cl. Spec. Mstr. Apr. 26, 2011) ("Doctor Kinsbourne has been criticized in the past for extrapolating from studies of the DPT vaccine to the DTaP vaccine. Here, he extrapolated from studies of infants and young children, whom he acknowledged have brains that are very different from older children and adolescents, to apply their findings and conclusions to a seizure disorder in an adolescent.")

The petitioners further argue that the DTaP vaccine's ability to cause seizures is so well-accepted that the Court should take judicial notice of this fact. The respondent's failure to provide evidence that DTaP "does no harm," the petitioners argue, means that the respondent's defense, not the petitioners' theory, is based on speculation and an expert's *ipse dixit*.

This argument asserts a presumption that findings as to the safety of the DPT vaccine create a presumption that all pertussis-containing vaccines are injurious. From this premise, the petitioners go on to argue that the respondent had a burden to prove that the DTaP vaccine is not injurious. The Court is unaware of any authority to support such a presumption for an injury not listed in HHS's vaccine injury table. Indeed, as Special Master Horner noted, "[t]he burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question." *Decision on Remand* at 5 (citing *Althen*, 418 F.3d at 1278). The petitioners' effort to shift the burden of proof is inconsistent with the law, and the Court rejects it.

Special Master Horner considered whether there was evidence that the DTaP vaccine, specifically, could cause infantile spasms and found nothing other than the Bellman study, which he found insufficient because the majority of the cases of infantile spasms it identified were symptomatic, unlike the cases at issue here, and the study's own authors suggested that the finding may have been attributable to recall bias. These are rational reasons for assigning little probative weight to the Bellman study, and this Court lacks authority otherwise to reweigh this evidence. *Porter*, 663 F.3d at 1249.

The petitioners' argument that the Court should take judicial notice of a seizure warning on the DTaP vaccine's packaging and judicial notice of a "Federal Circuit" decision that, itself, took judicial notice of the DTaP packaging warning is flawed. First, judicial notice cannot serve as "a remedy for a party's failure to introduce readily available evidence of crucial facts" before the special master. *Rodriguez v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 453, 461 (2010), *aff'd,* 632 F.3d 1381 (Fed. Cir. 2011). The petitioners do not assert that the DTaP packaging was unavailable when they litigated their theory of causation before the special master.

Further, the "Federal Circuit" decision that the petitioners refer to is in fact a decision of this court. (*See* ECF 140 at 10 ("The Federal Circuit in *Loving v. Secretary*, 86 Fed. Cl. 135, 146-147 *(Fed. Cl.* [sic.] *2009)* cited to several manufacturers' DTaP package inserts.") (italics in original).)

The *Loving* decision's use of judicial notice is distinguishable. In *Loving*, Judge Lettow of this court took notice of the "two to three days" timeframe listed on the DTaP vaccine's packaging to support the proposition that "adverse reaction to the vaccination typically will occur within three days of receiving the vaccine." *Id.* This part of the *Loving* decision was not evaluating whether the petitioners in that case established preponderant evidence of a causal theory under *Althen*'s first prong. Rather, the *Loving* decision was analyzing the temporal proximity between vaccination and injury under *Althen*'s third prong. *See id.* at 145 ("Here, the special master failed to examine the record in its entirety when he determined that the petitioners could not satisfy the temporal-relationship prong of *Althen.*"). Further, Judge Lettow in *Loving* did not rely on judicial notice alone to support his conclusion that the petitioners satisfied *Althen*'s third prong. After taking judicial notice of the packaging, the decision proceeded to describe evidence submitted by the respondents that supported the same proposition. *Id.* at 148.

In this case, the Court will not take judicial notice of the DTaP packaging or other materials that could have been, but were not, submitted to the special master in the first instance.

D. Rejection of the Double-Hit Theory

The petitioners' motion argues that the effectiveness of ACTH in controlling C.K.'s seizures was sufficient evidence that C.K.'s seizures were caused by the stress hormone CRH. The petitioners further argue that the rapid onset of the seizures implicates an innate immune reaction as the CRH-producing cause.

These arguments fail to address Special Master Horner's reasoned explanation as to why he did not find the effectiveness of ACTH in treating C.K.'s seizures dispositive. ACTH's effectiveness in C.K.'s case, at most, suggests that her seizures were triggered by CRH. It does not implicate vaccination as the cause of a seizure-triggering CRH release.

Similarly, identifying C.K.'s seizure with the rapidity of an innate immune response, at most, suggests that an immune response caused an increase in C.K.'s levels of CRH. Neither it nor any other evidence in the record show by preponderant evidence that vaccination can cause such an innate immune response.

The petitioners claim that the Iwasaki and Medzhitov article submitted with Dr. Kinsbourne's report "directly implicate[s] vaccinations as starting the seizure response in issue." (ECF 140 at 5.) The petitioners' motion fails, however, to provide a quote or any explanation of how the cited article implicates vaccinations in the manner proffered by the petitioners. The sentence in the petitioners' brief is followed by an unidentified block quote of Dr. Kinsbourne's own words in his report, not the Iwasaki and Medzhitov article. (*Compare* ECF 140 at 5 with Ex. 6-1 at 7, filed on compact disc as ECF 19.) The petitioners also fail to identify where and in what manner Iwasaki and Medzhitov's "direct[ ] implic[ation]" of vaccination was raised before

Special Master Horner. (*See* Ex. 6-1 at 7.) The Court finds no substance to this unelaborated assertion of authority. To the degree there might be any substance, the Court finds that the petitioners waived the argument.

III. CONCLUSION

For the foregoing reasons, the Court **DENIES** the petitioners' motion for review and **SUSTAINS** the special master's decision on remand. The clerk shall enter judgment accordingly.

It is so **ORDERED**.

s/ Richard A. Hertling
Richard A. Hertling
Judge