NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

MARYELLEN KOTTENSTETTE, NICHOLAS KOTTENSTETTE, AS BEST FRIENDS OF THEIR DAUGHTER (C.K.),
Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES
Respondent-Appellee.

2020-2282

Appeal from the United States Court of Federal Claims in Case No. 1:15-vv-01016-RAH, Judge Richard A. Hertling.

Decided: June 15, 2021

JOHN F. MCHUGH, Law Office of John McHugh, New York, NY, argued for petitioners-appellants.

CAMILLE M. COLLETT, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by BRIAN M. BOYNTON, C. SALVATORE D'ALESSIO, HEATHER L. PEARLMAN.

Before O'MALLEY, REYNA, and STOLL, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

Maryellen and Nicholas Kottenstette ("the Kottenstettes"), on behalf of their daughter, appeal the final judgment of the United States Court of Federal Claims and a prior non-final decision by that court in the same case. *Kottenstette v. Sec'y of HHS* (*Kottenstette II*), No. 15-1016V, 2020 WL 4592590 (Fed. Cl. July 27, 2020); *Kottenstette v. Sec'y of HHS* (*Kottenstette I*), No. 15-1016V, 2020 WL 953484 (Fed. Cl. Feb. 12, 2020). Two special masters made determinations in this case. *Kottenstette v. Sec'y of HHS* (*Special Master Decision II*), No. 15-1016V, 2020 WL 4197301 (Fed. Cl. June 2, 2020), *aff'd*, *Kottenstette II*, 2020 WL 4592590; *Kottenstette v. Sec'y of HHS* (*Special Master Decision I*), No. 15-1016V, 2017 WL 6601878 (Fed. Cl. Dec. 12, 2017), *vacated*, *Kottenstette I*, 2020 WL 953484. The first special master found for the Kottenstettes. *Special Master Decision I*, 2017 WL 6601878. The Court of Federal Claims vacated and remanded her decision, finding that she had applied an incorrect legal standard to one aspect of her analysis. By the time the case had been remanded, she had retired, so the case was assigned to a second special master. The second special master reweighed the evidence and determined that the Kottenstettes had not provided preponderant evidence that vaccines were a cause of their daughter's injury. *Special Master Decision II*, 2020 WL 4197301. The Court of Federal Claims affirmed that decision. *Kottenstette II*, 2020 WL 4592590. We *reverse* both Court of Federal Claims decisions.

BACKGROUND

The Kottenstettes' daughter, C.K., was born on June 1, 2012. Until October 2, 2012, she appeared to be a happy and healthy, normally developing child. On the morning of October 2, 2012, she had her four-month pediatrician

appointment, during which she received four vaccines: pneumococcal conjugate ("PCV"); inactivated poliovirus ("IPV"); haemophilus influenzae type b ("Hib"); and diphtheria, tetanus, and acellular pertussis ("DTaP"). During her appointment, she appeared "alert, vigorous, in no acute distress, well developed and well nourished." J.A. 124. Less than ten hours later, C.K. experienced the first of lifelong infantile spasms. During her initial infantile spasms, C.K. appeared alert and, other than unusual arm movements, did not appear to be unwell. Over time, however, C.K. has suffered vision impairment and major developmental delays due to her infantile spasms.

On September 11, 2015, C.K.'s parents, Maryellen and Nicholas Kottenstette, filed a petition on her behalf for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to 300aa-34. They alleged that C.K. suffers infantile spasms accompanied by a chronic encephalopathy and that vaccination was a cause of her condition.[1]

In support of their petition, the Kottenstettes filed an expert report and a supplemental expert report by Dr. Marcel Kinsbourne, a pediatric neurologist. The government filed an expert report by Dr. John Zempel, a pediatric neurologist and pediatric epileptologist.

Dr. Kinsbourne presented a "two hit model of seizure susceptibility" in which an infant has a pre-existing condition that makes them more susceptible to infantile spasms (the first hit) and undergoes an adverse or stressful event

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[1] "Encephalopathy is a term for any diffuse disease of the brain that alters brain function or structure." NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE, *Encephalopathy Information Page*, https://www.ninds.nih.gov/Disorders/All-Disorders/Encephalopathy-Information-Page (last visited May 10, 2021).

(the second hit) which triggers seizures which can lead to worsening psychomotor regression if not immediately controlled. J.A. 916. He opined that, in C.K.'s case, the first hit was the hyperexcitability of her infantile neural network, which may be caused by prenatal stress. He reasoned that C.K.'s four-month vaccines were likely the "second hit" as they "necessarily evoked an innate immune system reaction, which in turn generated proinflammatory cytokines." J.A. 916. Dr. Kinsbourne cited several studies to support his theory. He cited two of those studies as support for the proposition that vaccinations such as DTP and DTaP can trigger the onset of infantile spasms: the Bellman and Melchior studies.

The Bellman study found an increase in cases of infantile spasms in the week following DTP immunization as compared to controls, and fewer cases of infantile spasms in the second week after DTP vaccination. The authors of the Bellman study surmised that the pertussis part of the DTP vaccine "may precipitate the onset of spasms in those children in whom the disorder is already destined to develop," causing spasms to develop sooner than they otherwise would have. J.A. 911; J.A. 1234. It is undisputed that earlier onsetting uncontrolled infantile spasms generally cause greater long-term impact than spasms which occur later in infancy.

The Melchior study analyzed the effect of changing the date of administration of the DTP vaccine from five months of age to five weeks of age in Denmark. The children who received the earlier (five week) vaccination experienced the onset of infantile spasms before two months of age twice as often as the children who received the later (five month) vaccination. The author of the Melchior study concluded "that a causal connection between [pertussis] immunization and infantile spasms is very unlikely except in a few cases and that time-coincidence is the most likely factor. . . ." *Special Master Decision I*, 2017 WL 6601878, at *4.

The government's expert, Dr. Zempel,[2] disagreed with Dr. Kinsbourne's application of the two-hit model. He rejected Dr. Kinsbourne's opinion that vaccinations could be the "second hit" because Dr. Kinsbourne cited no medical literature or objective independent evidence from treating physicians for this proposition. He also objected to Dr. Kinsbourne's characterization of the Bellman and Melchior studies. He criticized the studies for discussing DTP rather than DTaP, the vaccine C.K. received. He understood that the Bellman study concluded that pertussis vaccine might precipitate the onset of spasms in children who would eventually develop them in any case but was not a direct cause of infantile spasms. And he stated that the Melchior study actually showed that there was "no change in the onset of infantile spasms" but for an occasional, coincidental "connection between immunization and infantile spasms." *Special Master Decision I*, 2017 WL 6601878, at *6.

On December 12, 2017, the first special master found that the Kottenstettes had prevailed on their allegations that C.K.'s October 2, 2012 vaccinations were a cause of her infantile spasms and resulting chronic encephalopathy. *Special Master Decision I*, 2017 WL 6601878, at *2.

She found that both sides' expert witnesses, Dr. Kinsbourne and Dr. Zempel, agreed on several points: (1) C.K.'s "cryptogenic infantile spasms have an unknown cause," *Id.* at *13; (2) before administration of her four-month vaccines, C.K. appeared to be clinically normal, but had an abnormal brain; (3) within hours of the administration of her four-month vaccines, C.K. had her first infantile spasms for

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[2] Dr. Zempel's report was not included in the record submitted on appeal. All characterizations of his report are taken from the first special master's decision, *Special Master Decision I*, 2017 WL 6601878, at *6-7, which were adopted by the second special master, *Special Master Decision II*, 2020 WL 4197301, at*5.

reasons that scientists and doctors have not been able to decipher; (4) C.K.'s infantile spasms have continued despite aggressive treatment and aging out of the age range at which infantile spasms normally abate; and (5) C.K. is now severely delayed in all categories and continues to suffer from infantile spasms.

On points on which the parties and their experts disagreed, the first special master made explicit findings of fact. First, she found credible Dr. Kinsbourne's opinion that adverse reactions to DTaP "could occur, but just at a lower incidence than adverse reactions to whole-cell [DTP]." *Id*. She based this finding on the fact that "[p]ertussis vaccine is known to be epileptogenic at times" and Dr. Kinsbourne's testimony that "[a]lthough in acellular [DTP], the pertussis is toxoided, there is still some high-toxoided toxin in it." *Id*. at *8. Second, she found that C.K. "would have fit into the Bellman study which, based on a week-by-week analysis, found that, among cryptogenic infantile spasms vaccinees, the onset of infantile spasms occurring within the first week after vaccination was higher than baseline cryptogenic infantile spasms children" and that the DTP vaccine "was a trigger to the onset of infantile spasms so that the spasms occurred sooner than they would have without vaccination[.]" *Id*. Third, she found that C.K., "even though she received DTaP, not [DTP], would have qualified to have been in the Bellman and Melchior studies because she had infantile spasms within a week of pertussis vaccination and the vaccination was a trigger, according to both the Bellman and Melchior studies, which prompted the onset of her spasms." *Id*. at *14. Fourth, she found that, "but for her onset of cryptogenic infantile spasms at four months of age, [C.K.] would have not had the disastrous outcome she had." *Id*. Fifth, she found credible Dr. Kinsbourne's testimony that the "explosive, sudden, and dramatic" onset of C.K.'s infantile spasms, which both experts agreed normally have an insidious onset, proved that "DTaP was a trigger of [C.K.'s]

infantile spasms." *Id.* at *15. Sixth, she was "satisfied with the evidence in the record that the medical literature's acceptance of pertussis vaccine as a trigger to onset of infantile spasms in a few cases within one week of vaccination is sufficient to prove causation in this case, buttressed by the evidence of an explosive onset of infantile spasms rather than the normal insidious onset of infantile spasms." *Id.*

The first special master then applied her factual findings to the three prongs set forth by this Court in *Althen*. *Althen* lists three prongs which petitioners must prove by preponderant evidence: "(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." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The first special master concluded, based on her findings of fact, that: (1) "DTaP vaccine can trigger the onset of infantile spasms" under *Althen* prong 1; (2) "there was a logical sequence of cause and effect in DTaP causing [C.K.'s] onset of infantile spasms" under *Althen* prong 2; and (3) "an onset within hours of DTaP vaccination is consistent with the effect of the vaccine's triggering an abrupt onset" under *Althen* prong 3. *Special Master Decision I* at *15. She thus ruled in favor of the Kottenstettes. *Id.*

The government sought review of the first special master's decision with the Court of Federal Claims. The Court of Federal Claims vacated and remanded, finding it "apparent from the special master's description of the evidence that the petitioners' causal theory was only *plausibly* linked to the DTaP vaccine at issue, and only *plausibly* linked to the developmental injury C.K. suffered" under *Althen*'s first prong. *Kottenstette I*, 2020 WL 953484, at *3. According to the Court of Federal Claims, the standard that the first special master used to determine if the Kottenstettes had shown "a medical theory causally

connecting the vaccination to the injury" "is not sufficiently distinguishable from the 'plausible' or 'reasonable' standard that the Federal Circuit rejected in" *Boatmon v. Secr'y of HHS*, 941 F.3d 1351 (Fed. Cir. 2019). *Id.* The Court of Federal Claims rejected only one of the first special master's many factual findings, determining that it was arbitrary and capricious for her to accept Dr. Kinsbourne's conclusion that DTP studies could apply to the DTaP formulation at lower rates without explaining why she accepted that conclusion. *Id.* at *5. The Court of Federal Claims vacated and remanded "so that the special master may consider the petitioners' theory and evidence under the correct legal standard." *Id.* at *6.

On remand, a different special master reweighed the evidence and reached the opposite conclusion. *Special Master Decision II*, 2020 WL 4197301. He denied the Kottenstettes' motion to reopen the evidentiary record. *Id.* at *3. He did not hear testimony, but rather opted to rely on transcripts of testimony heard by the first special master. *Id.*

Like the first special master, the second special master found that "C.K. was properly diagnosed with infantile spasms," "that it continues to be her correct diagnosis," and that C.K.'s "seizures began soon after her October 2, 2012 vaccinations." *Id.* at *4. But he disagreed with the first special master's factual findings on several points, leading him to make his own contrary findings. First, unlike the first special master, he did not credit Dr. Kinsbourne's testimony that there is a relationship between DTP and DTaP vaccine formulations, such that DTaP might cause adverse effects associated with DTP vaccination, albeit at a lower rate. *Id.* at *9. Second, he gave no weight to the Melchior study and minimal weight to the Bellman study. *Id.* at *10.

He went on to make additional factual findings concerning the theory presented by Dr. Kinsbourne as to the causation of C.K.'s infantile spasms—the "two-hit model"

of epileptogenesis, in which an individual with a pre-existing susceptibility (the first hit) experiences a stressor (the second hit) triggering the onset of seizures. *Id*. at *11. He found that both parties' experts agreed that "a stressor can trigger a seizure generally" and that "an immune response can lower the seizure threshold." *Id*. at *12. But he did not credit Dr. Kinsbourne's testimony that this relationship between stressors, the immune response, and the onset of seizures implicates vaccinations. *Id*. at *13. He did not credit Dr. Kinsbourne's theory in part because of (1) Dr. Kinsbourne's testimony that the innate immune response is both a normal and necessary part of the vaccine response which "occurs without negative consequences in the vast majority of cases;" (2) Dr. Kinsbourne's testimony that "scientific proof is lacking" as to his theory of causation, and (3) Dr. Kinsbourne's lack of qualifications as an immunologist. *Id*. at*13-14.

The second special master ultimately found that the Kottenstettes had failed to provide preponderant evidence of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury" under *Althen*'s second prong. *Id*. at *15. He found that the only evidence that vaccinations caused C.K.'s infantile spasms was the timing of the spasms. *Id*. This was insufficient proof for the second special master, who noted that the government's expert, Dr. Zempel, testified that fever is "by far the most powerful component of the immune response [] related to a decrease in seizure threshold" and that most infantile seizures onset during the first year of life. *Id*. at *15-16.

The second special master did not decide whether the Kottenstettes had shown a "medical theory causally connecting the vaccination and the injury" under *Althen*'s first prong. *Id*. at *14. He found that the Kottenstettes had established a "proximate temporal relationship" between vaccination and injury under *Althen* prong three. *Id*. at *18.

The Court of Federal Claims sustained the second special master's decision. *Kottenstette II*, 2020 WL 4592590.

The Kottenstettes timely appealed, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).[3]

STANDARD OF REVIEW

In Vaccine Act cases, this court reviews appeals from the Court of Federal Claims *de novo*. *Sharpe v. Sec'y of HHS*, 964 F.3d 1072, 1077 (Fed. Cir. 2020) (citing *Lampe v. Sec'y of HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)). This court in effect "performs the same task as the Court of Federal Claims and reviews the special master's legal determinations *de novo*, fact findings under an arbitrary and capricious standard, and discretionary rulings for an abuse of discretion." *Id*. (citing *Munn v. Sec'y of HHS*, 970 F.2d 863, 870-73, 870 n.10 (Fed. Cir. 1992)).

The arbitrary and capricious standard is "difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact." *Milik v. Sec'y of HHS*, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting *Lampe*, 219 F.3d at 1360). If the special master "'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,' then

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[3] This Court has jurisdiction to review both decisions of the Court of Federal Claims. The Court of Federal Claims entered final judgment on July 27, 2020. The Kottenstettes timely appealed on September 17, 2020. We note that, although the Court of Federal Claims entered its order vacating the first special master's decision on February 12, 2020, that order was not a final judgment which the Kottenstettes could appeal to the Federal Circuit on issuance. They instead had to wait until issuance of the final judgment on July 27, 2020.

reversible error is 'extremely difficult to demonstrate.'" *Id.* (quoting *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). So long as a special master's factual finding is based on record evidence that is "not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." *Id.* (quoting *Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1338 (Fed.Cir.2010)). Neither the Court of Federal Claims nor this court should "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of HHS*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

DISCUSSION

Petitioners seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that a covered vaccine was a cause of the injury they claim. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1). If a petitioner's injury is listed on the Vaccine Injury Table (a "Table Injury") and the petitioner shows that the injury manifested within a specified time, causation is presumed. *de Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(i). For injuries not listed on the Table or not occurring within the specified time, a petitioner must prove causation in fact. *de Bazan*, 539 F.3d at 1351; *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(ii). On appeal, the only issue before the court is whether the Kottenstettes have shown that vaccination caused C.K.'s non-Table injury.

To prove that a vaccination caused a non-Table Injury, a petitioner must demonstrate, by a preponderance of the evidence:

> (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.

Althen, 418 F.3d at 1278. If a petitioner establishes a prima facie case of causation, the burden shifts to the government to establish alternative causation by a preponderance of the evidence. *Walther v. Sec'y of HHS,* 485 F.3d 1146, 1151 (Fed. Cir. 2007); *see also* 42 U.S.C. § 300aa-13(a)(1)(B). If the government fails to establish alternative causation, the petitioner prevails. Close calls are to be resolved in favor of the petitioners. *Capizzano v. Sec'y of HHS*, 1440 F.3d 1317, 1326-27 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280).

The Kottenstettes argue on appeal that the Court of Federal Claims erred in setting aside the first special master's decision, that the second special master's decision was arbitrary and capricious for failing to honor the factual findings of the first special master, and that the second special master should have taken judicial notice of the alleged dangers of the DTaP vaccine.

We find that both Court of Federal Claims decisions were in error. First, we find that the first special master applied the correct legal standard. Thus, the first Court of Federal Claims decision vacating and remanding her decision is in error. We further find that the first special master's finding that studies relating to DTP vaccination could apply to the DTaP formulation was not arbitrary and capricious.

But even if the first Court of Federal Claims decision was correct in finding that the first special master had applied the wrong legal standard, we find that the second special master, on remand, improperly reweighed the evidence to come to conclusions contrary to those made by the first special master. Thus, we reverse the second Court of Federal Claims decision. It is not necessary to address the Kottenstettes' other arguments on appeal.

The Court of Federal Claims took two of the first special master's statements out of context to find that she applied the incorrect legal standard. First, the Court of Federal Claims took issue with the first special master's summarization of the legal standard as a search for "medical probability rather than certainty" and her statement that "medical probability means biologic credibility rather than specification of an exact biologic mechanism." *Kottenstette I*, 2020 WL 953484, at *2-3. The Court of Federal Claims found that "biologic credibility" "is not sufficiently distinguishable from the 'plausible' or 'reasonable' standard that the Federal Circuit rejected in *Boatmon*." *Id.* at *3. Second, the Court of Federal Claims found that the first special master used an "alternative approach to proof of causation that fit the petitioners' case into an existing study[.]" *Id.* But the first special master devoted over a page of her decision to reciting the correct legal standard. *Special Master Decision I*, 2017 WL 6601878, at *11-12. In the context of that statement of the legal standard and her application of the facts to the law, it is apparent that she applied the correct legal standard. *Cf. Kirby v. Sec'y of HHS*, No. 2020-2064, slip op. at 11-12 (Fed. Cir. May 19, 2021) (finding for the petitioner where the special master, unlike the special master in *Boatmon*, did not "'articulate[] a lower "reasonable" standard' in assessing the petitioners' medical theory of causation," but rather "recited the correct legal standard") (quoting *Boatmon*, 941 F.3d at 1359)).

The first special master's statement that "medical probability means biologic credibility rather than specification of an exact biologic mechanism" does not set a new lower "biologic credibility" standard; it correctly recites this court's statement in several precedential cases that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Knudsen*, 35 F.3d at 549; *see also Simanski v. Sec'y of HHS*, 671 F.3d 1368, 1384 (Fed. Cir. 2012) ("Although a finding of causation 'must be supported by a sound and reliable medical or scientific

explanation, 'causation' can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms.'"). *Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation.

The first special master also characterized in various ways our statement in *Knudsen* that "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). For example, she stated that this court "stated that when a vaccinee would fit within an epidemiological study, that alone is sufficient proof of vaccine causation" before reciting the above quoted section of *Knudsen*. *Special Master Decision I*, 2017 WL 6601878, at *13. But nowhere did she *apply* an "alternative approach to proof of causation that fit the petitioners' case into an existing study," as the Court of Federal Claims found. *Kottenstette I*, 2020 WL 953484, at *3. Despite her characterization of our holding in *Knudsen* that fitting within an epidemiological study alone is sufficient proof of causation, she did not rely solely on the Bellman and Melchior studies in finding causation. Rather, she was "satisfied with the evidence in the record" which included, *inter alia*, epidemiological studies, expert testimony, and information regarding C.K.'s medical history, "that the medical literature acceptance of pertussis vaccine as a trigger to onset of infantile spasms in a few cases within one week of vaccination is sufficient to prove causation in this case, buttressed by the evidence of an explosive onset of infantile spasms rather than the normal insidious onset of infantile spasms." *Special Master Decision I*, 2017 WL 6601878, at *15. Finally, as discussed below, her factual findings met the legal standard outlined in *Althen*, further confirming that she did not apply the incorrect legal standard.

The first Court of Federal Claims decision also erroneously found the first special master's acceptance of Dr. Kinsbourne's conclusion—that the DTP and DTaP formulations cause similar rare adverse effects, albeit at different rates—to be "[w]ithout any explanation" and therefore, arbitrary and capricious. *Kottenstette*, 2020 WL 953484, at *5. But the first special master did explain her finding. She noted, with citations to hearing testimony from Dr. Kinsbourne, that "[p]ertussis vaccine is known to be epileptogenic at times" and that, "[a]lthough in acellular [DTP], the pertussis is toxoided, there is still some high-toxoided toxin in it." *Special Master Decision I*, 2017 WL 6601878, at *8. She credited Dr. Kinsbourne's testimony that recipients of DTaP may still experience adverse reactions even though DTaP is less reactogenic than DTP. The first special master, as the factfinder who actually witnessed Dr. Kinsbourne's and Dr. Zempel's live testimony, had "broad discretion in determining [their] credibility." *See Bradley v. Sec'y of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). That discretion is "virtually unreviewable" by either this court or the Court of Federal Claims. *Id.* (quoting *Hambsch v. Dep't of Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986)). Thus, her determination that DTaP and DTP vaccinations could cause similar rare adverse effects, albeit at different rates, was based on record evidence that was not "wholly implausible." *See Lampe,* 219 F.3d at 1363. She "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision." *See Milik*, 822 F.3d at 1376 (quoting *Hines*, 940 F.2d at 1528).

But even if the Court of Federal Claims did not err in vacating the first special master's decision for applying the incorrect legal standard, we find that it erred in sustaining the decision of the second special master because the second special master improperly reweighed the evidence. Neither this court nor the Court of Federal Claims should reweigh the evidence under the arbitrary and capricious standard of review. *See Motor Vehicle Mfrs. Ass'n of U.S.,*

Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Nor should the second special master have reweighed the evidence to come to his own factual findings on remand, as the government admitted at oral argument. Oral Arg. at 23:00-23:35, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=20-2282_04072021.mp3. The Court of Federal Claims remanded for the limited purpose of "reconsideration under the correct legal standard[.]" *Kottenstette I*, 2020 WL 953484, at *1. The second special master exceeded that task on remand. He reweighed the facts to come to contrary findings on remand despite not witnessing the testimony on which he was passing judgment and despite declining to reopen the evidentiary record.

Taking the factual findings expounded by the first special master and applying them to the *Althen* prongs confirms her original conclusion that the Kottenstettes have shown by a preponderance of the evidence that C.K.'s vaccination caused her injury.

Under *Althen* prong one, the Kottenstettes were required to provide "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. They did so. They provided two epidemiological studies showing that DTP vaccination may trigger the onset of infantile spasms, which the first special master accepted and found informative. She further found that "[p]ertussis vaccine is known to be epileptogenic at times" and that "[a]lthough in acellular [DTP], the pertussis is toxoided, there is still some high-toxoided toxin in it." *Kottenstette*, 2017 WL 6601878, at *8. She credited Dr. Kinsbourne's testimony that recipients of DTaP can still experience adverse reactions even though DTaP is less reactogenic than DTP. As discussed above, that finding was not arbitrary and capricious. Finally, she found that early onset of infantile spasms, such as those triggered by four-month vaccinations, could lead to worse outcomes than later onset of infantile spasms. We find that these facts found by the first

special master provide sufficient evidence of "a medical theory causally connecting the vaccination and the injury." *See Althen*, 418 F.3d at 1278.

Under *Althen* prong two, the Kottenstettes were required to provide "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. They did so. As discussed above, the first special master found that the Kottenstettes had shown that both DTP and DTaP could provoke rare adverse events, albeit at different rates. She further found that C.K. was clinically normal but had an abnormal brain. She also found that although "the usual onset of infantile spasms is insidious," the onset of C.K.'s infantile spasms "was explosive, sudden, and dramatic" and that abnormal onset confirmed that C.K.'s "vaccinations, administered just a few hours earlier, triggered that onset." *Special Master Decision I*, 2017 WL 6601878, at *15. We find that these factual findings by the first special master provide sufficient evidence of "a logical sequence of cause and effect showing that the vaccination was the reason for the injury."

The second special master faulted the Kottenstettes for presenting a "mere suspicion of a temporal relationship" as evidence of causation under *Althen* prong two. *Special Master Decision II*, 2020 WL 4197301, at *15. But that is not an accurate characterization of the evidence. Rather, as the first special master found, the Kottenstettes provided evidence that the onset of C.K.'s infantile spasms was unusual. Most cases of infantile spasms have an insidious onset. But C.K.'s spasms began "explosive[ly]" mere hours after her vaccinations. *Kottenstette*, 2017 WL 6601878, at *15. Thus, causation here is confirmed not just by the temporal relationship, but also by the abnormal "explosive" onset. *Id.* That C.K.'s medical records do not show that she experienced other symptoms, such as fever or inflammation, does not detract from the abnormal onset of her spasms or from the first special master's other factual

findings showing that C.K.'s vaccinations were a cause of her injury.

Both special masters found that the Kottenstettes had prevailed in showing the third *Althen* factor, "a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. We agree.

CONCLUSION

The first special master applied the correct legal standard and her finding that DTaP and DTP vaccinations could cause similar rare adverse effects, albeit at different rates, was not arbitrary and capricious. The second special master improperly reweighed the evidence on remand. And the first special master's factual findings meet the standard propounded in *Althen*. Thus, we *reverse* both Court of Federal Claims decisions, and reinstate the first special master's finding for the Kottenstettes, including the monetary award set by that special master.

REVERSED

COSTS

Costs to the Appellants.