United States Court of Appeals for the Federal Circuit

DOUG PALUCK, RHONDA PALUCK, AS PARENTS AND NATURAL GUARDIANS, ON BEHALF OF THEIR MINOR SON, K.P.,
Petitioners-Appellees

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant

2014-5080

Appeal from the United States Court of Federal Claims in No. 1:07-vv-00889-CFL, Judge Charles F. Lettow.

Decided: May 20, 2015

SHEILA A. BJORKLUND, Lommen, Nelson, Cole & Stageberg, P.A., Minneapolis, MN, argued for petitioners-appellees.

PATRICK NEMEROFF, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellant. Also represented by JOYCE R. BRANDA; ALEXIS B. BABCOCK, Vaccine/Torts Branch, Civil Division, United States

Department of Justice, Washington, DC; MICHAEL S. RAAB, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC.

Before REYNA, MAYER, and CHEN, *Circuit Judges.*

MAYER, *Circuit Judge.*

The Secretary of Health and Human Services appeals a final judgment of the United States Court of Federal Claims setting aside the special master's findings of fact and conclusions of law and granting entitlement to compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa–1 to –34. ("Vaccine Act"). *See Paluck ex rel. Paluck v. Sec'y of Health & Human Servs.*, 113 Fed. Cl. 210 (2013) ("*Court of Federal Claims Decision II*"). We affirm.

BACKGROUND

The Court of Federal Claims provided a comprehensive account of the relevant facts and they need only be briefly summarized here. K.P. was born on January 15, 2004. He exhibited no apparent signs of disability during the first six to eight months of his life, but in October 2004 K.P.'s daycare provider referred him to K.I.D.S., an infant development service, for evaluation. *Id.* at 213. After extensive testing, K.I.D.S. determined that K.P. suffered from significant delays in his gross motor skills and some delays in his fine motor skills. *Id.* at 214. Evaluation conducted using the Bayley Scales of Infant Development protocol, however, determined that K.P.'s "cognitive skills (*i.e.*, ability to remember, problem solve, use and understand language, and identify early number concepts)" were "within normal limits." The evaluators from K.I.D.S. noted that K.P. was "a social boy with a bright smile" who made "a nice variety of sounds while babbling using both consonants and vowels." The evaluators ultimately concluded that K.P. presented a "mixed

picture," and that his "gross motor delays [were] impacting his ability to achieve age-level skills in other areas of development."

K.P. experienced recurrent rashes, which were later identified as a symptom of erythema multiforme. He also suffered from repeated ear infections. On December 27, 2004, K.P. saw Stephen L. McDonough, M.D., his pediatrician, for a check of his ears. McDonough evaluated K.P. as having normal muscle tone, noting that he had "good head control and fairly good truncal control." McDonough stated, however, that K.P. was "not pulling himself to stand or crawling yet." Although McDonough indicated that K.P. might have "possible mild gross motor delay," he also noted that K.P. was rolling over, trying to crawl, and had "several words."

McDonough saw K.P. on January 19, 2005 for his one-year well baby visit. At this appointment, K.P. received doses of the measles-mumps-rubella ("MMR"), pneumococcal, and varicella vaccines. After examining K.P., McDonough described K.P.'s neuromuscular condition as "abnormal," noting increased tone[1] in his upper extremities and the presence of ankle clonus, an abnormal reflex movement. Although K.P. could "bang [two] cubes held [in his] hands," "play ball with [the] examiner," "pull to stand," "stand holding on," "say single syllables," and "say dada/mama," he could not "get to sitting" or "stand alone."

On January 21, 2005, two days after he was vaccinated, K.P. had a temperature of 101.5 degrees. Seven days later, on January 28, 2005, K.P. had a recorded temperature of 101.3 degrees. In the two weeks following the

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[1] As Richard Frye, M.D., the Palucks' expert, explained, "tone" is a measurement of the ability of the muscles to maintain the body in proper posture in different positions, such as sitting or standing.

vaccinations, K.P. was generally fussy and did not nap or eat well.

In February 2005, Rhonda and Doug Paluck (the "Palucks"), K.P.'s parents, took him to the Pokorny Chiropractic Clinic, hoping to address his gross motor problems. On February 11, 2005, the chiropractor reported that K.P. was "spastic." On March 24, 2005, McDonough referred K.P. to Siriwan Kriengkrairut, M.D., a pediatric neurologist. In making the referral, McDonough noted that K.P. suffered from "gross motor delay, global developmental delay, and hypertonicity."

After evaluating K.P., Kriengkrairut concluded that he suffered from "marked spasticity of the extremities" and "[g]lobal delayed development." Kriengkrairut suggested to the Palucks that K.P.'s muscular abnormalities and developmental delays were possibly the result of a "central nervous system pathology."

On April 27, 2005, K.P. had a magnetic resonance imaging ("MRI") exam of his brain. The results of this MRI exam were initially deemed to be normal. Subsequently, however, the MRI results were reexamined, and it was determined that they evidenced a thinning of the corporal callosum. In May 2005, K.P. was evaluated by a speech therapist who determined that he possessed fewer language skills than he did in October 2004, and that his total language score was in the first percentile.

In July 2005, K.P. suffered a series of seizures and was hospitalized for three weeks. While in the hospital, he underwent another MRI exam, which showed further thinning of the corporal callosum. Theodore J. Passe, M.D., a radiologist who reviewed K.P.'s April and July 2005 MRI results, concluded that they were "consistent with a progressing leukodystrophy" which could have a "hereditary, toxic or metabolic etiolog[y]."

On October 27, 2005, K.P. had another MRI exam. Michael Frost, M.D., a physician who began treating K.P. in the summer of 2005, determined that this exam showed no significant changes in K.P.'s brain since the July 2005 MRI exam. Frost concluded that "the progression of a signal change" in K.P.'s brain "between 4/27/05 and 07/22/05 may have represented evolution of [one] toxic/metabolic event, which is now stable."

K.P. was subsequently diagnosed with an unspecified mitochondrial disorder. All parties agree that this mitochondrial disorder was most likely present from the time of K.P.'s birth. K.P. now lives in a state of severe neurological disability. He has "no purposeful movements" and "no specific smiling or distinctive eye contact." K.P. has a tracheotomy tube and breathes with the assistance of a ventilator.

In December 2007, the Palucks filed a petition for compensation under the Vaccine Act. They alleged that K.P. sustained a permanent injury to his brain as a result of the MMR, pneumococcal, and varicella vaccines he received on January 19, 2005. Frye, the Palucks' expert, testified that K.P.'s underlying mitochondrial disorder prevented him from coping with the oxidative stress from the vaccines he received. According to Frye, this led to "metabolic decompensation," and eventually caused neurodegeneration and developmental regression. The special master, however, rejected the Palucks' claim, concluding that Frye failed to provide a plausible medical theory causally connecting K.P.'s injury to the vaccines he received. *See Paluck ex rel. Paluck v. Sec'y of Health & Human Servs.*, No. 07-889V, 2011 WL 6949326, at *16 (Fed. Cl. Dec. 14, 2011) ("*Special Master Decision I*"). The special master determined, moreover, that K.P.'s neurological symptoms emerged too late to be causally linked to the vaccinations he received. *Id.* at *24–27. In the special master's view, if K.P.'s neurodegeneration was vaccine-induced, he would have exhibited symptoms of neurologi-

cal injury within two weeks of the date of his vaccinations. *Id. at* *27.

On appeal, the Court of Federal Claims concluded that the special master had "required a higher level of proof . . . than the Vaccine Act demands." *Paluck ex rel. Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 473 (2012) ("*Court of Federal Claims Decision I*"). According to the court, the special master had no reasonable basis for rejecting Frye's theory of causation. *Id.* at 474. The court further determined that "[i]t was arbitrary and capricious for the special master to set a hard and fast limit of two weeks" between vaccination and the onset of symptoms of vaccine-induced neurological injury. *Id.* at 482. Because the special master "misapprehend[ed] the testimony of Dr. Frye and ignor[ed] salient medical-record evidence of [K.P.'s] symptoms during the relevant time period," *id.* at 483, the court vacated the special master's decision and remanded for further proceedings.

On remand, the special master accepted the government's apparent concession that Frye had presented a plausible medical theory explaining how vaccination could aggravate an underlying mitochondrial disorder.[2] *See Paluck ex rel. Paluck v. Sec'y of Health & Human Servs.*, No. 07-889V, 2013 WL 2453747, at *42 (Fed. Cl. May 10, 2013) ("*Special Master Decision II*"). The special master determined, however, that K.P.'s condition did not deteriorate in the manner predicted by Frye's theory. In the special mas-

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[2] The special master determined that K.P.'s claim should be treated not as a new injury claim, but instead as a claim for the significant aggravation of his preexisting mitochondrial disorder. *See* 42 U.S.C. § 300aa–33(4) ("The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.").

ter's view, Frye's theory predicted "a dramatic and continual deterioration, beginning within two to three weeks after" vaccination. *Id.* at *49. The special master concluded, however, that K.P. did not manifest any symptoms of neurological injury within three weeks of his vaccinations, *id.* at *55–62, and did not experience the type of "linear" deterioration that Frye's theory of causation required, *id.* at *49.

On appeal, the Court of Federal Claims held that the special master had misconstrued Frye's theory of causation. *Court of Federal Claims Decision II*, 113 Fed. Cl. at 234–35. According to the court, "[t]o fall within Dr. Frye's theory and the applicable medical literature, it [was] sufficient if [K.P.'s] medical records show[ed] a decline in condition over time, notwithstanding periods of remission or modest improvement." *Id.* The court determined, moreover, that it was arbitrary and capricious for the special master to disregard probative medical record evidence showing that K.P. experienced progressive neurological deterioration in the months following his vaccinations. *Id.* at 235–39. Because the Palucks had demonstrated, "by a preponderance of the evidence, that [K.P.'s] existing medical setbacks were significantly aggravated by his receipt of the vaccinations within a medically acceptable time," the Court of Federal Claims vacated the special master's decision and remanded the case for a determination of the amount of compensation the Palucks were due. *Id.* at 241.

The government then filed a timely appeal to this court.[3] We have jurisdiction under 42 U.S.C. § 300aa–12(f).

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[3] Contrary to the Palucks' assertions, the government's appeal to this court was not untimely filed. The government filed its notice of appeal on April 25, 2014, which was within sixty days of the Court of Federal

DISCUSSION

A. Standard of Review

"In reviewing an appeal from a judgment of the Court of Federal Claims in a Vaccine Act case, we apply the same standard of review as the Court of Federal Claims applied to the special master's decision." *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009); *see also Koehn ex rel. Koehn v. Sec'y of Health & Human Servs.*, 773 F.3d 1239, 1243 (Fed. Cir. 2014). Although we review legal determi-

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Claims' entry of judgment on February 28, 2014. *See id.* § 300aa–12(f) (providing that an appeal to this court must be filed "within 60 days of the date" the Court of Federal Claims enters judgment).

The Palucks contend that the Court of Federal Claims' October 29, 2013, decision—which set aside the special master's decision denying entitlement and remanded for a determination of compensation—was a "final judgment" that triggered the running of the sixty-day appeal period. This argument is without merit. Because the Court of Federal Claims' October 29, 2013, decision determined entitlement, but remanded to the special master for consideration of the appropriate amount of compensation to be awarded, *see Court of Federal Claims Decision II*, 113 Fed. Cl. at 241, it was not an appealable final judgment. *See Flanagan v. United States*, 465 U.S. 259, 263 (1984) (The "final judgment rule requires that a party must ordinarily raise all claims of error in a single appeal following final judgment on the merits." (citations and internal quotation marks omitted)); *Teledyne Cont'l Motors v. United States*, 906 F.2d 1579, 1582 (Fed. Cir. 1990) (emphasizing that "a judgment limited to the issue of liability, where the assessment of damages or other relief remains open, is not final").

nations without deference, we review findings of fact under the arbitrary and capricious standard. *Griglock v. Sec'y of Health & Human Servs.*, 687 F.3d 1371, 1374 (Fed. Cir. 2012); *see also Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010).

B. The Vaccine Act

"Childhood vaccinations, though an important part of the public health program, are not without risk." *Terran ex rel. Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1306 (Fed. Cir. 1999). Recognizing that "a small but significant number" of individuals will be "gravely injured" as a result of inoculation, H.R. Rep. No. 99–908, 99th Cong., 2d Sess. 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6345, Congress created a federal no-fault compensation scheme under which awards were to "be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99–908, at 3, 1986 U.S.C.C.A.N. at 6344; *see Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (explaining that the Vaccine Act compensation system was "designed to work faster and with greater ease than the civil tort system").

A petitioner seeking compensation under the Vaccine Act must establish, by a preponderance of the evidence, that a covered vaccine caused the claimed injury. *See Moberly*, 592 F.3d at 1321. Where, as here, the claimed injury is not listed in the Vaccine Injury Table, *see* 42 U.S.C. § 300aa–14, a claimant may obtain compensation by showing that his injury was "caused in fact" by the vaccine or vaccines he received. *See Andreu*, 569 F.3d at 1374. In order to prove causation in fact, a petitioner must: (1) provide a medical theory causally connecting the vaccination to the injury; (2) demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) establish a proximate temporal relationship between the vaccination and

the injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). If the petitioner satisfies this burden, he is entitled to compensation unless the government demonstrates by a preponderance of the evidence that the injury was in fact caused by factors unrelated to the vaccine. 42 U.S.C. § 300aa–13(a)(1)(B).

The Palucks assert that their son suffered severe neurodegeneration as a result of the vaccines he received on January 19, 2005. They contend that these vaccines caused a significant aggravation of K.P.'s underlying mitochondrial disorder, leading to alterations in his brain development and subsequent neurodevelopmental regression. In support of their claim, the Palucks proffered several medical articles, including: (1) an article discussing four children suffering from both a mitochondrial disorder and autism who experienced developmental regression following vaccination, *see* John Shoffner et al., *Fever Plus Mitochondrial Disease Could Be Risk Factors for Autistic Regression*, J. Child Neurology 3 (2009) ("Shoffner"); (2) an article discussing a link between infection and subsequent neurodegenerative events in persons with mitochondrial disorders, *see* Joseph L. Edmonds et al., *The Otolaryngological Manifestations of Mitochondrial Disease & the Risk of Neurodegeneration with Infection*, 128 Archives of Otolaryngology-Head & Neck Surgery 30 (2002) ("Edmonds"); and (3) a case study of Hannah Poling, a child with a mitochondrial disorder, who experienced fever and severe developmental regression shortly after vaccination, *see* Jon S. Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child with Autism*, 21(2) J. Child Neurology 170 (2006) (the "Poling case study"). The Palucks also relied upon reports and testimony from Frye, a pediatric neurologist, who explained that in a child with an underlying mitochondrial disorder, vaccination can lead to an "overwhelming immune response" and subsequent neurodegeneration. Frye explained that "vaccines, by intention,

activate the immune system," leading to "potentially toxic" reactive oxygen species and reactive nitrogen species. In an individual with a mitochondrial disorder, these potentially toxic elements can accumulate, causing oxidative stress, and setting off "a cascade of intracellular events" that leads to "apoptosis or cellular death." Frye asserted that because cells in the brain are particularly vulnerable to oxidative stress, vaccination can cause persons with underlying mitochondrial disorders to experience neurodegeneration and developmental regression. Frye emphasized, moreover, that "the interaction between oxidative stress and mitochondria [is] something that's progressive over time."

On appeal, the government does not meaningfully dispute that Frye's theory of causation is medically plausible. Indeed, before the special master the government conceded that vaccination could have, in theory, exacerbated K.P.'s underlying mitochondrial disorder. *See Special Master Decision II*, 2013 WL 2453747, at *42. The government contends, however, that the Court of Federal Claims erred in setting aside the special master's finding that K.P.'s health did not deteriorate as quickly or as consistently as anticipated by Frye's medical theory. In the government's view, because the special master had a "rational basis" for "concluding that K.P.'s condition did not change following his vaccinations in the manner predicted by [Frye's] medical theory," the Court of Federal Claims exceeded its authority by reweighing the evidence and "second guess[ing]" the special master's "fact-intensive conclusions."

We do not find this argument persuasive. By statute, the Court of Federal Claims is empowered to "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 . . . ." 42 U.S.C. § 300aa–12(e)(2)(B). Where, as here, a special

master misapprehends a petitioner's theory of causation, misconstrues his medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law. *See Andreu*, 569 F.3d at 1375 (concluding that a special master erred in disregarding probative testimony from a petitioner's treating physicians); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (concluding that a special master "impermissibly raise[d] a claimant's burden under the Vaccine Act"); *Althen*, 418 F.3d at 1280–81 (concluding that a special master improperly required medical literature linking a particular vaccine to the claimant's injury). While review of the factual findings made by a special master is highly deferential, *see Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011), both this court and the Court of Federal Claims have a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, "considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision." *Hines ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

C. Progressive Neurological Decline

The special master acknowledged that K.P. experienced significant neurodevelopmental regression between January 19, 2005, the date he was vaccinated, and July 30, 2005, the date he was discharged from the hospital. *See Special Master Decision II*, 2013 WL 2453747, at *42 ("By virtually any metric, [K.P.] was worse."). He concluded, however, that K.P.'s post-vaccination deterioration did not align with Frye's medical theory because that deterioration was not "linear," *id.* at *49, and K.P. did not manifest identifiable symptoms of neurologic injury within three weeks of his vaccinations, *id.* at *62. In an exceptionally thorough and well-reasoned opinion, the

Court of Federal Claims correctly determined that the special master misapprehended Frye's medical theory and acted arbitrarily and capriciously in disregarding significant probative evidence showing that K.P. experienced rapid and progressive neurological deterioration within a medically acceptable interval following his vaccinations.

Frye testified that in a person suffering from a mitochondrial disorder, vaccine-induced neurodegeneration would proceed in two phases. In the first phase, "an inciting event," such as an immunization, activates the immune system and causes it "to get to the point where it initiate[s] the cascade of events that cause[s] dysfunction between the mitochondria and oxidative stress." According to Frye, in a child with a mitochondrial defect, an "adverse reaction" to a vaccine would be expected to appear within a week of vaccination. K.P. exhibited symptoms of an adverse reaction to inoculation shortly after his January 2005 vaccinations. Within forty-eight hours of being vaccinated, K.P. "showed signs of irritability, fever, and fatigue." *Court of Federal Claims Decision II*, 113 Fed. Cl. at 216. K.P. had a recorded temperature of 101.5 degrees two days after being vaccinated and a recorded temperature of 101.3 degrees seven days later. As experts for both sides agreed, fever is evidence of immune activation.[4]

The second phase of vaccine-induced neurodegeneration, Frye explained, is "something that's progressive over time," occurring over a period of "weeks and months." In this phase, there is a "downward spiral of activity between the mitochondria and oxidative stress," leading to

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[4] Although S. Robert Snodgrass, M.D., the government's expert, acknowledged that K.P.'s fever was evidence of immune activation, he suggested that the fever could have been caused by an infection rather than the vaccines K.P. received.

the death of brain cells and neurodegeneration. Frye emphasized that there was no rigid timeframe for when the clinical symptoms of vaccine-induced neurodegeneration would be expected to appear, explaining that the progression of neurological deterioration would "depend on the severity and type of mitochondrial disorder."

As the Court of Federal Claims correctly determined, the rapid and devastating neurological regression K.P. experienced in the wake of his vaccinations was fully consistent with Frye's medical theory. *See id.* at 238–39. Although K.P. "was not a completely healthy child when he received the vaccinations," *id.* at 228, there was no credible evidence that he suffered from any significant problems in his central nervous system. At the time of the January 2005 vaccinations, McDonough observed that K.P. had some gross motor delays and exhibited some increased tone in his upper extremities. McDonough also reported, however, that K.P. was able to "play ball with [the] examiner," "bang [two] cubes held by [the] hands," "pull to stand," "stand holding on," and say "dada/mama." Significantly, there was no persuasive evidence that K.P.'s increased tone and gross motor delays were caused by a central nervous system problem rather than by his underlying mitochondrial disorder. *See id.* at 222 ("The parties agreed that [K.P.'s] mitochondrial defect was likely affecting his health before the vaccinations."). To the contrary, given Frye's unrebutted testimony that mitochondrial disorders can impair muscle function and development, and the fact that K.P. did not exhibit any pronounced pre-vaccination language or cognitive delays, the Court of Federal Claims had ample support for its conclusion that K.P. had no significant neurological problems in the pre-vaccination period. *Id.* at 228 ("If [K.P.'s] problems prior to the vaccinations on January 19, 2005, were neurological, the impairment was small and not evident to the treating physicians.").

In the wake of his January 2005 vaccinations, K.P. experienced a precipitous and well-documented neurological decline. By February 11, 2005, twenty-three days after the date of the vaccinations, K.P.'s chiropractor determined that he was "spastic." As the special master acknowledged, "'[s]pasticity' means that the muscles are so hypertonic (that is, rigid) that movements are limited." *Special Master Decision I*, 2011 WL 6949326, at *21. The February 11, 2005, chiropractic report was the first time that any therapist or medical professional had found that K.P. suffered from spasticity, and, as Frye correctly noted, showed "that there was a very rapid change in [K.P.'s] central nervous system." According to Frye, the fact that K.P. developed spasticity within a month of vaccination indicated that the neurons in the motor cortex of his brain had been "severely damaged and [were] no longer controlling the neurons in the spinal cord." Thus, as the Court of Federal Claims properly concluded, "the chiropractor's notation that [K.P.] was 'spastic' on February 11, 2005," was "an identifiable neurodegenerative event" showing that "the neurodegenerative process [had] begun." *Court of Federal Claims Decision II*, 113 Fed. Cl. at 240.

K.P.'s pronounced neurodevelopmental regression was confirmed by both McDonough and Kriengkrairut, K.P.'s neurologist. On March 24, 2005, McDonough reported that K.P. was "hypertonic[]" and suffered from "global developmental delay." When Kriengkrairut evaluated K.P. in April 2005, she confirmed that he suffered from global developmental delay, noting that he was "unable to sit alone" and did "not babble." She determined, moreover, that K.P. suffered from "marked spasticity of the extremities," which was likely due to a "central nervous system pathology." By May 2005, K.P.'s speech therapist concluded that he had fewer language skills than he displayed in October 2004, and that his total language score was in the first percentile. By October 2005, K.P. had "no purposeful movements" and "no specific smiling

or distinctive eye contact." MRI exams—conducted in April and July 2005—showed thinning of the corporal callosum of K.P.'s brain and were consistent with progressive brain degeneration.

In the face of this compelling evidence of post-vaccination neurodevelopmental regression, the special master had no reasonable basis for concluding that K.P. did not experience the progressive neurodegeneration predicted by Frye's medical theory. As noted previously, Frye asserted that a child experiencing vaccine-induced neurodegeneration would decline in a manner that was "progressive over time." Contrary to the special master's assertions, nothing in Frye's testimony mandated a "linear" deterioration with no instances of slight or temporary improvement in symptoms. *See* 113 Fed. Cl. at 234 (explaining that neither the relevant medical literature nor Frye's theory required "a linear, downward slope" of injury). In concluding that K.P. did not experience the progressive decline predicted by Frye's theory, the special master noted that K.P.'s February 2005 chiropractic records indicated that he was "less rigid" on some days than on others. *Special Master Decision II*, 2013 WL 2453747, at *44. In focusing on the fact that K.P.'s muscle tone fluctuated somewhat in February 2005, the special master failed in his duty to consider "the record as a whole." 42 U.S.C. § 300aa–13(a)(1). Although K.P.'s chiropractic records indicate that he was "less rigid" on some days than on others, those records, when viewed as a whole, do not reflect any sustained improvement in his condition. To the contrary, the chiropractor evaluated K.P. as "spastic" on February 11, 2005, and he "never appeared to improve above his initial assessment." *Court of Federal Claims Decision II*, 113 Fed. Cl. at 236; *see also id.* at 241 (emphasizing that K.P. "did not continue to develop in any way after the vaccinations"). It was arbitrary and capricious for the special master to give short shrift to the evidence of K.P.'s sudden neurological regres-

sion—reflected in the chiropractor's finding of spasticity—and to place undue emphasis on the relatively insignificant variations in muscle tone recorded in the February 2005 chiropractic records. Indeed, because physical therapy can stretch muscles, the fact that K.P.'s muscle tone fluctuated during the period when he was receiving chiropractic therapy was "expected," and did not mean that his overall condition was improving. *Id.*

Significantly, moreover, the special master misread the handwritten notes from K.P.'s chiropractor. According to the special master, "[t]he chiropractor's opinion was that [K.P.] did not have an adverse reaction to a vaccine." *Special Master Decision II*, 2013 WL 2453747, at *46. As the government now acknowledges, the special master misread the chiropractor's notes and nothing they contain suggests that he had concluded that K.P.'s spasticity was not caused by the vaccines he received on January 19, 2005. Instead, the chiropractor had only concluded that K.P.'s injury was not the result of child abuse. K.P.'s chiropractic records are very significant in that they are "the most comprehensive contemporaneous records of [K.P.'s] condition in the several months after the vaccinations." *Court of Federal Claims Decision I*, 104 Fed. Cl. at 480; *see Cucuras ex rel. Cucuras v. Sec'y of Dep't of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (emphasizing the importance of contemporaneous medical records in evaluating Vaccine Act cases). The fact that the special master misconstrued those records undercuts his analysis and buttresses the Court of Federal Claims' decision to set aside his findings of fact and conclusions of law.

D. Timeframe for the Onset of Neurological Symptoms

The special master further erred in setting a hard and fast deadline of three weeks between vaccination and the onset of clinically apparent symptoms of neurological injury. *See Special Master Decision II*, 2013 WL 2453747,

at *55 ("The important time is within three weeks of January 19, 2005 . . . . Thus, for the Palucks to meet their burden of proof they must show that [K.P.] manifested signs or symptoms of neurodegeneration within this timeframe."). As the Court of Federal Claims correctly determined, the special master had no reasonable basis for concluding that an individual suffering from vaccine-induced neurodegeneration would necessarily manifest clinical symptoms of neurologic injury within three weeks of vaccination. *See Court of Federal Claims Decision II*, 113 Fed. Cl. at 240 ("Neither the medical literature nor the expert testimony stated with any certainty when neurodegeneration can be expected to begin in all cases."). The Shoffner study described twelve patients with both autism and a mitochondrial disorder who experienced developmental regression within two weeks of the onset of a fever. In four of those patients, the elevated temperature was determined to be "a febrile response to vaccination." The Edmonds article collected information about thirteen patients with mitochondrial disease who experienced "neurodegenerative events" following an infection. In most patients, the neurodegenerative event occurred within three to seven days after the onset of the infection, but in at least one patient it did not occur until nineteen days after infection. The Poling case study described a young girl with a mitochondrial disorder who developed a fever and lost the ability to climb stairs a few days after being vaccinated. Over the next three months, she lost the ability to communicate and developed autistic behaviors.

The Shoffner article, the Edmonds article, and the Poling case study—which collectively discuss only a very small number of patients—do not purport to establish any definitive timeframe for the onset of clinical symptoms of neurological regression in individuals afflicted with mitochondrial disorders. There is a wide variety of mitochondrial disorders and those disorders are as yet poorly

understood by the medical community. *See id.* at 238–41. Indeed, as the special master properly acknowledged, "mitochondrial disorders are variegated. What happens in one mitochondrial disorder may not happen in the next person with a mitochondrial disorder." *Special Master Decision I*, 2011 WL 6949326, at *13. Given the heterogeneity of mitochondrial defects and the paucity of scientific literature discussing the impact that vaccination has on persons suffering from such defects, the special master had no reasonable basis for setting a hard and fast deadline of three weeks for the onset of neurological symptoms. *See Althen*, 418 F.3d at 1280 (emphasizing that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body"). Accordingly, the fact that K.P.'s first clinically evident sign of neurodegeneration—spasticity—was documented twenty-three days, rather than twenty-one days, after vaccination does not preclude a finding that it was a symptom of vaccine-induced neurologic injury. *See Andreu*, 569 F.3d at 1380 (emphasizing that relevant medical "evidence must be viewed . . . not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard").

E. Unsupported Inferences

As the Court of Federal Claims correctly determined, moreover, the special master made inferences unsupported by the record when he concluded that K.P. did not experience progressive neurological deterioration in the immediate aftermath of his January 19, 2005 vaccinations. First, the special master reasoned that if K.P.'s condition had been significantly deteriorating in February 2005, the Palucks would have taken him to a medical doctor more frequently. *See Special Master Decision II*, 2013 WL 2453747, at *60 ("The Palucks have . . . not provided any evidence to explain why, if [K.P.] was as sick

as they claim, they did not take him to a medical doctor in February."). As the Court of Federal Claims correctly noted, however, K.P.'s "parents actually *were* taking him frequently to a medical provider, *i.e.*, the chiropractor" in February 2005. *Court of Federal Claims Decision II*, 113 Fed. Cl. at 236. Indeed, the Palucks took K.P. to the chiropractor nine times in three weeks during February 2005, apparently believing that his developmental problems were caused by a pinched nerve. *Id.* It was arbitrary and capricious for the special master to infer that K.P.'s condition did not deteriorate in February 2005 simply because his parents were attempting to ameliorate their son's symptoms through chiropractic therapy.

It was also arbitrary and capricious for the special master to infer that McDonough referred K.P. to a pediatric neurologist in March 2005 only because he was "frustrated" with the Palucks. In making the referral, McDonough stated that K.P. was "hypertonic[]" and suffered from "global developmental delay." The special master's suggestion that McDonough made the referral not because he believed K.P. was getting worse, but instead because he was "frustrated that the Palucks were not following his recommendations for physical therapy [and] occupational therapy," *Special Master Decision II,* 2013 WL 2453747, at *47, is devoid of any credible support in the record.

F. MRI Evidence and Contemporaneous Physician Statements

The special master also had no reasonable basis for disregarding MRI evidence indicating that K.P. experienced progressive post-vaccination neurological deterioration. An April 2005 MRI exam of K.P.'s brain showed a subtle thinning of the corporal callosum. An MRI exam conducted three months later, in July 2005, showed further thinning of the corporal callosum. Passe, the radiologist who evaluated these MRIs, concluded that

they were "consistent with a progressing leukodystrophy," i.e., consistent with progressive neurodegeneration.[5] Frost, a physician who began treating K.P. in the summer of 2005, likewise concluded that K.P.'s April and July MRI exams evidenced "neurodegenerative disease," which was "likely progressing leukodystrophy." As the Court of Federal Claims correctly concluded, moreover, the fact that K.P.'s April 2005 MRI exam showed only a very "subtle" thinning of the corporal callosum suggested that the thinning had only recently begun. *Court of Federal Claims Decision II*, 113 Fed. Cl. at 238. K.P.'s MRI records are consistent with a finding that his neurological decline began at the time of his vaccinations, and the special master provided no reasonable justification for discounting their significance.[6]

Finally, the special master erred in disregarding contemporaneous statements from K.P.'s treating physicians regarding the cause of his neurodegeneration. As we explained in *Andreu*, "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 569 F.3d at 1375 (citations

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[5] "Leukodystrophy" refers to a group of disorders characterized by degeneration of the white matter of the brain. *See* Dorland's Illustrated Med. Dictionary 1029 (32nd ed. 2012).

[6] Snodgrass contended that the thinning of K.P.'s corporal callosum may have begun even prior to the date of his vaccinations. *See Special Master Decision II*, 2013 WL 2453747, at *48. In support, he suggested that the thinning of the corporal callosum shown in the April 2005 MRI exam could have been the result of a prenatal infection. *Id.* There is, however, no credible evidence in the record demonstrating that any type of prenatal infection might have caused an injury to K.P.'s brain.

and internal quotation marks omitted). After reviewing the results of K.P.'s April and July 2005 MRI exams, Passe stated that K.P.'s neurodegeneration could have a "hereditary, toxic or metabolic etiolog[y]." Frost, after reviewing the April and July exams—as well as the results from a third MRI exam conducted in October 2005 which showed no further significant changes in K.P.'s brain—agreed that K.P.'s condition could have a "toxic" etiology. Frost concluded that "the progression of a signal change" in K.P.'s brain "between 4/27/05 and 07/22/05 may have represented evolution of [one] toxic/metabolic event, which is now stable."

As the special master acknowledged, "the term 'toxic' is broad enough to include an injury caused by a vaccine . . . ." *Special Master Decision II*, 2013 WL 2453747, at *48. Thus, the Palucks were entitled to rely on the statements from K.P.'s physicians that his condition could be due to a "toxic . . . event" as evidence supporting a causal nexus between K.P.'s vaccinations and his subsequent neurological regression. It was arbitrary and capricious for the special master to wholly discount the probative value of these statements simply because K.P.'s physicians suggested that his condition could also potentially be due to alternative causes. *See id.* at *49 ("While the Palucks have cited Dr. Passe's July 22, 2005 report as a statement of a treating doctor showing that the reason for [K.P.'s] decline was the vaccination . . . [this] argument is not persuasive because the Palucks have not addressed the other possible causes listed by Dr. Passe."). The Palucks' burden was to show, by a preponderance of the evidence, that K.P.'s mitochondrial disorder was significantly aggravated by the vaccines he received, not to rule out every other potential cause of his injury. *See de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) ("So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes." (footnote

omitted)); *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (emphasizing that "the government bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case").

CONCLUSION

Accordingly, the judgment of the United States Court of Federal Claims is affirmed.

AFFIRMED