NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

TODD SIMANSKI, JULIA SIMANSKI, AS PARENTS AND NEXT FRIENDS OF O.A.S., A MINOR,
Petitioners-Appellants

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2014-5077

Appeal from the United States Court of Federal Claims in No. 1:03-VV-00103, Judge Marian Blank Horn.

Decided: February 26, 2015

TODD AND JULIA SIMANSKI, Ankeny, Iowa, pro se.

TRACI R. PATTON, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent-appellee. Also represented by STUART F. DELERY, RUPA BHATTACHARYYA, VINCENT J. MATANOSKI, CATHARINE E. REEVES.

Before O'MALLEY, BRYSON, and HUGHES, *Circuit Judges.*

HUGHES, *Circuit Judge.*

Todd Simanski and Julia Simanski appeal the United States Court of Federal Claims's affirmance of a Special Master's denial of compensation for their child, O.A.S., under the National Childhood Vaccine Injury Act. In certain cases, identifying the injury that is a basis for a claim under the Vaccine Act is a prerequisite to establishing causation of an injury by a vaccine. Because the Special Master did not act arbitrarily or capriciously by finding that the evidence shows that O.A.S. suffers from a disease for which the Simanskis did not put forth a theory of causation, we affirm.

I

O.A.S. was born on November 2, 2000. Although she was diagnosed with intrauterine growth retardation and had decreased muscle tone for a newborn, she was otherwise healthy. At her two-month visit to her pediatrician, she was diagnosed with infectious gastroenteritis and her first set of scheduled vaccinations was deferred. On January 26, 2001, O.A.S. returned to the pediatrician and received doses of the diphtheria-tetanus-acellular pertussis, hepatitis B, Haemophilus influenzae type B, inactivated polio, and pneumococcal vaccines.

On January 30, 2001, O.A.S. went into respiratory arrest. After being rushed to Mercy Medical Center, she was intubated and placed on a ventilator. While at Mercy, she tested positive for respiratory syncytial virus (RSV) and she was initially diagnosed with bronchiolitis. During her stay at Mercy, doctors observed that O.A.S. was suffering from diaphragmatic palsy (or weakness), which is not a consequence of RSV. And twice the doctors were unable to remove her from the ventilator because she could not breathe independently. Doctors also ob-

served that O.A.S. had staring episodes, arching of the back, and stiffening of the extremities.

In February 2001, O.A.S. was transferred to the Mayo Clinic for further diagnosis and treatment. While at the Mayo Clinic, O.A.S. received intravenous immunoglobulin (IVIG) treatments, after which her health improved to the point where she could breathe on her own. Doctors at the Mayo Clinic also performed many tests on O.A.S.'s blood, nerves, and neuromuscular system. Based on the tests and their observations, doctors concluded that O.A.S. may have been suffering from sensorimotor peripheral neuropathy, i.e., impairment of the peripheral nerves, which are the nerves outside of the brain and spine. Other records from this time period suggested that O.A.S.'s doctors were also considering more specific diagnoses. For example, some medical records indicated "considering Guillain Barre [sic] syndrome," "probable post-infectious demyelinating neuropathy," weakness "consistent with a motor neuropathy or a sensorimotor axonal neuropathy," and "not unlike axonal [Guillain–Barré Syndrome]." Respondent's App. (R.A.) 113–14.

Guillain–Barré Syndrome (GBS) is a disease of unknown etiology that affects the peripheral nervous system. Doctors generally believe that GBS may begin through an autoimmune mechanism. The most common form, which the Simanskis allege O.A.S. may suffer from, is the demyelinating type. Demyelinating-type GBS results in an impairment of sensorimotor signals traveling through the body's nerves and is characterized by a degradation of myelin, a substance that covers peripheral nerves.

In March 2001, O.A.S. was transferred from the Mayo Clinic back to Mercy. Mercy records dated March 21, 2001 state that it was "probable" O.A.S. had GBS. R.A. 177. Although she was discharged from Mercy in late March, O.A.S. was readmitted in April 2001 due to res-

piratory failure. Test results during this stay at Mercy indicated that O.A.S.'s neurological condition was worsening. While at Mercy, O.A.S. was again placed on a ventilator. Since then, O.A.S. has required the permanent assistance of a ventilator.

In late April 2001, O.A.S. was transferred to Johns Hopkins University Hospital. Mercy's discharge papers state that the "lack of a definitive diagnosis has been a problem in addressing the extent of supporting the child." R.A. 86. Johns Hopkins records from April 2001 similarly indicate inconclusive diagnoses. One progress note states "post-infectious demyelinating neuropathy vs. spinal muscular atrophy vs. degenerative vs. other [not otherwise specified]." R.A. 86. Nonetheless, doctors at Johns Hopkins concluded that O.A.S.'s condition was "consistent with either a motor neuropathy or a sensorimotor axonal neuropathy." R.A. 86.

After her stay at Johns Hopkins, O.A.S. was transferred to the University of Iowa Hospital and she stayed there for over three months. In June 2001, O.A.S.'s treating physician recorded an improving clinical picture and after consulting a doctor from Atlanta, Georgia, noted that the Atlanta doctor "favors a diagnosis of an acute axonal neuropathy." R.A. 183.

O.A.S. returned to Mercy in August 2001. Her diagnosis at admission was "flaccid axonal neuropathy." She was discharged in September 2001.

In September 2003, following her pediatrician's recommendation, O.A.S. returned to the Mayo Clinic for further evaluation. During this visit, Dr. Nancy Kuntz, a pediatric neurologist at the Mayo Clinic, began to question whether O.A.S. had spinal muscular atrophy with respiratory distress (SMARD). *See* R.A. 185 (quoting doctor's note stating "[Question] SMARD"). SMARD is a genetic disease that can begin with the sudden onset of respiratory distress within the first thirteen months of

life. This disease often involves diaphragmatic palsy and, like GBS, it involves dysfunction of the nervous system.

In one report, Dr. Kuntz wrote that her observations "suggest[ ] progressive motor and sensory neuronopathy or axonopathy. I believe that this is compatible with a recently described entity called . . . SMARD. I believe that it would be very critical for us to confirm the diagnosis for [O.A.S.]." R.A. 185. Accordingly, Dr. Kuntz recommended that O.A.S. and her parents send genetic material to doctors who were investigating SMARD. Ultimately, the Simanskis did not send materials for genetic testing. Nonetheless, Dr. Kuntz diagnosed O.A.S. with SMARD.

The record indicates that from this point forward in O.A.S.'s life, doctors often, but not always, stated that O.A.S. had SMARD. In November 2003, O.A.S.'s pediatrician wrote a letter to an insurance company stating that O.A.S. had SMARD. In February 2004, a pediatric intensivist at Mercy summarized O.A.S.'s condition as "[k]nown neuromuscular disorder-SMA-RD type." R.A. 186. In October 2004, O.A.S.'s pediatrician noted Dr. Kuntz's diagnosis, but with the caveat that it had not yet been confirmed. And in 2004 and 2005, other treating doctors noted a neuromuscular condition of unknown origin. Additionally, O.A.S.'s pediatric neurologist stated in January 2007 that O.A.S. had "a clinical diagnosis of sensorimotor axonal neuropathy that also can be called [SMARD]." R.A. 186. Similarly, in 2008, 2011, and 2012, other treating physicians assessed O.A.S. as having either spinal muscular atrophy or SMARD.

II

On January 17, 2003, the Simanskis filed a petition under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa–1 to –34, alleging that O.A.S.'s January 2001 vaccinations triggered adverse reactions. After several years of delays, the Simanskis fulfilled the re-

quirements for filing a petition. They also filed medical records, affidavits, and expert reports from Dr. Yehuda Shoenfeld, an immunologist, and Dr. Paul Maertens, a pediatric neurologist, in support of their petition. In 2010, a Special Master declined to address the merits of the Simanskis' case, citing the Simanskis' failure to comply with a show-cause order. The Simanskis appealed, and we reversed the dismissal in 2012, ordering the Special Master to address the merits of the Simanskis' petition. *See Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368 (Fed. Cir. 2012).

On remand, the parties submitted several expert reports and further defined their positions. The government submitted expert reports from Dr. Christine McCusker, a pediatric immunologist, and Dr. Richard Finkel, a pediatric neurologist. The government and its experts asserted that the Simanskis' experts incorrectly assumed O.A.S. suffered from either GBS or a related disease, chronic inflammatory demyelinating polyneuropathy (CIDP), while recent medical records indicated that O.A.S. suffers from SMARD. Accordingly, the government argued that the vaccinations could not have caused SMARD, which is caused by a genetic mutation. The Simanskis and their experts took the position that O.A.S. suffers from GBS or CIDP, not SMARD, and that the vaccinations caused O.A.S.'s GBS or CIDP. The Simanskis did not present any alternative claim based on a diagnosis of SMARD.

After evidentiary hearings and additional briefing, the assigned Special Master issued a decision denying compensation. In a detailed opinion that reviewed the parties' filings and the evidence, the Special Master found that O.A.S. suffers from SMARD, not GBS or CIDP, and that the Simanskis did not put forth any evidence to establish that the vaccinations caused or aggravated SMARD. On petition for review, the United States Court of Federal Claims affirmed the Special Master's decision,

finding that it was not arbitrary, capricious, or unsupported by substantial evidence. *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 457 (2014).

The Simanskis appeal. We have jurisdiction pursuant to 42 U.S.C. § 300aa–12(f).

III

In Vaccine Act cases, we review de novo a decision by the Court of Federal Claims, applying the same standard of review as that court applies in reviewing a decision of a Special Master. *See Andreu v. Sec'y of Dep't of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). Accordingly, we will set aside any findings of fact or conclusions of law by a Special Master that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 42 U.S.C. § 300aa–12(e)(2)(B). Our review is uniquely deferential, and "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, 'reversible error will be extremely difficult to demonstrate.'" *Hazlehurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343, 1349 (Fed. Cir. 2010) (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that a covered vaccine caused the claimed injury. 42 U.S.C. §§ 300aa–11(c)(1), –13(a)(1). If the claimed injury is not listed in the Vaccine Injury Table, the petitioner may seek compensation by proving causation in fact. 42 U.S.C. § 300aa–11(c)(1)(C)(ii); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). Here, neither GBS nor CIDP are listed in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa–14; *Figueroa v. Sec'y of Health & Human Servs.*, 715 F.3d 1314, 1315 (Fed. Cir. 2013). It is undisputed that the Simanskis must prove causation in fact. *Simanski*, 671 F.3d at 1371.

To establish causation in fact, a petitioner must provide a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a showing of a proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In this case—where "the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury [O.A.S.] suffered"—identifying the injury is a prerequisite to the *Althen* analysis. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010); *see also Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1352–53 (Fed. Cir. 2011).

The Special Master's decision thoroughly reviewed all of the relevant evidence and the parties' positions, including the expert witnesses' testimonies. After focusing primarily on Dr. Maertens's and Dr. Finkel's opinions on whether O.A.S. suffered from GBS, CIDP, or SMARD, the Special Master found that the record evidence supports a finding that O.A.S. suffers from SMARD. R.A. 148. This finding was supported by a reasoned explanation of at least twelve categories of evidence relating to the etiology and nature of O.A.S.'s condition.

The categories of evidence included, among other things, the date of onset, respiratory failure, diaphragmatic palsy, ventilator assistance, responses to IVIG treatments, and the diagnoses from O.A.S.'s treating physicians since 2001. The Special Master found that Dr. Maertens conceded that the onset of GBS in a two-month old infant is "extremely rare," while the onset of respiratory failure at two months could occur with SMARD. R.A. 195. The Special Master also considered the consensus between the portions of Dr. Maertens's and Dr. Finkel's testimonies acknowledging that respiratory failure is consistent with SMARD. Further, the Special

Master's decision quotes Dr. Maertens's recognition that diaphragmatic palsy, although it could have other causes, was "a fundamental aspect of considering that a child has SMARD." R.A. 166. Likewise, Dr. Maertens testified that O.A.S.'s progression to permanent ventilator support "would probably go more towards SMARD." R.A. 197.

Given the foregoing evidence, we cannot say that the Special Master's finding that O.A.S. suffered from SMARD was "wholly implausible" or otherwise arbitrary and capricious. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000). On appeal, the Simanskis focus on the Special Master's evaluation of the various categories of evidence. But we do not "re-weigh 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 Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

The Simanskis also argue that O.A.S.'s positive responses to IVIG treatments presented "the most compelling case against a diagnosis of SMARD and in favor of GBS." Appellant's Informal Br. 14. The Special Master found that one of the criteria for establishing a diagnosis of GBS includes a positive response to IVIG treatment. But the Special Master considered all of the evidence relating to IVIG treatments and found this category of evidence to be "a closer call" because O.A.S. improved only slightly, if at all, following subsequent treatments and because O.A.S.'s treating pediatrician observed a "questionable" degree of response to the treatments. R.A. 209. Accordingly, the Special Master found that this evidence did not favor a finding of GBS or CIDP. On our review of the Special Master's decision, we may not "second guess" such "fact-intensive conclusions." *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993); *see also Porter*, 663 F.3d at 1249.

The Special Master's decision also accounts for the complicated circumstance of the medical community's understanding of what could possibly be affecting O.A.S. and the evolution of that understanding over time. The doctors at the Mayo Clinic initially stated that they were considering GBS as a possible diagnosis. In 2003, however, Dr. Kuntz changed her diagnosis to a "recently described" entity known as SMARD.[1] R.A. 87–88. Importantly, many other treating physicians subsequently concluded that O.A.S. suffered from or presented symptoms of the recently described SMARD.

The Special Master reviewed the foregoing evidence and concluded that O.A.S.'s treating physicians have "consistently referenced SMARD as the proper diagnosis since 2003." R.A. 212. This finding was not arbitrary or capricious. And to the extent that the finding relied on medical records from treating physicians, we note that we have held such records can be "quite probative" or "favored" when considering issues relating to claims under the Vaccine Act. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *see also Cucuras v. Sec'y of Dep't of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("Medical records, in general, warrant consideration as trustworthy evidence."). We should not "require special masters to ignore the impact of ever-changing technological advances and

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[1] The Court of Federal Claims and the Special Master found that Dr. Kuntz and other treating physicians may have learned of SMARD from a series of articles published in 2001 and 2003. The Special Master further found that there was no dispute that most pediatric neurologists did not know about SMARD until 2003. Dr. Maertens, for example, first learned of SMARD no sooner than 2005.

medical breakthroughs that might discredit the plausibility of a formerly accepted theory." *Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952, 959 (Fed. Cir. 2011).

Since the Simanskis did not establish the predicate of O.A.S. having GBS or CIDP, the Special Master found that it was not necessary to evaluate Dr. Shoenfeld's theory that the vaccinations caused GBS or CIDP. A review of the record indicates that Dr. Shoenfeld indeed assumed that O.A.S. had GBS or CIDP, not SMARD. *See, e.g.*, Petitioner's App. (P.A.) 55, ll. 10–12 ("I didn't even raise the possibility because nothing support[s] the SMARD, and all my testimony was concentrated on [GBS]."). Moreover, the Special Master found that the Simanskis did not present any alternative claim based on SMARD or any evidence on whether O.A.S.'s vaccinations played a causal or aggravating role under the assumption that she has SMARD. R.A. 217–18. The Simanskis do not challenge these findings. *See* R.A. 84 ("there was no need to explore in detail . . . whether the vaccines could have adversely affected [O.A.S.]'s SMARD via the *Althen* test"). Accordingly, the Special Master did not act arbitrarily or capriciously in declining to review Dr. Shoenfeld's opinions. *See Broekelschen*, 618 F.3d at 1345–46.

IV

We sympathize with the Simanskis, but we conclude that the Special Master's decision was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa–12(e)(2)(B). We have considered the remaining arguments and do not find them persuasive. Accordingly, we affirm the judgment of the Court of Federal Claims.

AFFIRMED

No costs.