NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

JED SNYDER AND LILIA SNYDER, Parents of N.S.,
Petitioners-Appellees,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2013-5068

Appeal from the United States Court of Federal Claims in No. 07-VV-0059, Judge Susan G. Braden.

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FRANK HARRIS, Parent of JORDAN HARRIS, a minor,
Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellant.

2013-5072

Appeal from the United States Court of Federal Claims in No. 07-VV-0060, Judge Susan G. Braden.

Decided: January 28, 2014

JOSEPH PEPPER and SYLVIA CHIN-CAPLAN, Conway, Homer & Chin-Caplan, P.C., of Boston, Massachusetts, argued for Petitioners-Appellees. On the brief was RONALD C. HOMER.

VORIS E. JOHNSON, JR., Assistant Director, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for Respondent-Appellant. With him on the brief were STUART F. DELERY, Acting Assistant Attorney General, RUPA BHATTACHARYYA, Director, VINCENT J. MATANOSKI, Deputy Director, and CATHERINE E. REEVES, Assistant Director.

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

WALLACH, *Circuit Judge*.

Petitioners-Appellees, by and through their parents, filed suits under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa–1 to 300aa–34 (2006) ("Vaccine Act"), alleging that they suffered from epilepsy or a seizure disorder, as a direct result of the diphtheria and tetanus toxoids and acellular pertussis vaccine ("DTaP"). The same Special Master presided over Petitioners' cases and denied compensation finding, in part, that a genetic mutation was the sole cause of the seizure disorders in both cases. *Harris v. Sec'y of Health & Human Servs.*, No. 07-60V, 2011 WL 2446321 (Fed. Cl. Spec. Mstr. May 27, 2011); *Snyder v. Sec'y of Health & Human*

Servs., No. 7-59V, 2011 WL 3022544 (Fed. Cl. Spec. Mstr. May 27, 2011). Upon review, the Court of Federal Claims reversed the Special Master in favor of Petitioners. *Harris v. Sec'y of Health & Human Servs.*, 102 Fed. Cl. 282 (2011); *Snyder v. Sec'y of Health & Human Servs.*, 102 Fed. Cl. 305 (2011). On remand, the Special Master determined the amount of compensation and entered judgment in these cases. *E.g.*, *Snyder v. Sec'y of Health & Human Servs.*, No. 07-59, 2013 WL 391169 (Fed. Cl. Spec. Mstr. Jan. 8, 2013). This court finds in favor of the Secretary of Health and Human Services ("government" or "Secretary"). Therefore, we reverse the Court of Federal Claims' decisions and direct the court to reinstate the Special Master's decisions denying compensation. The Special Master's decisions awarding compensation therefore are vacated.

BACKGROUND

These Vaccine Act cases involve an examination of the relationship between the DTaP vaccine and the seizure disorders from which the Petitioners suffer. Severe Myoclonic Epilepsy of Infancy ("SMEI"), also known as Dravet Syndrome, is a rare disorder that is characterized by generalized tonic, clonic, and tonic-clonic seizures, which are typically induced by fever and begin during the first year of life. Typically, SMEI is first manifested as a seizure that occurs when the child is between six and nine months in the context of a fever. While a child's early development is normal, SMEI stagnates mental development in the second year of life.

The SCN1A gene provides instructions for making sodium ion channels. These channels play a key role in a cell's ability to generate and transmit electrical signals. Abnormal function of these sodium ion channels may cause a person to have seizures. For example, although not definitive, variant SCN1A genes have been associated with, depending on the range of symptoms, familial

hemiplegic migraines, generalized epilepsy with febrile seizures plus ("GEFS+"), and SMEI. GEFS+ is a disorder that is considered sufficiently similar to SMEI that they are sometimes described as falling on one spectrum. GEFS+ is milder than SMEI, but GEFS+ occurs more frequently than SMEI.

Minors Jordan Harris and N.S. are the Petitioners-Appellees in these cases. Jordan was born on March 6, 2004. On May 7, 2004, Jordan received his first set of immunizations, including the DTaP vaccine. Several hours after these vaccinations, Jordan was taken to the emergency room upon experiencing a seizure preceded by a fever. Jordan was discharged two days later.

On July 7, 2004, Jordan received a set of immunizations, including a second dose of DTaP, and subsequently, on September 3, 2004, a third dose of DTaP. On September 28, 2004, when he was six months old, Jordan experienced a second seizure. He was admitted to a hospital and was examined by a neurologist. Jordan's magnetic resonance imaging ("MRI"), computed tomography scan ("CT scan"), and electroencephalogram ("EEG") results were all normal and he was discharged.

Over the next several years, Jordan experienced occasional seizures, and in August 2006, Jordan was referred for genetic testing. The genetic testing report identified two DNA variants in Jordan, one of which was a variant in the SCN1A gene. This variant was "predicted to disrupt the structure of the protein [that is encoded by the SCN1A gene] and alter its function." *Harris*, 2011 WL 2446321, at *2 (internal quotation marks omitted). The report further opined that the results were "consistent with a diagnosis of, or a predisposition to developing, SMEI or [Severe Myoclonic Epilepsy Borderline], the severe phenotype associated with SCN1A mutations." *Id.* (internal quotation marks omitted). The report neverthe-

less noted that Jordan's specific mutation has not been definitively demonstrated to be associated with SMEI.

Petitioner N.S. was born in November 2004. He developed normally through March 2005. On March 4, 2005, when he was four months old, N.S. received a dose of the DTaP vaccination. The next day, he experienced a seizure that was associated with a slight fever. N.S. was taken to the emergency room. In the hospital, N.S. had various tests, including a CT scan, which produced mostly normal results.

Upon discharge, N.S. saw a neurologist. The neurologist indicated that "[t]his could have been a febrile seizure" and noted the "seizure was several hours after getting the [DTaP] shot." *Snyder*, 2011 WL 3022544, at *2 (internal quotation marks omitted). The neurologist recommended careful observation but no medication, and an EEG was recommended, although the record reflects this test was not conducted.

N.S. continued to experience occasional seizures through the end of 2005. After one such occasion, N.S. returned to the neurologist, at which time an EEG and an MRI were administered. Results were normal.

After more seizures, N.S. was admitted to the hospital in May 2006, and a pediatric neurologist ordered genetic testing to rule out SMEI. N.S.'s genetic testing was positive for a mutation of the SCN1A gene. The pediatric neurologist thereafter diagnosed N.S. with Dravet syndrome (or SMEI).

In January 2007, Frank Harris, parent of Jordan, and Jed and Lilia Snyder, parents of N.S., invoked the jurisdiction of the Court of Federal Claims and the special master under 42 U.S.C. § 300aa-12(a), claiming the DTaP vaccination was a substantial cause of Petitioners' seizure disorders. On July 3, 2008, the cases were assigned to one Special Master because the cases presented the same

issues, were based on similar evidence, and were advocated by the same attorneys. On May 27, 2011, the Special Master issued his decisions denying compensation to Petitioners.

Specifically, the Special Master found the Secretary's arguments persuasive, stating it was not necessary to determine "whether DTaP can cause a significant neurological injury . . . because even if [Petitioners] were assumed to have met [their] burden of proof[,] . . . [t]he evidence convincingly shows" that the SCN1A gene mutation identified in both children was the "sole cause" of their seizure disorders. *Harris*, 2011 WL 2446321, at *1; *Snyder*, 2011 WL 3022544, at *1. The Special Master based his decisions on the Secretary's proffered expert opinions of Dr. Max Wiznitzer and Dr. Gerald V. Raymond, while discounting Petitioners' expert, Dr. Marcel Kinsbourne. The Special Master found that none of the scientific literature introduced during testimony in the record "clearly suggest[ed]" that an environmental factor, *e.g.*, a vaccination, is "necessary to cause symptoms." *Harris*, 2011 WL 2446321, at *16 (internal quotation marks omitted); *Snyder*, 2011 WL 3022544, at *16 (internal quotation marks omitted).

While finding that Petitioners' genetic mutations were the sole cause of their seizure disorders, the Special Master alternatively found that Petitioners failed to show causation, in part, because "Dr. Kinsbourne did not offer any ideas" of how Petitioners' seizure disorders would have been "but for" the vaccine. *Harris*, 2011 WL 2446321, at *33; *Snyder*, 2011 WL 3022544, at *34. The Special Master noted that "when asked whether the seizure disorders in these cases would not have been manifest 'absent the receipt of the DTaP' vaccine, Dr. Kinsbourne testified that he has 'no knowledge of that. That would be speculation . . . .'" *Harris*, 2011 WL 2446321, at *33; *Snyder*, 2011 WL 3022544, at *34.

The Special Master further determined that "[t]he uncertainty about [Petitioners'] outcome but for the vaccination that is inherent in Dr. Kinsbourne's testimony is not present in the testimony of Dr. Wiznitzer and Dr. Raymond." *Harris*, 2011 WL 2446321, at *33; *Snyder*, 2011 WL 3022544, at *35. These doctors testified that the DTaP vaccine did not cause Petitioners' seizure disorders. Based on this record, the Special Master concluded Petitioners' SCN1A mutations were the sole cause of their seizure disorders.

The Court of Federal Claims reversed the Special Master's decisions and entered final judgment in favor of N.S. on January 14, 2013, and in favor of Jordan on January 23, 2013. The Court of Federal Claims reversed on the basis that the Special Master had required Petitioners to satisfy a standard of scientific certainty rather than preponderance of the evidence, and had therefore applied the wrong standard of proof. Also, the Court of Federal Claims found that the Special Master erred in finding that the Secretary demonstrated alternate causation. According to the court, the Special Master unreasonably credited the Secretary's expert testimony over Dr. Kinsbourne's testimony. The Court of Federal Claims "view[ed] the entirety of the record on alternative causation as a classic case of 'conflicting' experts," and stated that in such circumstances the Special Master was required to find in favor of Petitioners. *Harris*, 102 Fed. Cl. at 304 (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 550–51 (Fed. Cir. 1994)); *Snyder*, 102 Fed. Cl. at 325 (quoting *Knudsen*, 35 F.3d at 551). The Court of Federal Claims thus set aside the Special Master's decisions and made its own findings, ultimately determining that Petitioners carried their burden of demonstrating that their conditions were caused-in-fact by the DTaP vaccination. On remand, the Special Master calculated the amount of compensation due to the Peti-

tioners. The Secretary appeals both decisions. This court has jurisdiction under 42 U.S.C. § 300aa-12(f).

DISCUSSION

The Secretary contends the record supports a finding that the SCN1A gene mutation is the sole cause of Petitioners' seizure disorders. Petitioners allege that administration of the DTaP vaccination was a substantial cause of the SMEI from which Petitioners suffer. Although these cases were appealed separately, the cases were consolidated and this court considers them together because of the substantial overlap of the evidence and issues in the two cases.

"We review an appeal from the Court of Federal Claims in a Vaccine Act case de novo, applying the same standard of review as the Court of Federal Claims applied to its review of the special master's decision." *Carson v. Sec'y of Health & Human Servs.*, 727 F.3d 1365, 1368 (Fed. Cir. 2013) (internal quotation marks and citation omitted). We give no deference to the Court of Federal Claims' or Special Master's determinations of law, but uphold the Special Master's findings of fact unless they are arbitrary or capricious. *Id.*; 42 U.S.C. § 300aa–12(e)(2)(B). As we have noted:

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

> which the medical evidence of causation is in dispute.

Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted).

The Vaccine Act created the National Vaccine Injury Compensation Program through which claimants can petition the Court of Federal Claims to receive compensation for vaccine-related injuries or death. In crafting the Program, Congress created the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), which sets forth "a list of vaccines, a parallel list of adverse medical conditions commonly associated with the use of each vaccine, and, for certain medical conditions, a time period in which the first symptoms should become apparent following vaccination." *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1307 (Fed Cir. 1999). "For cases involving injuries that do not fall within the Vaccine Injury Table, 42 U.S.C. § 300aa–14(a)—the so-called 'off-Table' cases—the petitioner has the burden to prove causation by a preponderance of the evidence." *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (citing 42 U.S.C. § 300aa–13(a)(1)(A)).

To prove causation in an off-Table case, "a petitioner must show that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Id.* (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)). This court has held that the causation standard in off-Table Vaccine Act cases is to be applied consistently with the principles set forth in the Second Restatement of Torts. *Id.* In making this showing, a petitioner must provide the following: (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. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)) ("*Althen* test"). Under these standards, it is the petitioner's burden to "prove 'actual causation' or 'causation in fact' by a preponderance of the evidence." *Id.* at 1321.

Once a petitioner establishes her prima facie case by satisfying the *Althen* test, the burden shifts to the Secretary to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa–13(a)(1)(B). In order to meet that burden, the Secretary must "identify[ ] a particular . . . factor (or factors) and present[ ] sufficient evidence to establish that it was the sole substantial factor in bringing about the injury." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008).

Here, the record fully supports the Special Master's finding that it was more likely than not that Jordan's and N.S.'s SCN1A gene mutations were the sole cause of their seizure disorders. As an initial matter, Petitioners argue that the Special Master legally erred by placing the burden on the Petitioners, and not on the Secretary, to show that other alternative triggers or factors unrelated to the vaccine did not cause the seizure disorders. The Special Master however properly considered the entire record and determined the Secretary met its burden of proof.

This court recently addressed this same issue when faced with the question of

> whether, in assessing whether a prima facie showing of causation has been made in an off-Table case, a special master may consider evidence of other possible causes for the injury in question, or whether evidence of other possible causes may be

> considered only in connection with the "factors unrelated" defense on which the government has the burden of proof.

Stone, 676 F.3d at 1379. In assessing a petitioner's prima facie case for causation, a special master may consider evidence of other possible causes for the injury in question. *Id*. That evidence is relevant to "whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question," *as well as* to a "'factors unrelated' defense on which the government has the burden of proof." *Id*. Therefore, *Stone* concluded that "the special master is entitled to consider the record as a whole . . . , and no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute." *Id.* at 1380.

As in *Stone*, the Special Master did not err by examining the record in its entirety, and subsequently, finding that the Secretary proved by preponderant evidence its "factors unrelated" defense by showing that the gene mutations were the sole cause of the seizure disorders. In addition, by examining the record as a whole, the Special Master did not require Petitioners to shoulder the burden of eliminating all possible alternative causes in making their prima facie case nor did he effectively place the burden of showing "factors unrelated" to the vaccine on Petitioners. *See id.* Rather, the Special Master was clear that his determinations were based on the Secretary's evidence, which he found to be convincing. We accordingly turn to these determinations to examine whether they were arbitrary or capricious. *See* 42 U.S.C. § 300aa–12(e)(2)(B).

The Special Master found persuasive the Secretary's experts, Dr. Wiznitzer and Dr. Raymond. In particular, the Special Master noted the extensive background and experience of Drs. Wiznitzer and Raymond. The Special

Master found that Dr. Wiznitzer has an active clinical practice in pediatric neurology. The Special Master also found that Dr. Wiznitzer teaches medical students about child neurology and conducts research, including on topics related to the effectiveness of medications for epilepsy. The record further shows that Dr. Wiznitzer has been interested in Dravet syndrome since the 1980s, and has treated children with that condition.

The record also reflects that Dr. Raymond, board-certified in neurology and clinical genetics, is an associate professor of neurology at Johns Hopkins University and the director of neurogenetic research at the Kennedy Krieger Institute. Dr. Raymond conducts research, teaches medical students and residents about neurology and genetics, and maintains a clinical practice. Among his patients, approximately half suffer from epilepsy, including those diagnosed with Dravet syndrome.

Drs. Raymond and Wiznitzer attributed Jordan's and N.S.'s seizure disorders solely to their SCN1A mutations, and as a result, testified that Jordan and N.S. would have suffered seizures eventually, whether or not they received the DTaP vaccine. In reaching their opinions, they considered several factors generally relied upon by researchers in the relevant field and from which Drs. Raymond and Wiznitzer consider when counseling their patients. *See Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (applying *Daubert* factors to the Special Master's evaluation of expert witnesses in Vaccine Act cases).[1] The Special Master found the meth-

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[1] The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error;

odology these experts applied convincing. *See, e.g., Snyder*, 2011 WL 3022544, at *4; s*ee also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) ("[The objective of *Daubert*'s gatekeeping requirement] is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.").

According to Dr. Raymond, Petitioners' SCN1A mutations were not inherited from either parent, and therefore, their mutations were "de novo" mutations, which are more likely to present a severe disease. *Harris*, 2011 WL 2446321, at *14; *Snyder*, 2011 WL 3022544, at *15. Dr. Raymond also opined that Petitioners' mutations are located in the region of the genome that is highly conserved across different species, which presumably is strong circumstantial evidence that the mutation is pathogenic. With respect to Jordan, Dr. Raymond indicated that Jordan's genetic mutation "is a change in the sequence of amino acids that control how DNA is transcribed into messenger RNA," and such "splice site" mutations tend to indicate a disease. *Harris*, 2011 WL 2446321, at *14. With respect to N.S., Dr. Raymond observed that N.S.'s mutation occurred within the DNA that codes the pore of the sodium ion channels, and that "[a]lmost all mutations that have been found in the pore region of the sodium channel have been found in cases of SMEI." *Snyder*, 2011 WL 3022544, at *15.

Drs. Wiznitzer and Raymond further opined that the cases reported in scientific literature supported their conclusion that Petitioners' genetic mutations were the

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and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–95 (1993).

sole cause of their seizure disorders. For example, Drs. Wiznitzer and Raymond testified that the exact mutation Jordan has was reported in a 2009 article by Kumakura et al.[2] The example showed, according to the experts, that this particular mutation tends to control the person's development. With respect to N.S., Drs. Wiznitzer and Raymond provided that N.S.'s variant has been reported to be disease-associated and such cases were reported in literature by, for example, Ohmori et al. and Claes et al.[3] According to Drs. Wiznitzer and Raymond, these examples show that this particular mutation tends to control the person's development, and both experts opined that children who had this exact mutation also developed SMEI.

While finding Drs. Wiznitzer and Raymond persuasive, the Special Master found Petitioners' expert, Dr. Kinsbourne, unconvincing. First, the Special Master noted the relative difference in experience among Dr. Kinsbourne, Dr. Wiznitzer, and Dr. Raymond as "one reason for finding that the evidence establishes that the genetic mutation was the sole cause of [Petitioners'] developmental change." *Harris*, 2011 WL 2446321, at *11; *Snyder*, 2011 WL 3022544, at *12.

The Special Master found that "[i]n his entire career, Dr. Kinsbourne has not focused on genetics or seizure disorders. The basis of Dr. Kinsbourne's opinions comes

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[2] Akira Kumakura, et al., Novel de novo splice-site mutation of SCN1A in a patient with partial epilepsy with febrile seizures plus, 31(2) Brain & Dev. 179 (2009).

[3] Iori Ohmori, et al., *Significant correlation of the SCN1A mutations and severe myoclonic epilepsy in infancy*, 295(1) Biochemical & Biophysical Research Comm. 17 (2002); Lieve Claes, et al., *De novo SCN1A mutations are a major cause of severe myoclonic epilepsy of infancy*, 21(6) Human Mutation 615 (2003).

from his interpretation of medical articles about genetic epilepsies. This research was done for the purpose of presenting an opinion in this case." *Harris*, 2011 WL 2446321, at *4; *Snyder*, 2011 WL 3022544, at *6. In addition, the Special Master noted "Dr. Kinsbourne essentially stopped practicing pediatric neurology in 1981," and therefore, "Dr. Kinsbourne was not a practicing pediatric neurologist in 2000, when the SCN1A mutation started being linked to GEFS and SMEI." *Harris*, 2011 WL 2446321, at *21; *Snyder*, 2011 WL 3022544 at, *21–22. Although the Special Master acknowledged "Dr. Kinsbourne read literature on SCN1A to support his work as an expert witness," he found it "difficult to see how Dr. Kinsbourne's efforts can equal the knowledge gained by Dr. Wiznitzer and Dr. Raymond." *Harris*, 2011 WL 2446321, at *21; *Snyder*, 2011 WL 3022544, at *22.

Indeed, the record shows that both Dr. Wiznitzer and Dr. Raymond study neurologic problems associated with genetic abnormalities as a regular part of their full-time careers, and they counsel patients with genetic mutations that cause neurological problems. The Special Master noted that "[t]heir professional duties give them a depth of knowledge that is not matched by Dr. Kinsbourne. For example, Dr. Wiznitzer attended an international conference about SCN1A just before the hearing in this case." *Harris*, 2011 WL 2446321, at *21; *Snyder*, 2011 WL 3022544, at *22. Accordingly, the Special Master concluded Drs. Wiznitzer's and Raymond's opinions "merit consideration" and determined that Dr. Kinsbourne's testimony was not persuasive. *Harris*, 2011 WL 2446321, at *22; *Snyder*, 2011 WL 3022544, at *22. This court does not discern error in this conclusion. *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (On review, we do "not 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.").

The Special Master likewise found Drs. Wiznitzer's and Raymond's opinions were consistent with scientific literature. For example, the researchers of the Berkovic article did not believe that "avoiding vaccination, as a potential trigger, would prevent onset of this devastating disorder in patients who already harbor the SCN1A mutation."[4] In yet another article by Claes et al., researchers studying observable physical manifestations of carrying SCN1A mutations determined that "genotype-phenotype correlations seem to be fairly strict."[5] The same conclusion was reached in the Ceulemans article: "detailed analyses of all published patients for whom sufficient clinical and genetic information is available clearly demonstrate phenotype/genotype correlation."[6] Most significantly, the McIntosh article analyzed medical and vaccination records to investigate whether there was an association between vaccination and onset of seizures in patients with Dravet syndrome who had mutations in the SCN1A gene.[7] It concluded that the vaccine had no

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[4] Samuel F. Berkovic, et al., *De novo mutations of the sodium channel gene SCN1A in alleged vaccine encephalopathy: a retrospective study*, 5 Lancet Neurology 488, 491 (2006).

[5] Lieve Claes, et al., *The SCN1A variant database: a nonvel research and diagnostic tool*, 30 Human Mutation E904, E910 (2009).

[6] Berten P.G.M. Ceulemans, et al., *Clinical correlations of mutations in the SCN1A gene: From febrile seizures to severe myoclonic epilepsy in infancy*, 30(4) Pediatric Neurology 236, 241 (2004).

[7] Anne M. McIntosh, et al., *Effects of vaccination on onset and outcome of Dravet syndrome: a retrospective study*, 9 Lancet Neurology 592 (2010).

effect on the outcome of children with SCN1A mutation. The Special Master further found that Petitioners' medical records and statement of treating doctors supported Drs. Wiznitzer's and Raymond's theory. These determinations were not arbitrary or capricious. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000) ("[If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.").

The Court of Federal Claims views the record in a different light. Upon review of the experts' testimony, the Court of Federal Claims found all the experts "helpful and instructive." *Harris*, 102 Fed. Cl. 303 n.29; *Snyder*, 102 Fed. Cl. at 325 n.35. Thus, the court characterized the record as a "classic case of 'conflicting experts,'" where the evidence was in "equipoise," requiring a finding against the Secretary for failure to meet its burden of proof establishing that the SCN1A mutation was the sole cause of Petitioners' seizure disorders. *Harris*, 102 Fed. Cl. at 303 (quoting *Knudsen*, 35 F.3d at 550–51); *Snyder*, 102 Fed. Cl. at 325 (quoting *Knudsen*, 35 F.3d at 550–51). This, however, is not that "classic case of conflicting experts," nor is the evidence in these cases in "equipoise."

The Special Master in these cases made particular findings, supported by the record, in favor of the Secretary. Although a true equipoise of evidence may defeat the party with the burden of proof, the Special Master here did the analysis necessary to decide the Secretary had the stronger case based on testimony and the intellectual strength of the evidence, as well as the arguments presented. *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 824 (Fed. Cir. 1988) (quoting *United States v. General Motors Corp.*, 561 F.2d 923, 933 (D.C. Cir. 1977)) ("The mere fact that experts disagree does not mean that the party with the burden of proof loses. The finder of fact has to make the effort to decide which side has the

stronger case. This can be based on the demeanor of the witnesses (if so, the trial judge should say so) or the intellectual strength of the evidence and arguments based thereon.").

In particular, the Special Master found that Dr. Kinsbourne "did relatively little to rebut" Drs. Wiznitzer and Raymond's testimony, and Dr. Kinsbourne failed, for instance, to "explain why the conclusion of the researchers [in the McIntosh article] was wrong." *Harris*, 2011 WL 2446321, at *23; *Snyder*, 2011 WL 3022544, at *23. Also, the Special Master noted that "when asked whether the seizure disorders in these cases would not have been manifest 'absent the receipt of the DTaP' vaccine, Dr. Kinsbourne testified that he has 'no knowledge of that,'" and "[w]hen asked to explain how [Jordan and N.S.] would have been different today if [they] had not received the vaccine, Dr. Kinsbourne stated that he did not know." *Harris*, 2011 WL 2446321, at *33; *Snyder*, 2011 WL 3022544, at *34. The Special Master thus concluded that "[t]o the extent that Dr. Kinsbourne's opinion has been informed by reading medical articles, the articles generally do not support the arguments [Petitioners advance]. The studies that investigated whether a pertussis vaccine affected the development of a person with an SCN1A mutation concluded that the vaccine did not cause the epilepsy." *Harris*, 2011 WL 2446321, at 24; *Snyder*, 2011 WL 3022544, at 25.

These findings were not arbitrary or capricious, and in turn, show that the Secretary met her burden of proof with preponderant evidence. To the extent Petitioners argue otherwise, we cannot reweigh the evidence and substitute our judgment for that of the Special Master.

CONCLUSION

Based on the foregoing, we reverse the Court of Federal Claims' decisions and direct the court to reinstate the Special Master's decisions denying compensation. The

Secretary has shown that the evidence supports a finding that the SCN1A gene mutation was, more likely than not, the sole cause of Petitioners' seizure disorders. We also vacate the Special Master's decisions awarding compensation.

REVERSED