# In the United States Court of Federal Claims

No. 09-318V
(Filed Under Seal: February 4, 2013)
(Reissued for Publication: February 22, 2013)

**TO BE PUBLISHED**

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| KELLY ARANGO, Parent of, ISABELA OROZCO, a Minor, | ) | National Vaccine Injury Compensation Program; National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34; DTaP Vaccine; Acute Encephalopathy; Seizures; 42 C.F.R. § 100.3(b)(2)(i)(E). |
| Petitioner, | ) | |
| v. | ) | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | ) | |
| Respondent. | ) | |

David E. Marmelstein, David E. Marmelstein & Associates, Enfield, Conn., for petitioner.

Ryan D. Pyles, Trial Attorney, Gabrielle M. Fielding, Assistant Director, Vincent J. Matanoski, Acting Deputy Director, Rupa Bhattacharyya, Director, Torts Branch, Stuart F. Delery, Acting Assistant Attorney General, Civil Division, U.S. Department of Justice, Washington, D.C., for respondent.

## OPINION AND ORDER[1]

GEORGE W. MILLER, Judge

Petitioner, Kelly Arango, on behalf of her daughter, Isabela Orozco, filed a motion for review (docket entry 42, Sept. 20, 2012) of Special Master Sandra Lord's August 23, 2012 decision (docket entry 40) denying compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 to -34, established by the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2006)) (the "Vaccine Act"). Petitioner filed for compensation on May 11, 2009, alleging that Isabela was injured by the diphtheria, tetanus, and acellular pertussis

[1] Pursuant to Rule 18(b), Appendix B of the Rules of the Court of Federal Claims, this Opinion and Order was initially filed under seal. The parties were afforded fourteen days in which to propose redactions. Neither party proposed any redactions. Accordingly, the Opinion and Order is released in its entirety.

("DTaP"); haemophilus influenza type B ("Hib"); inactivated poliovirus ("IPV"); Prevnar (pneumococcal 7-valent conjugate); and rotavirus vaccines she received on March 8, 2008. Special Master Lord held an entitlement hearing on March 25, 2011 in New York City. The special master ruled that petitioner failed to prove a Table injury because Isabela only suffered seizures, not an acute encephalopathy. As to causation-in-fact, the special master found insufficient evidence of causation: merely a temporal relationship between Isabela's vaccination and her infantile spasms. Thus, the special master dismissed the petition.

Petitioner timely filed a motion for review under § 300aa-12(e) of the Vaccine Act. *See* Pet'r's Mot. for Review and Supp'g Mem. of Law ("Pet.") (docket entry 42, Sept. 20, 2012). Petitioner asserts that the special master's decision should be vacated and the Court should remand the case back to the special master for determination of appropriate compensation. *Id.* at 14.

## I. Background[2]

### *A. Isabela's Medical History*

Isabela Orozco was born on November 27, 2007. *Arango*, 2012 WL 4018028, at *2. On November 29, 2007 and December 28, 2007, she received vaccinations without incident. *Id.* As part of her four-month well-child check up, she received DTaP, Hib, IPV, Prevnar (pneumococcal 7-valent conjugate), and rotavirus vaccines on March 28, 2008. *Id.*

In the days following her March 28 vaccinations, Isabela began to experience symptoms of what would eventually be diagnosed as infantile spasms. *Id.* at *2–4. Petitioner reported these symptoms to Isabela's pediatrician, Dr. Jennifer Henkind, in a April 3, 2008 phone call, noting that "Isabela seems to 'zone out' and eyes roll to the side of her head, doesn't turn her head when mom talks to her, 'snaps out of it' a few minutes later. Has been doing this a few times a day for the past few days." *Id.* at *2. Isabela was brought to the pediatrician's office on April 3, and while there she again experienced "rhythmical shaking in all four extremities." *Id.* She was then taken to the Stamford Hospital Emergency Room and admitted to the hospital, where she was treated by Dr. Philip Overby, a neurologist. *Id.* Isabela underwent a 24-hour electroencephalogram ("EEG") on April 23, 2008, and it revealed an electroclinical seizure, non-localizable, and multifocal spikes and poly-spikes. *Id.* at *3.

Following a week in which Isabela experienced seizures lasting several seconds in clusters of four to five minutes, Dr. Overby once again examined Isabela on May 5, 2008. *Id.* An EEG revealed that Isabela was experiencing hypsarrhythmia, which is "characteristic of infantile spasms." *Id.* Isabela was prescribed the anti-epileptic medications Phenobarbital and Keppra. *Id.* Dr. Overby noted that Isabela was most likely experiencing cryptogenic, rather than symptomatic, infantile spasms. *Id.* She was admitted to the Montefiore Epilepsy Monitoring

[2] The parties do not dispute the underlying facts of this case, which, for purposes of this Opinion and Order, are taken from the special master's decision, *Arango v. Sec'y of Health & Human Servs.*, No. 09-318V, 2012 WL 4018028 (Fed. Cl. Spec. Mstr. Aug. 23, 2012). For a detailed recitation of the underlying facts, see *id.* at *3–16.

Unit. *Id.* While there, Isabela was prescribed adrenocorticotropic hormone ("ACTH"), and on May 12, 2008, she was discharged with a diagnosis of infantile spasms, hypsarrhythmia, hypotonia, and developmental delay. *Id.* Dr. Overby noted on May 20, 2008 that Isabela was partially responding to the ACTH treatment. *Id.* Over the next three months, Isabela's condition appeared to improve significantly. *Id.* Her seizures had ceased, and she regained previously lost developmental milestones. *Id.* She received another Hib vaccine on July 8, 2008 without experiencing any symptoms. *Id.*

On August 28, 2008, however, she was given a hepatitis B vaccine, and shortly thereafter her symptoms returned. *Id.* at *3–4. Petitioner phoned Dr. Henkind's office on September 2, 2008 to report that Isabela appeared to have experienced a seizure. *Id.* at *3. Dr. Henkind's office noted that it would "hold all further vaccines until done with spasm treatment and has been stable." *Id.* (quoting Pet'r's Ex. 4, at 93). On September 18, 2008, another EEG was performed on Isabela, and it revealed "numerous abnormalities, including hypsarrhythmia." 2012 WL 4018028, at *4. Dr. Overby restarted Isabela's ACTH treatment and also prescribed Topamax, another anti-convulsant medication. *Id.* Dr. Henkind noted during a September 24, 2008 appointment that Isabela's seizures had returned "within 24 hours of last vaccine given." *Id.* (quoting Pet'r's Ex. 4, at 22).

Isabela's diagnosis of infantile spasms remains unchanged, and her development has been delayed. 2012 WL 4018028, at *4. She stopped taking Prednisone and Keppra, but her Topamax has been increased, and in addition she has been prescribed Depakote, another anti-epileptic medication. *Id.*

## II. Procedural History

Petitioner filed her petition on May 11, 2009 (docket entry 1). The petition claims that Isabela's injury satisfies the requirements both for an encephalopathy Table injury and that the vaccine was the cause-in-fact of Isabela's encephalopathy. 2012 WL 4018028, at *1. Respondent subsequently filed a Vaccine Rule 4(c) report (docket entry 9, July 28, 2009); petitioner filed an expert report from Dr. Overby (docket entry 16, May 27, 2010); respondent filed an expert report from Dr. Mary Anne Guggenheim, a pediatric neurologist (docket entry 17, Aug. 11, 2010); and petitioner filed a diagnostic report (docket entry 23, Feb. 18, 2011). Special Master Lord held an entitlement hearing on March 25, 2011. Both parties filed post-hearing briefs (docket entry 34, July 12, 2011; docket entry 36, Aug. 26, 2011). The special master issued her Decision on August 23, 2012 finding that petitioner failed to establish either a Table encephalopathy or causation-in-fact of an off-Table injury.

## III. Jurisdiction and Standard of Review

Pursuant to the Vaccine Act, the Court of Federal Claims has jurisdiction to review decisions of special masters. 42 U.S.C. § 300aa-12(e). The Court reviews the legal conclusions of the special master *de novo* and defers to the special master on findings of fact, unless the Court determines that such findings are arbitrary or capricious. *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1248–49 (Fed. Cir. 2011); *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). "'[R]eversible error will be extremely difficult to demonstrate' where the special master 'has considered the relevant evidence of

record, drawn plausible inferences and articulated a rational basis for the decision.'" *Porter*, 663 F.3d at 1253–54 (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

## IV. Discussion

Petitioner challenges only the special master's holding that Isabela's injury was not a Table injury. Pet. 1–2. To establish a Table injury, petitioner must show that Isabela suffered an "illness, disability, injury, or condition set forth in the Vaccine Injury Table . . . and the first symptom or manifestation of such illness, disability, injury, or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-11(c)(1)(C)(i). The Vaccine Injury Table is found at 42 U.S.C. § 300aa-14(a) and 42 C.F.R. § 100.3(a).[3] In this case, petitioner alleges that Isabela suffered an encephalopathy. Pet. 1–2. Of the vaccines Isabela received on March 28, 2008, only the DTaP vaccine is associated in the Vaccine Injury Table with an encephalopathy. 42 C.F.R. § 100.3(a)(II). The time period for manifestation of an encephalopathy is seventy-two hours after administration of the DTaP vaccine. *Id.*

A Table "encephalopathy" is defined as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." § 300aa-14(b)(3)(A). The Secretary of Health and Human Services' Qualifications and Aids to Interpretation ("QAI") further limit an encephalopathy to cases in which the vaccine "recipient manifests, within the applicable period, an . . . acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." § 100.3(b)(2).

An acute encephalopathy is defined as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i). In particular:

> For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

§ 100.3(b)(2)(i)(A). Section 100.3(b)(2)(i)(D) of the QAI further states that a "significantly decreased level of consciousness" is indicated by "the presence of at least one of the following clinical signs for at least 24 hours or greater":

> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

[3] The statute permits regulations promulgated by the Secretary of Health and Human Services to modify the statutory version of the Table. 42 U.S.C. § 300aa-14(c)(1).

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

The QAI also sets forth symptoms that the Table considers insufficient to prove an acute encephalopathy:

> The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. *Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy*.

§ 100.3(b)(2)(i)(E) (emphasis added).

The special master found that, because Isabela's only symptoms were seizures, petitioner failed to prove that Isabela suffered an acute encephalopathy within seventy-two hours of her DTaP vaccine. 2012 WL 4018028, at *14 ("Isabela did not suffer an acute encephalopathy in the 72 hours following her vaccination; she suffered seizures."). The special master found that it was not enough that within seventy-two hours of the vaccination *something* happened which led to Isabel's chronic encephalopathy. *Id.* at *15. Rather, the Table requirement is that an *acute encephalopathy* must occur within seventy-two hours of the vaccine. *Id.* Since Isabela never experienced symptoms sufficient to prove an acute encephalopathy, the special master found that she had not suffered a Table encephalopathy. *Id.* at *14–15.

Petitioner argues that the special master erred by finding that Isabela's seizures within seventy-two hours of her DTaP vaccine did not constitute an acute encephalopathy. First, petitioner cites Dr. Henkind's testimony that she would have admitted Isabela to the hospital if she had been aware of the symptoms that Isabela experienced in the seventy-two hours after her vaccine (March 28 through April 1, 2008). Pet. 10 (quoting Hr'g Tr. 29:16–30:6 (docket entry 31, April 28, 2011)). Petitioner seems to argue that this testimony is sufficient to satisfy § 100.3(b)(2)(i). *See* Pet. 3 (quoting § 100.3(b)(2)(i)(A) (defining an acute encephalopathy as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)")). Second, petitioner argues that the actual cause of Isabela's injury is unknown. Pet. 10–12. The Court understands petitioner to be arguing that, if the actual cause of the injury is unknown, it should be considered a Table injury. *See* Pet. 3 (quoting § 100.3(b)(2)(iii) ("If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.")). Neither of petitioner's two arguments is reason to reverse the special master's decision.

Petitioner's first argument, based on § 100.3(b)(2)(i), ignores the exception contained in § 100.3(b)(2)(i)(E). It is true that § 100.3(b)(2)(i) defines an acute encephalopathy as an encephalopathy that is severe enough to require hospitalization. The QAI requires, however, additional evidence other than seizures. § 100.3(b)(2)(i)(E) ("Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy."). Petitioner does not dispute, however, that Isabela's symptoms were seizures. Therefore, the special master correctly determined that Isabela's symptoms were insufficient to establish an acute encephalopathy.

Petitioner's second argument—that the actual cause of Isabela's injury is unknown—relies on an incorrect reading of § 100.3(b)(2)(iii), which does not govern how a petitioner may prove an encephalopathy. Rather, that regulation governs how a respondent may rebut a petitioner's proof of an encephalopathy. *See Nilson v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 678, 682–83 (2006). Given that the special master correctly determined that Isabela's seizures did not constitute an acute encephalopathy, the special master did not consider the question of whether respondent had proved a non-vaccine cause of Isabela's injury. *See Argueta v. Sec'y of Health & Human Servs.*, No. 07-784V, 2011 WL 2945803, at *2 n.5 (Fed. Cl. Spec. Mstr. June 30, 2011). Thus, § 100.3(b)(2)(iii) is irrelevant to petitioner's Table injury claim and therefore does not excuse petitioner from the requirement of proving that Isabela's injury satisfied the QAI requirements for an acute encephalopathy.

## CONCLUSION

In view of the foregoing, the Court upholds the special master's findings of fact and conclusions of law as well as the special master's decision denying petitioner's claim for compensation under the Vaccine Act. Accordingly, petitioner's motion for review is **DENIED** and Special Master Lord's August 8, 2012 decision is **AFFIRMED**.

**IT IS SO ORDERED.**

s/ George W. Miller
GEORGE W. MILLER
Judge