In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-57V
Filed: October 21, 2020
UNPUBLISHED

JAVIER COLON on behalf of S.C., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Seizures; Microcephaly; Developmental Delay; Neurogenetic Condition; IQSEC2 gene variant; Insufficient Proof; Failure to Prosecute

Michael A. London, Douglas & London, P.C., New York, NY, for petitioner.
Alexis B. Babcock, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On January 11, 2019, petitioner filed a claim on behalf of his child, S.C., under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that S.C. suffered an adverse reaction, gastrointestinal issues, digestive issues, reflux, skin rashes, seizures and spasms as a result of numerous childhood vaccines administered between January 11, 2016 and January 4, 2017.[2] (ECF No. 1.)

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Specifically, the petition identifies the following vaccinations. On January 11, 2016: diphtheria, tetanus, and acellular pertussis ("DTaP"); hepatitis B ("Hep B"); Rotavirus; haemophilus influenza B ("Hib"); inactivated polio ("IPV"); and pneumococcal. On March 29, 2016: DTaP; Hep B, Rotavirus, IPV; pneumococcal. On June 6, 2016: DTaP; Hep B; Rotavirus; IPV; and pneumococcal. On November 16, 2016: measles mumps and rubella ("MMR"); hepatitis A ("Hep A"); and pneumococcal. On December 2, 2016: influenza ("flu"). On January 4, 2017: flu. (ECF No. 1, pp. 1-2.)

I. Procedural History

This case was initially assigned to Special Master Roth. (ECF No. 4.) Along with the petition, petitioner filed medical records marked as Exhibits 1-4. (ECF No. 1.) Additional medical records marked as Exhibits 5-8 were later filed on April 19, 2019 along with a Statement of Completion. (ECF Nos. 8-9.) Subsequently, respondent confirmed that no additional records were outstanding and Special Master Roth ordered respondent to file his Rule 4(c) Report on June 24, 2019. (ECF No 10; Scheduling Order (Non-PDF), 6/24/2019.) Respondent did so on August 22, 2019, recommending against compensation. (ECF No. 11.)

On August 22, 2019, Special Master Roth ordered petitioner to file an expert report by November 20, 2019; however, the case was reassigned to my docket shortly thereafter on September 3, 2019. (Scheduling Order (Non PDF), 8/22/2019; ECF No. 13.) I subsequently granted five motions for extensions of time, allowing petitioner a full eleven months to file an expert report supporting his claim. (ECF Nos. 15-19.)

On May 14, 2020, petitioner filed a status report indicating that "[c]ounsel for petitioner has spoken with potential experts who have informed them that they will not be able to submit an expert report on behalf of the petitioner." (ECF No. 20.) However, petitioner subsequently filed a further status report on June 15, 2020, indicating that petitioner nonetheless wished to continue the case and that petitioner's counsel intended to move to be relieved as counsel. (ECF No. 21.)

In light of petitioner's stated intention to continue the case despite being unable to retain expert support, I held a status conference to explain why an expert report is necessary to continue the case and to advise that I would be issuing an order to show cause why the case should not be dismissed. I issued that order to show cause on July 16, 2020, setting a September 16, 2020 deadline for petitioner's filing of an expert report. (ECF No. 23.)

On September 16, 2020, petitioner's counsel filed a status report indicating that there was a good faith misunderstanding by petitioner that prevented compliance with my order to show cause and requesting an additional 30 days to comply. I allowed a final 30-day extension of petitioner's expert report deadline, but cautioned that petitioner's obligations under the order to show cause remained in effect and that failure to file an expert report by October 19, 2020, would result in dismissal of this case. (ECF Nos. 24, 25.)

Petitioner filed a status report on October 19, 2020 indicating that he is unable to submit an expert report by the deadline. (ECF No. 26.)

II. Factual History

S.C. was born on November 9, 2015. (Ex. 3, p. 1.) During gestation, an ultrasound at six months revealed large ventricles. (Ex. 7, p. 36.) Microcephaly was

present at birth (Ex. 5, p. 12; Ex. 3, p. 32) and doctors initially suspected either a congenital cytomegalovirus infection or an intrauterine insult during the first trimester (Ex. 2, p. 83; Ex. 3, p. 34).

S.C. first presented with possible GERD or reflux and feeding problems (x2 days) at about 9 weeks of age on January 15, 2016. (Ex. 2, p. 85.) Eventually, S.C. had a gastronomy tube inserted on December 13, 2016. (Ex. 3, p. 289, 303.) S.C. sought treatment at Pediatric GI/Nutrition PANS clinic for his continued reflux and feeding difficulty. (Ex. 3, p. 256.) S.C. was diagnosed with cerebral palsy by Dr. Susan L. Hyman following a pediatric developmental and behavioral consultation. (Ex. 3, p. 799-801.) Dr. Hyman indicated that S.C.'s "oral motor coordination leading to the need for gastronomy, the cortical use of vision, constipation, and growth delay are all associated with cerebral palsy [ ] and the underlying causes of the descriptive diagnosis of cerebral palsy and global developmental delay." (Ex. 8, p. 809.)

Rash is first mentioned at S.C.'s March 9, 2016 well child visit, at which time chronic and worsening seborrhea is documented. (Ex. 2, pp. 77-78.) That condition did continue to worsen for a time; however, S.C.'s skin condition appears to have been attributed to nut allergy as it was noted to resolve when his mother stopped or decreased her nut intake. (Ex. 3, pp. 33, 472.)

At seven months, focal seizures were questioned on June 17, 2016, based on activity of the left leg. (Ex. 2, p. 60.) Subsequently on July 27, 2016, generalized seizures were reported, including altered consciousness, drooling, lip smacking, and unresponsiveness. (*Id*. at 57.) An EEG was abnormal, showing hypsarrhythmia consistent with S.C.'s microencephaly. (Ex. 3, p. 91.)

On January 29, 2018, S.C. was evaluated by a neurogeneticist who felt that S.C.'s medical history, including microcephaly, severe developmental delays, history of infantile spasms, failure to thrive, gastronomy tube dependence, obstructive sleep apnea, and brain malformations had a genetic cause. (Ex. 3, p. 836.) Subsequently, S.C. was confirmed to have a maternally inherited IQSEC2 gene variant. (*Id*. at 998.) Although "challenging to interpret," it was felt that S.C.'s gene variant was "likely pathogenic" and "a candidate gene for his condition." (*Id*.) The doctor specifically assured S.C.'s parents that a single gene mutation was sufficient to be disease-causing. (*Id*. at 1013.)

Although S.C.'s medical history has only been briefly summarized, S.C.'s complete medical records have been reviewed. It is clear that S.C.'s parents developed a subjective belief that his condition(s) were vaccine-caused and reported to his physicians that there was a temporal association between his vaccinations and onset of his symptoms. However, none of S.C.'s physicians opined that S.C. ever experienced any vaccine reaction or that any of his symptoms could have been caused by his vaccinations. Moreover, contrary to the allegation of vaccine-causation, the records are clear that S.C.'s treating physicians felt that other, more compelling explanations existed for S.C.'s condition.

S.C.'s parents did succeed in securing a letter from a nurse-practitioner recommending against future vaccinations. However, this letter is inadequate to support causation, especially when examining the record as a whole. On July 11, 2018, a nurse-practitioner provided a letter indicating that:

> This letter is written on behalf of [S.C.] at the request of his parents [S.C.] was recently seen by Dr. David Bearden, one of our neurogenetic providers at the University of Rochester Medical Center. He has been diagnosed with a genetic mutation (spelling change), that is maternally inherited (passed on from Mom), called IQSEC2. It is likely a pathogenic variant that is a candidate gene for his condition. Based on [S.C.]'s genetic disorder and parental description of multiple adverse vaccine-related reactions, we are recommending that he avoid further vaccines in the future. [S.C.] has been fully vaccinated up to this time and we believe avoiding future vaccines creates minimal additional risk.

(Ex. 3, pp. 1013-14.)

Importantly, although this letter includes some evidence that one of S.C.'s physicians apparently acquiesced to his parent's desire to avoid further vaccinations, the stated rationale of this letter relies on the minimal risk in avoiding future vaccination and does not demonstrate that any vaccines caused or contributed to S.C.'s condition. Moreover, the letter is careful not to ratify the parental report of any vaccine reactions. As reflected in his notes, vaccine reactions were not a part of Dr. Bearden's impression nor was vaccine avoidance among his recommendations. (*Id*. at 1004.)

III. Discussion

To receive compensation in the Vaccine Program, petitioner must prove either (1) that S.C. suffered a "Table Injury" – *i.e*., an injury falling within the Vaccine Injury Table – corresponding to a covered vaccine, or (2) that he suffered an injury that was actually caused by a covered vaccine. *See* 42 U.S.C. §§ 13(a)(1)(A) and 11(c)(1). To satisfy the burden of proving causation in fact, a petitioner must show by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). No "Table Injury" was alleged in this case. Nor did an examination of the record uncover any evidence that petitioner suffered a "Table Injury." Further, upon my review, S.C.'s medical records do not contain preponderant evidence indicating that S.C.'s alleged injury was vaccine-caused or in any way vaccine-related.

Under the Vaccine Act, a petitioner may not be given a Program award "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 13(a)(1). In this case, S.C.'s medical records do not indicate any

link between his injuries and his vaccines apart from his parents' own reported concerns regarding a temporal association. None of S.C.'s treating physicians opined that his condition was vaccine-caused or aggravated. Instead, the record shows that S.C.'s treating physicians believed that S.C.'s condition was the effect of other, more compelling causes such as congenital gene mutations. Even assuming *arguendo* that some or all of S.C.'s symptoms occurred in temporal proximity to his vaccinations, this is inadequate to demonstrate causation in the absence of a Table Injury. *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to *Althen* Prong Two when respondent conceded that petitioner met Prong Three).

Because the medical records fail to establish either a Table Injury or any causal connection between S.C.'s condition and his vaccinations, it was incumbent upon petitioner to secure the expert opinion of a competent physician. 42 U.S.C. § 13(a)(1). Thus, because petitioner has failed to secure an expert opinion, he is unable to meet his burden in this case and the case must be dismissed for insufficient proof. To the extent petitioner nonetheless expressed a desire to continue this claim (ECF No. 21), I have already allowed petitioner over one year to secure the expert report needed to support his claim. Accordingly, petitioner has had a full and fair opportunity to present his claim and I find in the alternative that his failure to produce an expert report to support this claim constitutes a failure to prosecute and that dismissal is therefore also appropriate pursuant to Vaccine Rule 21(b)(1).

IV. Conclusion

Although petitioner has my sympathy for what he, S.C., and his family have endured, for the reasons discussed above this petition is **DISMISSED** for insufficient proof and for failure to prosecute. The clerk of the court is directed to enter judgment in accordance with this decision.[3]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[3] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.