In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-192V
Filed: January 9, 2020
UNPUBLISHED

PRISCILLA GONZALEZ, Parent, on Behalf of A.W., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Decision Dismissing Petition; Influenza ("flu") vaccine; ADEM; parainfluenza 3 infection; postinfectious ADEM

Timothy M. Kotfila, Kotfila & Jordan, Springfield, MA, for petitioner.
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

DISMISSAL DECISION[1]

On February 9, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that her daughter, A.W., suffered acute disseminated encephalomyelitis ("ADEM") or viral encephalitis as a result of her receipt of the influenza ("flu") vaccination on November 24, 2014. (ECF No. 1.) On October 31, 2017, respondent filed a Rule 4(c) Report concluding that compensation was not appropriate. (ECF No. 19.)

On February 12, 2018, petitioner filed an expert report from Dr. Craig Schacher in support of her petition. (ECF No. 21; Ex. 8.) Respondent filed a responsive expert report from Dr. Andrew MacGinnitie on October 18, 2018. (ECF No. 30; Ex. A.) On June 28, 2019, petitioner filed a status report, indicating that petitioner did not intend to submit a supplemental expert opinion. (ECF No. 36.) This case was reassigned to my docket on August 29, 2019. (ECF No. 38.)

[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.

On November 22, 2019, I held a status conference. I advised counsel that Dr. Schacher's opinion was insufficient to carry petitioner's burden of proof. Subsequently, I issued an Order to Show Cause, asking petitioner to show cause for why this case should not be dismissed. In the order, I explained that in order to avoid dismissal of her claim, petitioner must file an expert opinion that persuasively establishes that A.W. suffered a postvaccinal, rather than postinfectious, ADEM or other vaccine-caused encephalitis. (ECF No. 39.)

On January 6, 2020, petitioner filed a response to my Order to Show Cause, stating that A.W. "has no additional information, other than the exhibits, medical record and expert's report filed to date, in support of her petition." (ECF No. 40.)

FACTUAL HISTORY

A.W. was born on May 1, 2013 and received an influenza vaccination on November 24, 2014 during her routine infant health check. (Ex. 2, p. 8-10.) About five weeks later, A.W. was suffering from vomiting and diarrhea for six days and visited her pediatrician on January 6, 2015. (*Id*. at 5.) A.W. was diagnosed with gastroenteritis. (*Id*. at 6.) On January 27, 2015, A.W. was seen at the emergency room and then admitted into Baystate Medical Center for "left hemiparesis and altered mental status in the setting of recent vomiting." (Ex. 2, p. 28, 34.) A.W. was diagnosed with ADEM given her MRI findings, but viral encephalitis was also considered as a possibility because A.W.'s testing revealed she was positive for parainfluenza 3. (*Id*. at 28, 32.)

During the neurology consultation, Dr. Brooke Surran stated that A.W.'s "viral panel was positive only for parainfluenza 3, which is an uncommon but known cause of encephalitis," and that "[p]arainfluenza or her recent GI illness could have been the trigger for ADEM, though both are uncommon causes." (Ex. 2, p. 48-49.) Dr. Donna J. Fisher, during A.W.'s pediatric infectious disease consultation, opined that A.W.'s "clinical picture of lethargy, possible seizure with abnormal MRI and EEG, in the setting of several weeks of subacute illness with tactile fever, morning vomiting, and diarrhea, is very suggestive of a post-viral [ADEM], especially in light of positive Parainfluenza 3 result." (*Id*. at 54.) During the course of her treatment at Baystate, A.W. experienced seizures and Dr. Megan Edwards indicated that "[c]linical presentation is along spectrum of acute encephalitis due to virus (no clear reports of parainfluenza detected in CSF literature) vs post-acute encephalomyopathy." (Ex. 7, p. 1177.) A.W. was discharged from PICU on February 7, 2015. (*Id*. at 15.)

A.W. visited Dr. Surran for a neurological follow-up evaluation on February 18, 2015. (Ex. 2, p. 6.) Dr. Surran noted that A.W. remained on levetiracetam therapy, of which A.W. is tolerating well, and that A.W. "had not had further episodes concerning seizure activity; however, occasionally she will have stiffening of her left arm behind her back in what seems to be a tonic posture." (*Id*. at 7.) Overall, Dr. Surran's impression was that A.W. "is a delightful 21-month-old girl who unfortunately has suffered what

seems to be viral encephalitis with resulting left-sided hemiparesis, possibly due to parainfluenza viral infection." (*Id*.)

DISCUSSION

To receive compensation in the Vaccine Program, petitioner must prove either (1) that she suffered a "Table Injury" – *i.e*., an injury falling within the Vaccine Injury Table – corresponding to a covered vaccine, or (2) that she suffered an injury that was actually caused by a covered vaccine. *See* §§ 13(a)(1)(A) and 11(c)(1). To satisfy her burden of proving causation in fact, 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 and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the special master from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion.

A. *Althen* Prong One

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)).

In this case, petitioner's sole expert, Dr. Schacher, indicated that he could not opine that post-vaccinal ADEM is more likely than not in this case, stating "[i]f one feels that statistically this ADEM is more likely to be post infectious from the parainfluenza 3 virus that was found in her system, I will not argue with that." (Ex. 8, p. 2.) Rather, his opinion relied on proposing that, regardless of whether A.W. had ADEM or encephalitis, A.W.'s influenza vaccination indirectly contributed to her condition by increasing her risk of developing the parainfluenza 3 infection that in turn was likely the cause of her condition (whether ADEM or encephalitis). (*Id*.) Dr. Schacher cited two

studies (Cowling[2] and Diereg[3]) to support his opinion. However, neither Dr. Schacher's opinion, nor the two studies he cites, provide preponderant evidence establishing a medical theory of vaccine causation. Indeed, Dr. Schacher's characterized his own theory as only "plausible." *See Boatmon v. Secretary of Health & Human Services*, 941 F.3d 1351 (Fed. Cir. 2019) (reaffirming that a "plausible" or "possible" causal theory fails to satisfy petitioner's burden of proof). Moreover, Dr. Schacher's opinion was persuasively rebutted by Dr. MacGinnitie's opinion. (Ex. A, pp. 4-6.)

B. *Althen* Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as 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'") (quoting *Althen*, 418 F.3d at 1280). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or

[2] The Cowling study observed 115 children over nine months and purported to find a statistically significant increased risk of *noninfluenza* infection among those that received the flu vaccination versus those that received the placebo though there was no statistically significant difference in the overall risk of acute respiratory infections and febrile acute respiratory infections. (Ex. 9, p. 3.). Significantly, they did not measure immune status, but only tracked incidences of respiratory infections and tested for the presence of 19 different respiratory viruses. As a threshold matter, the authors acknowledged that this finding could be artefactual. (Ex. 9, p. 4.) However, to the extent the authors posit the finding to have been a real effect, they also suggest that the "results could be explained by temporary nonspecific immunity after influenza virus infection, through the cell-mediated response or, more likely, the innate immune response to infection. Participants who received [the flu vaccine] would have been protected against influenza in February 2009 but then would not have had heightened nonspecific immunity in the following weeks." (Ex. 9, p. 3.) This appears to suggest the statistical difference may be due to residual effects of increased numbers of influenza infections among the nonvaccinated group rather than due to any effect of the vaccine in the vaccinated group.

[3] The Diereg study observed 381 children, and based on anecdotal reports of symptoms and swabs, noted influenza-vaccinated children to have experienced higher rates of Influenza-like, noninfluenza illnesses. They cautioned, however, that "prior health-seeking behavior may have contributed to this difference." (Ex. 10, p. 1.) Moreover, even with a somewhat larger study population compared to the Cowling study, the Diereg authors stressed that "this study lacked power to tease apart the relative significance of each virus, virus combinations and multiplicity of infection." (Ex. 10, p. 8.)

court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed.Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

Upon my review of the record and considering the opinions of A.W.'s treating physicians, the record showed that A.W. suffered an HPIV-3 infection and the treating physicians felt A.W.'s condition was likely to be attributable to parainfluenza. As described above, treating physician opinions are ordinarily accorded a degree of deference. This is because, "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.'" *Capizzano*, 440 F.3d at 1326. Notably, none of A.W.'s treating physicians, who oversaw her care throughout the twelve days she was initially hospitalized in PICU, attributed her illness to her influenza vaccination. These opinions were also endorsed by respondent's expert, Dr. MacGinnitie, who opined that A.W. suffered viral encephalitis caused by a parainfluenza 3 infection. (Ex. A, p. 7.)

Nonetheless, Dr. Schacher opined that A.W.'s illness, whether it was postvaccinal ADEM, post infectious parainfluenza induced ADEM, or parainfluenza 3 viral encephalitis, was "most likely directly or indirectly due to her influenza vaccination," because "there are several studies showing that those children who are vaccinated against the 'flu' have a significantly higher risk of experiencing a non-influenza viral infection such as parainfluenza." (Ex. 8, p. 2.) However, the Federal Circuit has stated in *Knudsen* and again in *Boatmon* that statistical evidence alone is not enough to meet the *Althen* prong two showing of evidence of actual causation. *Knudsen,* 35 F.3d at 550; *Boatmon,* 941 F.3d at 1362-63. In light of the fact that Dr. Schacher's opinion is based solely on the idea of a statistical *risk* of parainfluenza infection after vaccination and not on evidence demonstrating that A.W.'s influenza vaccine *did cause* her parainfluenza 3 infection, petitioner falls short in presenting a *prima facie* case. Neither of the studies cited by Dr. Schacher establish a biological cause and effect between influenza vaccination and parainfluenza infection. *See supra*, n. 2-3. Nor did Dr. Schacher adequately explain such cause and effect relationship. Therefore, Petitioner failed to provide a logical sequence of cause and effect explaining how influenza vaccination caused A.W.'s injury, and thus, failed to satisfy *Althen* prong two.

C. ***Althen* Prong Three**

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* Here, accepting that the onset period was five weeks, it appears an appropriate temporal relationship could exist in this case. However, even assuming petitioner met prong three based on the five weeks onset period,[4] a temporal relationship alone

[4] Although Dr. Schacher placed onset at five weeks post-vaccination, consistent with her initial episode of vomiting and diarrhea, Dr. MacGinnitie placed onset at nine weeks, based on her later presentation to the

cannot establish causation. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."). Petitioner's failure to meet prongs one and two means that petitioner cannot be compensated. *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013) (citing *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 Prong Two when respondent conceded that petitioner met Prong Three).

CONCLUSION

This petition is now **DISMISSED** for failure to establish a *prima facie* case of entitlement to compensation. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[5]

IT IS SO ORDERED.

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

Emergency Room. (Ex. 8, p. 1; Ex. A, p. 2.)

[5] Entry of judgment can be expedited by each party's filing of a notice renouncing the right to seek review. Vaccine Rule 11(a).