

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 11-151V
Filed: November 8, 2011
Unpublished

TRACY ARAKELIAN and DAREN *
ARAKELIAN, Individually and as Parents *
and Natural Guardians of CHARLES *
ARAKELIAN, an Infant, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Denial; Influenza vaccine; Adult
vaccine dose administered to child;
Guillain-Barré Syndrome, GBS;
Chronic inflammatory demyelinating
polyneuropathy, CIDP

W. Farley Jones, E. Stewart Jones, PLLC, Troy, NY, for Petitioners.
Chrysovalantis P. Kefalas, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION¹

GOLKIEWICZ, Special Master.

On March 9, 2011, a Petition in this matter was filed alleging that petitioners’ son developed Guillain-Barré Syndrome (“GBS”) and chronic inflammatory demyelinating polyneuropathy (“CIDP”) due to his receipt of an influenza vaccine administered on November 4, 2006. Petition (“Pet.”) at 1. Regarding the medical records, petitioners note a rash that occurred approximately thirteen days after vaccination. Pet. at 2 (citing P Ex 2 at p. 12; P Ex 6). Petitioners also note a flu-like illness in January 2007 and a gastrointestinal illness in April 2007. Pet. at 2 (citing P Ex 2 at pp. 14, 18-21). Petitioners reported fatigue, aches, loss of energy, back

¹ The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

aches, headache and painful feet reported to the pediatrician in June and August 2007. Pet. at 2 (citing P Ex 2 at pp. 22, 25). Consultation with an orthopedist on August 30, 2007, resulted in referral for a neurology examination. Pet. at 3 (citing P Ex 6). The evaluation occurred, during which a resident noted she was unable to obtain deep tendon reflexes, but petitioners' son was discharged with advice to watch for further symptoms. Id.

Petitioners returned to the hospital with their son on September 2, 2007, when he was admitted for concerns regarding Guillain-Barré Syndrome. Pet. at 3 (citing P Ex 8). Hospitalized for more than one week, petitioners' son was eventually discharged on September 10, 2007, with the diagnosis of inflammatory demyelinating polyneuropathy. Id. at 4 (citing P Ex 8). Treatment continued and on September 24, 2007, Dr. Kang at Children's Hospital of Boston felt petitioners' son was suffering from chronic inflammatory demyelinating polyneuropathy ("CIDP"). Id. (citing P Ex 10). During a September 27, 2010 visit, Dr. Kang suggested there was a small risk of relapse with the vaccinations petitioners' son was then due to receive. Id. (citing P Ex 22). Dr. Kang opined that the vaccine could have caused the CIDP. P Ex 10 at p. 7. "His parents asked about the influenza vaccine. Just before his symptoms developed, he accidentally received an adult dose of influenza vaccine. I think there is a possibility that this was the trigger for the CIDP, but it is not clear whether this reaction would have occurred with a pediatric form of the vaccine." P Ex 10 at p. 7. Dr. Kang's initial record on September 24, 2007, notes that symptoms began "6 months ago," which would be March or April 2007 and four to five months after vaccination. P Ex 10 at p. 1.

Petitioners supplied the opinion of Dr. Donald Marks. Affidavit of Donald H. Marks, M.D., Ph.D., filed October 27, 2009.² Dr. Marks opined that the adult dosage of the flu vaccine "significantly increased the risk of that child developing an adverse reaction, including demyelinating polyneuropathy." Id. at p. 2. Further, "[m]y research and clinical practice have revealed a significant relationship between flu vaccine in children and the development of permanent neurological conditions" and that "review of the records does not indicate any other likely cause" Id. Dr. Marks provided no citations to the medical records or to supporting medical literature. Dr. Marks also did not provide a medical theory of how the vaccination can cause the injury, evidence a logical sequence of cause and effect in petitioners' son's case, or discuss an appropriate medical time frame in which such an injury would occur following vaccination. Affidavit of Dr. Marks; see also R Rule 4(c) Report at pp. 16-18.

On June 30, 2011, respondent filed her Rule 4(c) Report, which recommended against awarding compensation. Along with the Rule 4(c) Report, respondent filed expert reports from Dr. Michael Cohen and Dr. Neal Halsey. In his report, Dr. Cohen opined that the influenza vaccine was not causative and that petitioners' son's polyneuropathy was more likely due to the cytomegalovirus ("CMV"), as his CMV titers were elevated. R Ex A, filed June 30, 2011. Dr. Cohen also noted the long delay between vaccination and onset of the child's polyneuropathy. In the other expert report, Dr. Halsey also comments on the onset of the condition occurring almost

² This date is prior to the filing of this Petition. A previous Petition was filed for petitioners' claim herein. That case was dismissed without prejudice as there was civil action pending at the time, which is forbidden by the Vaccine Act. Arakelian v. Sec'y of the Dept. of Health & Human Servs., No. 09-731V, Order Concluding Proceedings. For economy-sake, the exhibits filed in case 09-731V were transferred when the case was re-filed properly.

nine months after vaccination; Dr. Halsey states that this “time interval between vaccination and the onset of neurologic findings on physical exams is inconsistent with even the theoretical risk that the vaccine . . . might have contributed to or caused” the condition. R Ex C at 6, filed June 30, 2011. As petitioners had alleged that an adult-size dose of the influenza vaccine caused harm to their son, Dr. Halsey noted “there is no evidence that the higher dose (twice the pediatric dose) poses any increase in the risk of adverse effects other than local reactions and fever.” R Ex C at 5. Further, Dr. Halsey argues that it is unclear whether petitioners’ son received an adult or a pediatric dose of the flu vaccine. Id. Dr. Halsey also notes that petitioners’ son had an upper respiratory infection prior to onset of his condition, which occurs in one-fourth of patients with CIDP. Id. at 6. Dr. Halsey also comments on petitioners’ expert report from Dr. Donald Marks, noting that Dr. Marks provided no support for his opinion that the adult dose of the influenza vaccine increases the risk of demyelinating polyneuropathy in a toddler. Dr. Halsey also discusses Dr. Marks’s assertion that there are no other potential causes evidenced in the medical records. Dr. Halsey points to a flu-like illness and a gastroenteritis, which are known to be associated with demyelinating conditions, petitioners’ son suffered prior to his polyneuropathy and in a more appropriate time frame for triggering the condition. Id.

In light of respondent’s experts’ reports, on September 23, 2011, a status conference was held, following which petitioners were given thirty days to inform the court of how petitioners wished to proceed. Order, filed September 23, 2011. On October 24, 2011, petitioners’ counsel contacted the undersigned’s office, informing the court that petitioners’ wish to conclude their Petition.

Upon review of the record and based upon the expert reports filed, petitioners fail to provide preponderant evidence that the vaccination their son received on November 4, 2006, caused his injuries. Dr. Marks’ opinion fails the test of reliability given the lack of citations to the medical records and supporting medical literature. In fact, no medical theory was advanced regarding how the vaccine could have caused the alleged injury. In contradistinction, respondent’s experts advanced serious issues of medically inappropriate timeframes and more likely causes for petitioners’ son’s injury. Petitioners did not address these issues. Based upon the current record, it is clear that the evidence preponderates against petitioners’ claim. Thus, in accordance with section 13(a), the undersigned has no option but to **deny** petitioners’ claim for want of proof.

The Clerk of the Court is directed to enter judgment accordingly.

IT IS SO ORDERED.³

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master

³ This document constitutes a final “decision” in this case pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision. Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.