

Filed: November 30, 2017

UNPUBLISHED

No. 16-799V

Special Master Gowen

Dismissal, Insufficient Proof; Petitioner's Motion; Haemophilus Influenzae Type B ("Hib"); Diphtheria Tetanus ("DT"); Asthma; Reactive Airway Disease.

## DECISION<sup>1</sup>

## I. Procedural History

<sup>2</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

initial status conference, it was discussed that S.N. received a Hib vaccine in the United States on December 12, 2013. He has traveled to and received medical treatment in the United States and Israel at various times. However, the majority of his medical treatment has been in Mexico City, Mexico, where the family currently resides and where the father is employed. The parties and I candidly discussed the difficulties in translating the records that are written in Spanish; obtaining additional medical documentation; and securing an expert opinion. I allowed petitioner 90 days, until December 12, 2016, to file this additional documentation and a status report proposing how to proceed.

On December 9, 2016, petitioner filed translations of some of the Spanish medical records. She also filed a status report which provides that further medical records relating to S.N.'s condition may exist in Mexico. However, these records may be obtained only with authorization of Mexican government officials. Furthermore, those records generally only reflect the date and nature of treatments. Petitioner stated that all records relating to causation have been filed. Petitioner requested permission to consult with an expert and determine whether an opinion in support of her claim could be rendered. I instead ordered petitioner to file a reasonably detailed affidavit to supplement the limited medical records and provide a more complete chronology of events, including S.N.'s vaccinations and adverse reactions within 30 days, by January 11, 2017. I ordered petitioner to file an expert report within 60 days thereafter and for respondent to file a responsive expert report 60 days after that.

Petitioner missed the deadline to file the affidavit. On January 27, 2017, petitioner filed a status report indicating that she filed an affidavit as Exhibit 3 in July 2016 and "there is nothing more to report as to the connection between [S.N.'s] condition and his Hib vaccination." Petitioner also provided one medical article on the connection between the Hib vaccine and asthma.<sup>3</sup> She indicated that she would proceed to retain an expert report. That deadline was set for March 28, 2017.

Petitioner was granted two extensions of time to locate an expert, first to May 29, 2017, then to July 28, 2017. Petitioner then filed a third motion for extension of time indicating that she had located a team of experts who had supported a similar vaccine-asthma claim and were willing to review petitioner's case, however, petitioner's counsel was temporarily unable to fund the substantial retainer they required. Petitioner's third motion requested an additional 90 days, until October 26, 2017, to file the expert report. I granted the third motion but cautioned that I did not routinely grant such lengthy extensions and that counsel should not expect further extensions. I also instructed counsel to evaluate whether this case justifies a large expenditure of funds in light of the other problems in the case, including the availability of medical records and the novelty of the theory.

On September 28, 2017, petitioner filed a "motion for judgment on the record." The motion provides that petitioner's counsel has "seen an expert report by an available expert provided to counsel in a similar case, substantiating probable cause[, but] petitioner here has opted not to fund such an expert report." Petitioner acknowledged the difficulty of obtaining

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<sup>3</sup> Frank DeStefano et al., Childhood Vaccinations and Risk of Asthma, 21 *Pediatr. Infect. Dis. J.* 498 (2002) [Exhibit 20].

medical documentation due to the family's residence in Mexico. Petitioner therefore moved for a decision on the record as it stands.<sup>4</sup>

Respondent's response to the motion was due by October 12, 2017. After that deadline passed, respondent contacted my law clerk to request a status conference, which was scheduled for November 29, 2017. During the status conference, it was explained that after petitioner's counsel had filed the motion, he had difficulty reaching petitioner and had advised respondent's counsel that a stay might be requested. Respondent's counsel decided not to file a response. Petitioner's counsel indicated that he has regained contact with petitioner. He confirmed that petitioner is seeking a decision and the entry of judgment on her claim in the Vaccine Program, to preserve the possibility of filing a civil action in the future. Respondent did not object to this course of action. This matter is now ripe for adjudication.

## **II. Analysis**

A petitioner must establish entitlement to compensation in the Vaccine Program, through one of two ways. The first way is to establish that the vaccinee suffered a "Table Injury," i.e., that he or she received a vaccine listed on the Vaccine Injury Table and subsequently developed a corresponding injury within a corresponding period of time. § 300aa-11(c)(1). The second way is to establish that the vaccine actually caused the onset or significant aggravation of a condition in the vaccinee. § 300aa-13(a)(1)(A). To prove actual causation, petitioner must present (1) a medical theory; (2) a logical sequence of cause and effect; and (3) a medically acceptable temporal relationship between the vaccination and the injury. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under the Vaccine Act, the Program may not award compensation solely based on a petitioner's own claims. Rather, a petitioner must support his claim with either medical records or the opinion of a competent physician. § 13(a)(1).

In the present case, petitioner does not allege, nor do the medical records indicate, that S.N. suffered a Table Injury. Thus, to prevail on entitlement, petitioner must establish that the vaccines actually caused S.N.'s injuries. Petitioner has filed a vaccination chart from a doctor in the United States which provides that S.N. received a DT vaccine on August 8, 2013; a Hib vaccine on December 12, 2013; and a DT vaccine on July 24, 2014. Exhibit 2 at 1.

The majority of the medical records are written in Spanish. The certified translations filed by petitioner reflect that S.N. was prescribed cough syrup in late January 2014 and again in early February 2014; he had tonsillitis in March 2014; and he had a swollen upper respiratory tract in October 2014 and again in January 2015. In December 2014 and throughout 2015, he

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<sup>4</sup> Petitioner filed this motion as a "Motion for Judgment on the Administrative Record." Upon review, the text of the motion also requests "an order amending the caption, replacing all names with initials." There is no further explanation or justification for this request.

The current case caption redacts the minor's name to his initials. To the extent that petitioner – an adult – is requesting redaction of her own name without stating that clearly or providing any justification, that request is denied.

was variously diagnosed with sinusitis, rhinitis, asthma, and allergies. Exhibit 3a. There is no indication that S.N. was ever tested for allergies. It is well known that in New York City, Mexico City, and other urban areas have significant issues with air pollution and a substantial incidence of asthma without any connection to vaccines.

These medical records are insufficient to demonstrate actual causation between the vaccines and S.N.'s condition. While there may be a temporal association between the vaccines and certain respiratory issues, the medical records do not explain a theory, logical sequence of cause and effect, or that the temporal association is medically acceptable.

Petitioner has declined to submit an expert report. She has submitted one medical journal article, which evaluated whether asthma was more prevalent in relation to five different vaccines. There was no association between asthma and diphtheria, tetanus and acellular pertussis ("DTaP"); oral polio; or measles, mumps, and rubella ("MMR"). The prevalence of asthma was somewhat elevated in the presence of both Hib and hepatitis B in those study cohorts. The authors noted that the Hib results "were not considered consistent by HMO", could not be readily explained, and were "probably a random chance finding." Exhibit 20 at 5. This article does not support an association between DT and asthma, and at best suggests a weak association between Hib and asthma. It does not fulfill petitioner's burden under the Vaccine Act and Althen. Therefore, it is appropriate to dismiss petitioner's claim for insufficient proof.

### **III. Conclusion**

**This case is dismissed for insufficient proof. The Clerk of the Court shall enter judgment accordingly.**

**IT IS SO ORDERED.**

**s/Thomas L. Gowen**  
Thomas L. Gowen  
Special Master