In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

JOSEPH VIRISSIMO, *parent, on behalf of M.V.*,	*	No. 24-1168V
Petitioner,	*	Special Master Christian J. Moran
v.	*	Filed: July 30, 2025
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael H Coggeshall, Gillock & Coggeshall, Las Vegas, NV, for petitioner;
Parisa Tabassian, United States Dep't of Justice, Washington, D.C., for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

Petitioner, Joseph Virissimo, filed a petition for compensation on July 31, 2025, alleging that the meningococcal conjugate ("MCV4") vaccine and tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine his child M.V. received on August 4, 2021, caused M.V. to suffer from Stevens-Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis ("TEN"). On July 22, 2025, Mr. Virissimo filed a motion for a decision dismissing his petition.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (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), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

I. Procedural History

Mr. Virissimo filed his petition on July 31, 2024, alleging that the MCV4 and Tdap vaccines his child M.V. received on August 4, 2021, caused M.V. to suffer from SJS and TEN. With the petition, Mr. Virissimo filed several medical records, as well as an expert report from an immunologist, Dr. Jeffrey Davidson. Exhibit 10.

Dr. Davidson opined that vaccinations do, in rare instances, cause SJS/TEN, and that the vaccines M.V. received were the cause of her SJS/TEN. Exhibit 10 at 2-3. Dr. Davidson referred to case reports, case series, systemic reviews, and a VAERS analysis regarding SJS/TEN following vaccination. Id. at 3-7. He noted that M.V. had no other vaccines, drugs, or infections in the months prior to the onset of her SJS/TEN. Id. at 8. He further opined that the timing of her onset—August 17, 2021, which was 13 days post-vaccination—was within the range of reported onsets for vaccine-induced SJS/TEN in the Ball and Su papers, which examined VAERS reports. Id. at 9.

Dr. Davidson addressed "potentially confounding facts" in his report. Exhibit 10 at 10. He acknowledged that M.V. had a positive antinuclear antibody but stated that this does not necessarily indicate an autoimmune disease, as it can occur in the relatives of people with autoimmune diseases. Moreover, "the substantiating rheumatology panel show[ed] anti-DS antibody [and] every other autoimmune test to be negative," which Dr. Davidson stated, "essentially rules out an underlying immune or autoimmune disease." Id. (emphasis in original). Dr. Davidson also noted a single hospital note from August 26, 2021, that M.V. "was slightly sick 1-2 weeks before," but stated that this was after her vaccinations and that no symptoms were reported to the pediatrician on the day of vaccination. Id.

In sum, Dr. Davidson based his opinion that the vaccines caused M.V.'s SJS/TEN on the lack of alternative triggers such as acute illness or medications; the onset of symptoms within the reported interval after vaccination; and the existence of studies and reports documenting SJS/TEN rarely arising after vaccination. Exhibit 10 at 11.

The case was reassigned to the undersigned on December 10, 2024. Respondent was ordered to file his Rule 4(c) Report and a responsive expert report. Order, issued Jan. 3, 2025. Respondent filed his Rule 4(c) Report on March 20,

2025, arguing against compensation. Respondent argued that Dr. Davidson had not presented a reliable medical theory causally linking M.V.'s vaccinations to her SJS/TEN, nor established a logical sequence of cause and effect showing that they were the actual reason for her alleged injury. Resp't's Rep. at 14. Respondent noted that the "vast majority" of the literature relied upon by Dr. Davidson discussed unrelated vaccines, and argued that he had not presented reliable scientific or medical evidence establishing an appropriate timeframe. Id. at 15. Respondent also highlighted several references in the medical records to M.V. experiencing a viral illness in the weeks leading up to the onset of her SJS/TEN, as well as multiple positive tests during her hospitalization between August 19 and September 13, 2021, which were not discussed by Dr. Davidson. Id. at 14.

Respondent further contended that, regardless of whether M.V. had any infections, a mere proximate temporal relationship or the elimination of other potential causes, without more, cannot meet petitioner's burden of showing actual causation. Resp't's Rep. at 14-15. Respondent acknowledged that M.V.'s dermatologist commented that her SJS was "possibly" related to one of the vaccines, but she did not disclose the basis of this opinion or how she ruled out the infections as alternative causes. Id. at 15.

On April 23, 2025, respondent filed an expert report from an immunologist, Dr. Emanual Maverakis. Exhibit A (corrected).[2] Dr. Maverakis opined that the vaccinations M.V. received did not have any connection to her development of SJS/TEN. Id. at 5. He explained that SJS/TEN is mediated by cytotoxic CD8+ T cells, and that CD8+ T cell responses are undetectable in the majority of vaccinated individuals; therefore, "there is no mechanistic link between the pathophysiology of SJS/TEN and the immune response induced by vaccination." Id. at 5-6. Dr. Maverakis further disputed that there is any association between SJS/TEN and vaccination, and commented on the low relative risk. Id. at 6-7.

Dr. Maverakis described the studies of Dr. Kirsti Kauppinen which "strongly suggest that the quantity of antigen is a critical determinant in the development of SJS/TEN," and argued that the antigenic dose M.V. received "would have been insufficient to trigger such a severe T cell-mediated reaction." Exhibit A at 7-8. Dr. Maverakis further explained that SJS/TEN can be idiopathic, and opined that M.V.'s SJS/TEN was idiopathic with an unknown cause, or caused by a pre-vaccination infection. Id. at 8-11.

[2] Respondent filed a corrected version of Exhibit A to clarify a statement in the report. See Order, issued May 21, 2025. The corrected exhibit was filed as ECF No. 35.

Finally, Dr. Maverakis responded directly to several points in Dr. Davidson's report. He again concluded that there "is no reputable, reliable medical theory showing that vaccines can cause SJS/TEN," and opined that M.V. had been ill prior to vaccination, and that her SJS/TEN was more likely idiopathic with an unknown cause or caused by an infection. Exhibit A at 11-13.

Mr. Virissimo was given the opportunity to file a supplemental report in response to Dr. Maverakis's report. Order, issued June 9, 2025. Instead of filing a report, Mr. Virissimo moved to have his case dismissed.

II. Analysis

To receive compensation under the National Vaccine Injury Compensation Program ("Program"), a petitioner must prove either 1) that the vaccinee suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations, or 2) that the vaccinee suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, Mr. Virissimo filed medical records and an expert report in support of his claim. Nevertheless, Mr. Virissimo wishes to have his claim dismissed and judgment entered against him. Given Mr. Virissimo's clear intent that a judgment issue in this case, the undersigned will construe this as a motion filed pursuant to 42 U.S.C. § 300aa-21(b) (regarding involuntary dismissal).

To conform to § 12(d)(3), a decision must "include findings of fact and conclusions of law." To conform to section 12(d)(3), a decision must "include findings of fact and conclusions of law." For causation-in-fact cases, the Federal Circuit has defined elements of a petitioner's claim. Petitioners bear a burden to show by a preponderance of the evidence that the vaccination brought about their injury by providing:

(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 & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Mr. Virissimo has not presented a medical theory to explain how a MCV4 and/or Tdap vaccine could cause SJS/TEN. Although Dr. Davidson's report summarizes case reports, case series, and analyses of VAERS data, in the context of litigation, this evidence often does not receive much consideration as evidence of causation. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). Typically, analyses of VAERS reports have limited usefulness because in part the researchers are not aware of how many doses of a vaccine have been administered. See Flores v. Sec'y of Health & Hum. Servs., No. 10-489V, 2013 WL 5587390, at *12-13 (Fed. Cl. Spec. Mstr. Sep. 12, 2013) ("the VAERS system does not provide information as to the 'background rate' of a certain condition in a certain population"), mot. for rev. denied, 115 Fed. Cl. 157, 164 (2014), aff'd without op, 586 Fed. App'x 588 (Fed. Cir. 2014); Werderitsh v. Sec'y of Health & Hum. Servs., No. 99-319V, 2005 WL 3320041, at *15 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (denying motion for discovery for VAERS reports because, in part, petitioner did not have access to denominator data). Thus, Mr. Virissimo has not met his burden under Althen. See Puckett v. Sec'y of Health & Hum. Servs., No. 21-1125V, 2024 WL 3160589, at *3-5 (Fed. Cl. June 3, 2024).

Thus, this case is DISMISSED WITH PREJUDICE for insufficient proof. The Clerk shall enter judgment accordingly. See Vaccine Rule 21(b).

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master