

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**No. 21-0358V**

SUSAN V. MENDOZA, as personal  
representative of ESTATE OF LUCIO  
VILLANUEVA,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 29, 2025

*Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for  
Petitioner.*

*Alec Saxe, U.S. Department of Justice, Washington, DC, for Respondent.*

**DECISION DISMISSING CASE**<sup>1</sup>

On January 8, 2021, Lucio Villanueva filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act”). Mr. Villanueva alleged that he suffered a right shoulder injury related to vaccine administration (“SIRVA”), a defined Table Injury, or in the alternative a caused-in-fact or significant aggravation injury, after receiving an influenza (“flu”) vaccine on September 24, 2020. Amended Petition, filed Sept. 28, 2022, at 1, ¶¶ 1, 8, ECF No. 24. Following Mr. Villanueva’s death from unrelated causes on November 5, 2022, Susan V.

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<sup>1</sup> 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), 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, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

Mendoza (his daughter and personal representative of his estate) was substituted as Petitioner. ECF Nos. 28-32.

I hereby DENY entitlement in this case, because Petitioner cannot preponderantly establish that Mr. Villanueva received the flu vaccine in his *right* deltoid as alleged. Additionally, there are significant other deficiencies which further undercut Petitioner's claim. Thus, entitlement cannot be substantiated – even pursuant to a causation-in-fact or significant aggravation claim – and dismissal of the matter is appropriate.

### I. Relevant Procedural History

Due most likely to the then-potential removal of SIRVA from the Vaccine Program's injury table,<sup>3</sup> and the concomitant need to act quickly, Mr. Villanueva filed a cursory petition without accompanying medical records or appropriate citations to those records. Petition, filed Jan. 8, 2021, ECF No. 1. Fifteen months later, he filed the declaration<sup>4</sup> and medical records required by the Vaccine Act. Exs. 1-10, filed Apr. 7, 2022, ECF No. 17; see Section 11(c). On June 16, 2022, the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 20.

On September 28, 2022, Mr. Villanueva filed an amended petition with additional detail and medical records citations. ECF No. 24. Approximately nine months thereafter, following the death of her father, Ms. Mendoza was substituted as Petitioner. ECF No. 32.

On August 25, 2023, Respondent filed his Rule 4(c) Report opposing compensation. ECF No. 34. He argued therein that Mr. Villanueva received the flu vaccine in his *left* deltoid as the vaccine record states, rather than the *right* deltoid as alleged. *Id.* at 11-18. Thus, he insisted that Petitioner could not prove any vaccine-related injury, given the situs of that injury. *Id.* at 18-20.

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<sup>3</sup> On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule, 86 Fed. Reg. 21209 (Apr. 22, 2021).

<sup>4</sup> This declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Ex. 10.

On October 21, 2024, I ordered Petitioner to show cause why her claim should not be dismissed for insufficient evidence, given Respondent's situs argument. In response, Petitioner filed certified medical records from Mr. Villaneuva's urgent care treatment in September 2020; a copy of the subpoena authorized and served upon her primary care provider ("PCP") in November 2021; a status report expressing Petitioner's belief that there are PCP medical records supportive of her claim which had not yet been provided, and a response addressing the issues raised in my order. Exs. 15-16, filed Nov. 15, 2024, ECF No. 36; Status Report, filed Nov. 15, 2024, ECF No. 37; Petitioner's Response to Order to Show Cause ("Show Cause Response"), filed Dec. 8, 2024, ECF No. 38. In her response, Petitioner again insists there is a September 24, 2020 treatment record which Mr. Villanueva's PCP refuses to provide, even in response to a subpoena served on November 9, 2021, which is supportive of her claim. Show Cause Response at 2-4.

## II. Analysis Related to Situs

### A. Mr. Villanueva's Assertions

The vaccine record in this case states that Mr. Villaneuva received the flu vaccine on September 24, 2020, in his *left*, rather than *right*, deltoid (and thus is contrary to Petitioner's allegations). Ex. 1. Even though this record is the type of documentation that was likely created in a computer with a dropdown menu, it still warrants some evidentiary weight.

In the initial petition, Mr. Villanueva stated simply that he "was vaccinated in the *right* deltoid on or about September 24, 2020" (Petition at ¶ 1) and "experienced pain in his vaccinated shoulder" within 48 hours (*id.* at ¶ 2). In his sworn declaration, executed and filed approximately fifteen months later, on April 7, 2022, he provided further detail. Ex. 10. Mr. Villanueva stated that he received the flu vaccine when at his PCP's clinic for a physical examination, accompanied by his wife (who was also receiving a physical) and his daughter. *Id.* at ¶ 1. He explained that, while his wife and daughter were in the bathroom, the PCP's assistant

collected my urine and drew blood on my right arm and gave me an *injection* on my right upper arm. Then after that, [the PCP] came in to give me the flu shot on my left upper arm. During that time, I was the only one in the room as my daughter had to accompany my wife to the restroom to get [a] urine sample. When my wife and daughter came back, [the PCP] gave my wife the flu shot.

*Id.* at ¶ 2 (emphasis added).<sup>5</sup>

Mr. Villanueva maintained that he related these events to his wife and daughter the next day after experiencing fever and pain and swelling in his right upper arm, adding that his daughter informed the PCP of the mistake. Ex. 10 at ¶ 2. He also recounted a trip to the PCP's clinic on October 1, 2020, the purpose of which was to discover what exactly had occurred on September 24, 2020, including the identity of the assistant who drew his blood and administered the right arm flu shot. *Id.* at ¶¶ 5-6. Mr. Villanueva insisted that his failure to recognize the assistant in question was because she was wearing a mask and gown when she drew his blood and administered the flu vaccine. *Id.* at ¶ 6. Although he did not provide affidavits or sworn declarations from his wife, daughter, or granddaughter, attesting to these events, he did seek subpoena authority in November 2021, which revealed no additional medical records from his PCP.

In an amended petition filed on September 28, 2022, Mr. Villanueva again alleged that he received the flu vaccine in his right deltoid, even though the vaccine record reflects a left arm injection site. Amended Petition at ¶¶ 1, 1 n.1. Insisting the vaccine record is incorrect, Mr. Villanueva asserted that “[a]ll medical records in this case reflect an injury and treatment that were administered to [his] right arm.” *Id.* at ¶ 1 n.1.

#### *Information in the Contemporaneously Created Medical Records*

Evidence contained in the contemporaneously created medical records do not corroborate the witness statement contentions on situs. They instead portray Mr. Villanueva as possessing prior and current conditions which could easily account for his right shoulder pain. And both Mr. Villanueva and his daughter attributed his symptoms to his prior condition during initial PT and orthopedic appointments in October and November 2020. Furthermore, the contemporaneously-created medical records show Mr. Villanueva was previously diagnosed with dementia. Thus, his memory was unfortunately less reliable during this time, and his recollections are otherwise not adequately supported by additional evidence.

In August and September 2018 (approximately two years prior to vaccination), Mr. Villanueva (83 years old at the time) was treated for *right shoulder pain* as well as neck and back pain, and tingling in both hands. Ex. 5 at 11, 116-37. X-rays of his right shoulder taken on August 7, 2018, revealed “[o]steoarthritis of the acromioclavicular joint [and]

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<sup>5</sup> Although Petitioner alleges that he received a *flu* vaccine in his left arm on September 24, 2020, in his initial and amended petitions, Mr. Villanueva's sworn declaration states only that he received an “injection” after having his blood drawn from his right arm. Ex. 10 at ¶ 2. The omission of the specific type of injection Mr. Villanueva believes he received may be due to simple oversight, but it also may be an indication that he did not feel comfortable definitively stating that the injection was likely the flu vaccine.

[c]alcific tendinitis.” *Id.* at 123. The physician ordered pain medication, joint cream, a right shoulder MRI, an EMG, and physical therapy (“PT”). *Id.* at 114-22. The EMG revealed “decreased nerve conduction” of the right and left ulnar sensory nerves, but it does not appear that Mr. Villanueva attended PT or underwent the prescribed MRI. *Id.* at 132. Additionally, Mr. Villanueva’s right shoulder pain diagnosis was included in a list of diagnoses discussed during a February 12, 2019 appointment with his PCP when treated for dizziness and knee pain. Ex. 2 at 20.

On September 26, 2020 (two days post-vaccination), Mr. Villanueva visited an urgent care facility complaining of right shoulder swelling. Ex. 8. The earlier provided medical record<sup>6</sup> from this visit notes that he was accompanied by his daughter, an LPN.<sup>7</sup> Ex. 8. Observing swelling and painful range of motion (“ROM”), but no fracture on x-rays taken,<sup>8</sup> the urgent care physician prescribed cephalexin<sup>9</sup> and provided a referral for an MRI. *Id.* That MRI (performed on September 27, 2020) revealed multiple findings, including a “[l]ateral subacromion spur indenting the supraspinatus tendon and partial tears of the supraspinatus tendon and deltoid, biceps, and triceps muscles. Ex. 4 at 32.

On October 15, 2020, Mr. Villanueva began PT based on his PCP’s referral. Ex. 3 at 4; see Ex. 2 at 42 (PT referral). At the initial evaluation, it was noted that both Mr. Villanueva and his daughter (who accompanied him) attributed his right shoulder symptoms to a fall at least four years prior. Ex. 3 at 4. Mr. Villanueva reported that the fall had occurred ten years ago, while his daughter placed its occurrence “4-5 years ago.” *Id.* Mr. Villanueva continued to attend PT throughout October to early December 2020. See Ex. 3.

On November 4, 2020, Mr. Villanueva sought treatment for his right shoulder pain from an orthopedist. Ex. 6 at 16. At this visit, he reported that his pain had been present “for a long time,” but was recently increasing. *Id.* The orthopedist instructed Mr. Villanueva to use Tylenol and Voltaren gel to control his pain and to continue his PT as tolerated. *Id.*

On December 3, 2020, Mr. Villanueva (accompanied by his granddaughter) was seen by a neurologist for dementia, “characterized by short term memory loss, intact long

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<sup>6</sup> In early 2024, Petitioner obtained a more complete version of this medical record. See Ex. 15. The information contained in and reliability of the later version of this medical record is discussed below. See *infra* Section II.B.

<sup>7</sup> LPN stands for licensed practical nurse. MEDICAL ABBREVIATIONS at 347 (16<sup>th</sup> ed. 2020).

<sup>8</sup> This one-page medical record does not include the results of these x-rays.

<sup>9</sup> Cephalexin is “a semisynthetic first-generation cephalosporin, effective against a wide range of gram-positive and a limited range of gram-negative bacteria.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (“DORLAND’S”) at 330 (32<sup>th</sup> ed. 2012).

term memory, asking the same questions over and over, and increased irritability and agitation, especially towards his wife.” Ex. 4 at 13. Previously diagnosed by another physician, Mr. Villanueva had declined the recommended medication. At this visit, his granddaughter reported that Mr. Villanueva suffered from right shoulder pain since mistakenly being injected twice when receiving the flu vaccine in September 2020. *Id.* This entry is the first mention of the flu vaccine as a potential cause of Mr. Villanueva’s right shoulder symptoms.

When Mr. Villanueva was next seen by his orthopedist two days later, he elected to receive a steroid injection to help combat his right shoulder pain. Ex. 6 at 12. Before administering the injection, the orthopedist performed an arthrocentesis of the joint which revealed cloudy fluid. *Id.* at 12-13. This sample was sent for testing. *Id.* at 13.

When seen by an infectious disease specialist three days later, Mr. Villanueva was diagnosed with Methicillin-susceptible *Staphylococcus aureus* (“MSSA”), consistent with MSSA septic arthritis. Ex. 7 at 10. Accompanied by his granddaughter, who reported that Mr. Villanueva’s daughter was a nurse who could assist with any at home infusion, Mr. Villanueva was prescribed an extended course of IV cefazolin.<sup>10</sup> *Id.* At this visit, it was noted that Mr. Villanueva “initially attributed [his right shoulder pain] to the influenza vaccine which he received in the same arm.” *Id.* at 9.

In January 2021, Mr. Villanueva transitioned to oral antibiotics. Ex. 7 at 5. He continued to attend PT through July 2021. *E.g.*, Ex. 9 at 60-65 (PT discharge summary).

### **B. Evidence Offered Ater Ms. Mendoza’s Substitution as Petitioner**

After her substitution as Petitioner in this case, Respondent’s objection to compensation, and my discussion of the noted deficiencies, Ms. Mendoza expressed a desire to continue to this vaccine claim. To that end, she provided a more complete medical record from the urgent care appointment Mr. Villaneuva attended two days post-vaccination on September 26, 2020, a copy of the subpoena served on Mr. Villanueva’s PCP, and argument emphasizing her belief that Mr. Villanueva’s PCP possess medical records related to vaccination that he has not provided which would be supportive of Petitioner’s claim.

The medical record from Mr. Villanueva’s September 26, 2020 visit to urgent care that Petitioner provided in November 2024, shows it was obtained in April 2024. Ex. 15 at 1 (certification executed on March 5, 2024). And it contains a history which includes a

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<sup>10</sup> Cefazolin is “a first-generation cephalosporin, a semi-synthetic analogue of the natural antibiotic cephalosporin C, effective against a wide range of bacteria.” DORLAND’S at 311.

sudden onset from a flu shot administered two days earlier. *Id.* at 4. However, there is an unexplained asterisk beside the mention of a flu shot as follows:

Mechanism of injury includes PAIN FROM FLU SHOT\*

(*id.* at 4). In addition, multiple notations of “Change History” can be found in the different sections of the record (*id.* at 4-7). Although these notations may be innocuous, their meaning cannot be ascertained given the dearth of information related to the process by which this record was procured. Petitioner has failed to describe how this later version of the record was obtained, or attest to whether any information was added to the record on a *post hoc* basis, in an attempt to supplement or clarify the record.

Although this later-provided urgent care record provides some additional support - *if* determined to be an accurate, contemporaneously created recitation - of the information Petitioner provided in 2020, its probative value is still undercut by the fact that it is based upon information originating only from Mr. Villanueva. And the uncertainty created by Mr. Villanueva’s failure in October and November 2020 to mention the flu shot, instead suggesting his symptoms were due to a prior condition, still remains.

Petitioner insists that Mr. Villanueva’s PCP possesses additional documentation supportive of her claim, but the record does not support this assertion. According to even Mr. Villanueva’s account of the events in question, his PCP disputed his claim of the administration of two flu vaccines at the relevant time. Mr. Villanueva was asked to identify the assistant he believed had administered an earlier flu shot in his right arm and was unable to do so. The PCP has provided a vaccine record showing administration in Petitioner’s left arm and resisted attempts to alter or supplement that record.

Had Petitioner provided more readily-available evidence to substantiate Mr. Villanueva’s account of the events that occurred in late 2020 and as described in this Decision, I would be more likely to see the wisdom of further efforts to obtain additional information from Mr. Villanueva’s PCP. But given the overall record in this case (which includes other deficiencies related to prior and current conditions more likely to have caused Mr. Villanueva’s symptoms), it is unlikely that Petitioner will prevail either on the situs issue or remaining requirements for entitlement. Thus, I find such further efforts are not warranted.

I have no doubt that Mr. Villanueva truly *believed* that he received some type of injection (thought to be a flu vaccine) in his right deltoid after a blood draw by his PCP’s assistant, followed by a flu vaccine administered as stated in the vaccine record by his PCP. But considering the record as a whole, to include Mr. Villanueva’s diagnosed dementia, and the likelihood that he experienced only a blood draw or different injection,

Petitioner has failed to provide the preponderant evidence needed to support his recollection of these events. Even if Mr. Villanueva suffered some immediate right reaction aggravating his right shoulder condition, Petitioner has failed to preponderantly show this was due to a flu vaccine, mistakenly administered in his right arm, in addition to the one noted in his vaccine record that was administered in his left arm.

### **Conclusion**

The Vaccine Act prohibits me from finding a petitioner entitled to compensation based upon the petitioner's claims alone. Section 13(a). To date, and despite ample opportunity, Petitioner has failed to provide the evidence needed to establish that Mr. Villaneuva likely received a flu vaccine on September 24, 2020, in his *right* deltoid as alleged. Instead, the preponderant evidence supports a flu vaccine given only in his *left* deltoid. In addition, there appear to be other deficiencies likely fatal to this claim, and no other version of the claim would likely be tenable.

Petitioner was informed that failure to provide preponderant evidence to overcome the situs defect would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for this claim. Accordingly, this case is DISMISSED for insufficient evidence. The Clerk of Court shall enter judgment accordingly.<sup>11</sup>

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**

Brian H. Corcoran  
Chief Special Master

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<sup>11</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.