In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 22-1507V

Filed: July 2, 2025

ADRIAN WILLIAMS,	*
	*
Petitioner,	*
v.	*
	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*
	*

Harry E. Forst, Esq., Harry E. Forst, Attorney at Law, New Orleans, LA, for petitioner.
Alec Saxe, Esq., U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING AND DISMISSAL DECISION[1]

Roth, Special Master:

On October 12, 2022, Adrian Williams ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleges that she developed septic shock after receiving the tetanus-diphtheria-acellular pertussis ("Tdap") and influenza ("flu") vaccines on September 9, 2017. Petition, ECF No. 1.

The parties dispute whether petitioner satisfies the Vaccine Act's severity requirement—specifically, whether she experienced residual effects or complications of her alleged vaccine injury for more than six months. § 11(c)(1)(D)(i).

[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), 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.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, and after reviewing the medical records, testimony, and other evidence submitted, I find that petitioner has not established that she suffered any effects of the alleged vaccine-related injury for more than six months.

I. Procedural History

Petitioner filed her original petition on March 31, 2020, at which time she had a civil action pending against Rite Aid and the administering pharmacist for vaccine-related injuries. That petition was dismissed on July 20, 2022, for lack of jurisdiction. *Williams v. Sec'y of Health & Human Servs.*, No. 20-367V, 2022 WL 3369717 (Fed. Cl. Spec. Mstr. July 20, 2022). Petitioner then dismissed her civil action on August 11, 2022. ECF No. 1-2.

On October 12, 2022, petitioner started a new case by filing a petition accompanied by medical records. ECF Nos. 1, 3. The matter was assigned to the undersigned on January 25, 2023, following Pre-Assignment Review ("PAR"). ECF Nos. 12-13.

On July 10, 2023, respondent filed a Rule 4(c) Report, arguing that petitioner had not met the Vaccine Act's six-month severity requirement. ECF No. 21. Petitioner was subsequently ordered to submit corroborating evidence in support of the six-month severity requirement, which she filed on September 20, 2023. ECF Nos. 22, 25.

In a January 22, 2024 status report, after review of the additional evidence filed, respondent submitted that he was not satisfied the requirement was met. ECF No. 29. Petitioner was ordered to either file additional supporting evidence or confirm the record was complete on the issue of severity. ECF No. 30. On February 5, 2024, petitioner filed a status report indicating that no further evidence would be submitted. ECF No. 31.

On March 21, 2024, petitioner moved for a ruling on the record. Motion, ECF No. 33. Respondent responded on April 22, 2024, maintaining his position that petitioner failed to demonstrate residual effects or complications from her alleged vaccine injury lasting more than six months. Response, ECF No. 34. Petitioner replied on April 25, 2024, stating simply that she relied on the evidence previously submitted. Reply, ECF No. 35.

The matter is now ripe for ruling.

II. Legal Framework

A. Overall Fact-Finding Framework

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioner after-the-fact. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948).

B. Severity Requirement

The only question here is whether petitioner satisfied the severity requirement. The Vaccine Act requires petitioner show by preponderant evidence that she "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." § 11(c)(1)(D)(i); *see Song v. Sec'y of Dep't of Health & Human Servs.*, 31 Fed. Cl. 61, 65-66 (1994), aff'd, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Finding that petitioner has met the severity requirement cannot be based on petitioner's word alone, though a special master need not base their finding on medical records. *See* § 13(a)(1); *see Colon*, 156 Fed. Cl. 541.

There are several cases addressing the sufficiency of evidence provided to satisfy the six-month severity requirement. For example, in *Kirby*, the special master's finding that Ms. Kirby's injury lasted for more than six months was upheld by the Circuit. *Kirby*, 997 F.3d at 1378. The special master determined that the petitioner satisfied the severity requirement based on her testimony, corroborating documentation, and expert testimony, despite medical records documenting that the petitioner reported "feeling fine". *Id*. at 1381. The Circuit distinguished the petitioner's case from *Cucuras* "where the petitioners said one thing to their physician and another thing to the special master." *Id*. at 1383 (citing 993 F.2d at 1527-28). The Circuit held that a reasonable fact finder could find that petitioner's testimony of ongoing pain did not conflict with the records, as the records were also silent about the "nonexistence" of such symptoms, meaning that the records did not specifically document the absence of certain symptoms. *Kirby*, 997 F.3d at 1383. The petitioner's testimony that her symptoms persisted for over a year was supported by medical records showing discharge from in-person physical therapy with instruction to continue with home exercises in addition to the home exercise instruction sheets that she produced at trial. *Id*. at 1380-81.

Special masters have found that continuing a course of medication that is actively treating a condition for over six months can meet the severity requirement; however, taking medication prophylactically to evade recurrence cannot. *Prepejchal v. Sec'y of Health & Human Servs*., No. 15-1302V, 2018 WL 5782865 at *16 (Fed. Cl. Spec. Mstr. Oct. 5, 2018); *Watts v. Sec'y of Health & Human Servs*., No. 17-1494V, 2019 WL 4741748 at *7 (Fed. Cl. Aug. 13, 2019). There is a distinction between taking medication without evidence of symptoms versus taking medication to prevent symptoms and/or relapse, the latter of which can meet the severity requirement. *See also Faup v. Sec'y of Health & Human Servs*., No. 12-87V, 2015 WL 443802 at *4 (finding that the ongoing need for medication to prevent symptoms and/or relapse of the alleged vaccine-caused illness constitutes a residual effect or complication of that illness). However, the severity requirement may not be met merely by speculation that if a petitioner was not taking a medication, they would experience further symptoms related to the vaccine injury. *Toebe v. Sec'y of Health & Human Servs.*, No. 91-1623V, 1992 WL 101638 at *3 (Fed. Cl. Spec. Mstr. Apr. 23, 1992).

The Federal Circuit addressed the six-month severity requirement in *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999 (Fed. Cir. 2022). The Circuit held that petitioner failed to satisfy the six-month requirement when her child's platelet count normalized less than three months post-ITP onset because "relatively non-invasive ongoing [platelet] monitoring" was not a "residual effect" pursuant to § 11(c)(1)(D)(i). *Id.* at 1001, 1003, 1006–07. The Circuit noted that the child experienced later bruising that was not related to his vaccine injury and that his ongoing testing "did not reveal, constitute, or cause any somatic change". *Id.* at 1001. Defining the language in § 11(c)(1)(D)(i), the Federal Circuit determined that "[t]he term 'residual effects[]' . . . requires a change within the patient that is caused by the vaccine injury." *Id.* at 1004. It continued that "'[r]esidual' suggests something remaining or left behind from a vaccine injury . . . . Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, . . . their residues are similarly defined." *Id.* at 1005–06. The Federal Circuit stated that the use of the words "suffered" and "complication" in association with "residual effects" in § 11(c)(1)(D)(i) "suggest[s] that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." *Id.* at 1006. It concluded that "[r]ead together, 'residual effects' and 'complications' appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease' or may be outside the ordinary progression of the vaccine injury." *Id.*

The Federal Circuit in *Wright* noted that "it is sufficient that the vaccine injury be both a but-for cause of the residual effect and a substantial factor in bringing about the residual effect, even if it is not the predominant factor." 22 F.4th at 1005 (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). However, "even if legally caused by his thrombocytopenic purpura, [the child's] testing was not a 'residual effect'". 22 F.4th at 1005. This is because the "[t]he tests revealed [that the child] had no lingering symptoms or recurrence of thrombocytopenic purpura[;]" and because "there [was] no showing or argument that [the testing] was detrimental to [the child's] health such that it might qualify under § 300aa–11(c)(1)(D)(i) as a 'residual effect' or a 'complication' of thrombocytopenic purpura." *Id.* at 1006. The Federal Circuit concluded that the ongoing monitoring was "neither an 'ongoing disability' nor indicative

that he 'suffered' or was 'seriously injured' within Congress's intended meaning of the severity requirement." *Id.* at 1007 (internal citations omitted).

The Federal Circuit further clarified that its decision in *Wright* "do[es] not disturb existing case law holding that a course of treatment lasting longer than six months can be a 'residual effect.'" 22 F.4th 1007. The Circuit cited to *H.S. v. Sec'y of Health & Human Servs.*, No. 14-1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015), in which the special master determined that restrictions on physical activity, including restrictions from participating in gym class, recess, and sports, following a concussion constituted a "residual effect" because the restriction was medically necessary to prevent aggravation of the injury. *Id.*; *H.S.*, No. 14-1057V, 2015 WL 1588366, at *3. The Circuit also cited to *Faup*, wherein the special master held that the petitioner fulfilled the six-month requirement because her child needed medication for her arthritis for more than six months. *Wright*, 22 F.4th at 1007; *Faup*, 12-87V, 2015 WL 443802, at *4. The Federal Circuit noted that "[d]uring a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary." *Wright*, 22 F.4th at 1007. The Circuit also clarified that *Wright* "do[es] not decide [ ] whether a course of testing or monitoring that is part of the management or treatment of a condition, necessary even in the absence of possible symptoms, could be a 'residual effect'" as monitoring may be considered an ongoing part of treatment if "the patient's somatic condition increases the risk of recurrence." *Id.*

In sum, special masters may consider the whole record in evaluating whether there is preponderant evidence for the severity requirement and may find the severity requirement satisfied even if a petitioner's medical records for the alleged injury are not continuous for the six months following the injury. *See Kirby*, 997 F.3d 1378. However, there must be evidence beyond petitioner's word alone, such as other corroborating records or reports, to establish the severity requirement by a preponderance of evidence. *See Colon*, 156 Fed. Cl. 534.

III. The Factual Record

A. Medical History

1. Pre-Vaccination Medical History

Petitioner's medical history includes hypertension, cardiac arrest, sepsis, left knee pain, chronic right-sided weakness, vertigo, and a severe latex allergy. *See generally* Pet. Ex. 3; Pet. Ex. 4. She became septic after gall bladder surgery in 2011 and coded with cardiopulmonary arrest. She was hospitalized for an extended period and suffered complications with residual neck pain and right arm and hand weakness. Pet. Ex. 3 at 30, 192, 240. She was later diagnosed with chronic right hand pain, brachial neuritis, right radial nerve palsy, right wrist drop, and cervical spondylosis for which she received extensive therapies. *See generally* Pet. Ex. 3 at 6-916.

2. Post-Vaccination Medical History

Petitioner received the subject vaccinations on September 9, 2017. Two days later, on September 11, 2017, she presented to the emergency room with complaints of two days of fatigue,

and three days of weakness and nausea which began after receiving flu, pneumonia and tetanus immunizations. She felt weak all over. She denied pain and fever. Pet. Ex. 3 at 924. A history and physical conducted by Dr. Chen noted that two days ago, petitioner began experiencing increasing left arm soreness originating at the site of her vaccinations that was worse with exertion. She then became weak, fatigued, with nausea and started vomiting. He also noted a history of chronic neck and right arm pain described as numbness and weakness since a hospitalization in 2011. Pet. Ex. 3 at 932-38, 981-85. On examination, petitioner was afebrile but tachycardic. There was mild erythema and a four-centimeter area of induration[3] on the left deltoid that was warm to the touch. She was started on IV antibiotics for a presumed infection. *Id*. at 933, 935, 937-38.

Petitioner's treaters considered multiple potential sources of infection, including left arm cellulitis, gastrointestinal infection, and a tubo-ovarian abscess. Pet. Ex. 3 at 921, 932, 937-38, 954, 976. At intake, Dr. Najul-Seda noted possible cellulitis due to flu shot. *Id.* at 921. Dr. Chen documented "septic shock", with the immunization site on petitioner's left deltoid as a possible source of cellulitis. *Id.* at 937. A CT of the abdomen did not show a clear bowel source of infection but showed diverticulosis. It also showed a mass potentially consistent with a tubo-ovarian abscess, but an ultrasound determined this was an ovarian cyst. *Id*. at 941, 971-73, 976

Petitioner improved and was discharged on September 20, 2017. The primary diagnosis was septic shock, source unknown, that improved with IV Zosyn and vancomycin. Pet. Ex. 3 at 938-945, 1020-22. Oral medications to be started at discharge included Keflex, Lasix, Cozaar, Imodium, and magnesium oxide. *Id.* at 943-45.

There are no medical records for further treatment of sepsis or cellulitis following petitioner's discharge. There are no medical records of any further complaints associated with her left arm. Petitioner returned to her neurologist and resumed occupational therapy for her long-standing right arm injury. Pet. Ex. 3 at 2425-2504. In medical visits subsequent to her hospitalization, she denied any new complaints. *Id.* at 2385, 2502, 2522.

B. Testimony and Statements

1. Petitioner's Affidavit

Petitioner submitted an affidavit dated March 19, 2020. Pet. Ex. 5 at 1. She affirmed receipt of Tdap and flu vaccinations at a Rite Aid Pharmacy in Louisiana on September 9, 2017. She developed soreness in her arm shortly after that was worse with exertion. Over the next few days, she experienced fatigue, nausea, and vomiting. *Id*. She presented to Ochsner Medical Center on September 11, 2017, was diagnosed with sepsis, and was hospitalized for ten days. *Id.* Petitioner affirmed that she suffered complications from that hospitalization for more than six months. *Id.*

2. Petitioner's Deposition Testimony

Petitioner was deposed on October 30, 2019, in her civil lawsuit against Rite Aid and the pharmacist. Pet. Ex. 8. She testified to having chronic pain, vertigo, and right-sided nerve damage

[3] Induration refers to an abnormally hard spot or place. *Induration*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 921 (33rd ed. 2019) [hereinafter DORLAND'S].

since 2011 following a gallbladder surgery and resulting sepsis. Pet. Ex. 8 at 16-17, 20, 39. She had been receiving disability benefits since 2014. *Id*. at 18. In 2015, she suffered a knee injury from a slip-and-fall incident and had an ongoing lawsuit associated with that fall. *Id.* at 26-28.

Petitioner testified that on the day of the subject vaccination, she only presented for the flu and pneumonia vaccines but was offered a tetanus shot due to her recent exposure to a rusty nail. Pet. Ex. 8 at 40-41. She stated that she received the Tdap and flu vaccines in her right arm and the pneumococcal vaccine in her left arm. *Id.* at 42. The medical records document the Tdap vaccine given in the right arm, and the flu and pneumococcal vaccines in the left. Pet. Ex. 6 at 3.

Petitioner stated that she developed soreness within hours of the vaccinations. She rested, but her symptoms worsened the next day, and neighbors drove her to the hospital. Pet. Ex. 8 at 70-73. She reported arm pain, fever, and vomiting at the hospital. *Id.* at 75-76. She stated that she was admitted to the ICU and diagnosed with cellulitis of the left arm. *Id.* at 76-78. IV antibiotics were administered, her condition improved, and she was discharged home ten days later. *Id.* at 78, 81-82.

Petitioner stated that after discharge from the hospital, she had left arm soreness for about a week and persistent left arm cramping about three to four times per week that lasted between five and twenty minutes. Pet. Ex. 8 at 83-85, 87. She stated that she never reported left arm cramping to any provider, but claimed an unnamed physician recommended she take over-the-counter magnesium supplements for the cramping, which she currently takes. Pet. Ex. at 85-88; Pet. Ex. 10.

Petitioner had preexisting right hand weakness that is unrelated to her alleged vaccine injuries. As a result, she has difficulties with lifting, with hygiene, and driving and requires assistance with some tasks. Pet. Ex. 8 at 89-91. She confirmed that all treatment for her alleged vaccine-related injury occurred during her initial hospitalization. *Id.* at 92-93.

C. Other Evidence

a. Report of Jerrold S. Dreyer, M.D., F.A.C.P., F.I.D.S.A.

Petitioner filed an expert report[4] from Dr. Jerrold S. Dreyer, an infectious disease specialist, that described the events following petitioner's receipt of the vaccines on September 9, 2017. Pet. Ex. 7.

Dr. Dreyer wrote that petitioner presented to the ER two days after her vaccinations with nausea, vomiting, hypotension, and left arm pain at the injection site. Pet. Ex. 7 at 2. Her heart rate was 120-130 beats per minute, her white blood cell count was 18,000, her BUN/creatinine level was 26/4.0, her procalcitonin level was 35.6, and her lactic acid level was 5.0. Dr. Dreyer opined that her procalcitonin level was indicative of infection, and her lactic acid level was consistent

[4] Dr. Dreyer did not reference any medical records or literature in support of his opinions. He relied on petitioner's deposition testimony in her civil action as the basis for his opinion that she suffered left arm cramping in excess of six months. Pet. Ex. 7 at 2

with septic shock. *Id.* There was a 4-centimeter area of induration on her left deltoid, and she was diagnosed with left upper extremity cellulitis. *Id*.

Dr. Dreyer opined that petitioner was hospitalized for ten days due to septic shock caused by the vaccinations she received. Pet. Ex. 7 at 2. He further opined that petitioner suffers from post-sepsis syndrome ("PSS"), which affects up to 50% of sepsis survivors and can include long-term effects such as disabling muscle and joint pain. *Id.* He opined that petitioner's reported cramping was more likely a residual effect or complication of her PSS than a direct result of the vaccine itself, stating: "[i]t is not likely that [she] would have developed cramping but for the sepsis secondary to the vaccine injury." *Id.*

b. Medical Literature

Petitioner filed three pieces of literature in support of her claim. Pet. Ex. 19; Pet. Ex. 20; Pet. Ex. 24.

The first article is titled "Post-Sepsis Syndrome" and is from the Sepsis Alliance website. Pet. Ex. 19. It defines PSS as a condition affecting up to 50% of sepsis survivors that is associated with both physical and psychological symptoms, including but not limited to fatigue, muscle and joint pain, swelling of the limbs, difficulty sleeping, depression, loss of self-esteem, memory loss, and post-traumatic stress disorder. *Id.* at 1-2. The article does not include cramping as a symptom of PSS, nor does it identify magnesium as a treatment. Pet. Ex. 19. There is no discussion of symptoms limited to a single limb. *Id.*

The second article is from the UK Sepsis Trust, addresses PSS, and states that around 40% of sepsis survivors report physical, cognitive, or psychological after-effects. Pet. Ex. 20 at 2. Symptoms include lethargy, muscle weakness, joint and muscle pain, insomnia, shortness of breath, hair loss, changes in sensation in limbs, anxiety and depression, and memory impairment. *Id.* at 3. Like the first article, muscle cramping is not included as a symptom.

Petitioner also filed an article from the *Journal of Musculoskeletal and Neuronal Interactions* that discusses magnesium in the treatment of muscle cramps. Pet. Ex. 24 at 1. The article describes muscle cramps as sudden, painful, and sustained contractions of the skeletal muscle fibers that may be idiopathic or disease-related and can stem from neurologic, renal, or metabolic conditions. *Id*. The intervention studied was oral, intramuscular, and IV supplementation "with magnesium salts at any dose." *Id*. at 2. Magnesium was described as one of the minerals required by the body for nerve transmission and muscle contraction. *Id.* at 1. The authors found insufficient evidence to support the use of magnesium for treating idiopathic muscle cramps. *Id.* at 3. Petitioner highlighted portions of the article that align with her claim; however, the authors concluded that magnesium supplementation "probably makes little to no difference" in reducing the frequency or severity of muscle cramps, particularly in older adults. *Id.* at 4.

IV. Discussion

There is no dispute that petitioner received three vaccinations on September 9, 2017: Tdap in her right arm, and flu and pneumococcal vaccines in her left arm. Pet. Ex. 6. There is no dispute

that she was hospitalized from September 11 to September 20, 2017, and diagnosed with sepsis as well as left arm cellulitis. Pet. Ex. 3 at 917-2370. The cause of the sepsis, however, was noted to be unclear. *Id*. at 976, 990, 994.

Petitioner testified that, following her discharge from the hospital on September 20, 2017, the only ongoing symptoms she experienced were left arm soreness which resolved within a week of her discharge and left arm cramping. Pet. Ex. 8 at 83-84. She claimed that the left arm cramping continued to occur three to four times per week, lasting five to twenty minutes each time, and is worse with cold weather. *Id.* at 85-88. She stated that a doctor at Ochsner told her before she left the hospital to take an over-the-counter magnesium supplement for the cramping, but she could not remember which doctor. *Id*. at 86. She continues to take the magnesium supplement. She did not believe she would see any physician again for her injuries because the magnesium "works." *Id*. at 83, 86-88.

A. The Parties' Arguments

1. Petitioner's Submissions

Petitioner filed a motion for ruling on the six-months severity requirement, stating that the issue was thoroughly briefed in a previous submission and was also addressed in petitioner's original case. However, that case was dismissed for lack of jurisdiction and closed. Motion, ECF No. 33; ECF No. 25; *Williams v. Sec'y of Health & Human Servs*., No. 20-367V, 2022 WL 3369717 (Fed. Cl. Spec. Mstr. July 20, 2022).[5]

Petitioner then referenced her September 20, 2023 filing, which was submitted in response to the Court's order directing petitioner to file corroborating evidence in support of the six-month severity requirement. ECF Nos. 22, 25. In that submission, she argued that the medical records, her sworn testimony, and the expert opinion of Dr. Jerrold Dreyer demonstrate that she meets the severity requirement because she continues to suffer the residual effects of her vaccine injury which caused her ten-day hospitalization for septic shock. ECF No. 25 at 1.

Petitioner submitted that Dr. Dreyer opined that she suffers from PSS, a condition that can include long-term physical effects like disabling joint and muscle pain. ECF No. 25 at 2; Pet. Ex. 7. According to Dr. Dreyer, petitioner's ongoing left arm cramping is a residual effect or complication of sepsis that she would not have developed but for the vaccine-induced sepsis hospitalization. *Id*.

Petitioner pointed to the literature on PSS filed in support of her argument and explained that her symptoms for which she continues to take magnesium align with those described in the literature. ECF No. 25 at 3; Pet. Ex. 19; Pet. Ex. 20. Petitioner emphasized that Dr. Dreyer noted her cramping, that magnesium was initiated during her hospitalization and was continued post-discharge. She argued that the literature and the "open-ended" prescription for magnesium satisfies

[5] Petitioner's previous dismissed case is not part of the record in the instant matter, and any materials filed as part of that docket will not be reviewed herein.

the six-month requirement, even though evidence supporting the efficacy of magnesium for cramping is limited. ECF No. 25 at 3, 5-6; Pet. Ex. 24.

Petitioner argued that she was not taking magnesium upon admission to the hospital but was prescribed it during her stay. Her magnesium blood levels were monitored, and she was prescribed magnesium oxide upon discharge. ECF No. 25 at 4; Pet. Ex. 11; Pet. Ex. 21; Pet. Ex. 22. Petitioner cited to medical records to support her claim that she was instructed to take 400 mg once daily and that the recommendation was indefinite. ECF No. 25 at 4; Pet. Ex. 12; Pet. Ex. 21; Pet. Ex. 22; Pet. Ex. 23 at 1, 3, 5-6, 8.

Petitioner conceded that one record notes the magnesium prescription was to be taken for ten days but asserted that other records contradict that entry because they do not contain a stop date. She conceded that the discharge summary listed the medication as "new," with "no refills," but argued this did not explicitly instruct her to stop. ECF No. 25 at 6-7; Pet. Ex. 12; Pet. Ex. 23. She added that a later pharmacy record included instructions for refill and pickup with no end date. *Id.* Petitioner argued that the record is supportive of the understanding that magnesium was to be taken as needed, which she continues to do. ECF No. 25 at 7.

Petitioner argued that she is not required to prove causation with certainty, she "only has to prove more likely than not her injury and residuals came from the vaccine." ECF No. 25 at 8. She noted that based on the medical records, the treating physician considered left arm cellulitis, tubo-ovarian abscess, and GI infection as the likely causes of her sepsis but ultimately concluded that cellulitis was likely the cause after ruling out the others. *Id.* at 9.

Finally, petitioner referenced the Centers for Disease Control and Prevention ("CDC") definition of cellulitis as a common bacterial skin infection that can result in redness, swelling, and pain, arguing that the most probable source of her cellulitis was the injection site of a vaccine. Dr. Dreyer agreed that the vaccines caused sepsis and PSS requiring continued magnesium use. ECF No. 25 at 9.

2. Respondent's Submissions

Respondent maintained the position set forth in his Rule 4(c) Report and January 22, 2024 status report that petitioner has not provided preponderant evidence of residual effects or complications lasting more than six months. Response at 1, ECF No. 34. Accordingly, respondent argued that the petition should be dismissed for failure to meet the severity requirement, relying on the record as it stands because petitioner's motion did not present new arguments or evidence. *Id.*

In his Rule 4(c) Report, respondent summarized petitioner's report of the flu, Tdap, and pneumococcal vaccines on September 9, 2017, and her ER visit two days later for left arm pain, weakness, and nausea. Respondent's Report ("Resp. Report") at 2, ECF No. 21. She was diagnosed with septic shock and acute renal failure, and she had a four-centimeter area of induration on examination. *Id.* The possible sources of infection considered included left arm cellulitis, GI infection, or a tubo-ovarian abscess. Petitioner's condition improved with treatment, and she was

discharged on September 20, 2017. At the time of discharge, the source of her sepsis was uncertain. *Id*.; Pet. Ex. 3 at 992, 1020.

Respondent added that the only treatment petitioner sought post-discharge was for her preexisting and ongoing right arm brachial plexus injury. There was no mention of sequelae from her hospitalization, her sepsis, or further discussion of her allegedly causal vaccinations contained in those treatment records. Resp. Report at 3.

Respondent argued that, under the Vaccine Act, petitioner bears the burden of proving by preponderant evidence that she suffered residual effects or complications of her alleged vaccine injury for more than six months, or that her injury resulted in inpatient hospitalization and surgical intervention. Resp. Report at 3. Because petitioner did not undergo surgery during her hospitalization, she must show ongoing residual effects or complications of her allegedly injury through at least March 11, 2018. Respondent asserted that no such evidence exists, and petitioner's medical records are "devoid of any complaints or treatment related to her sepsis diagnosis following her nine-day hospitalization." *Id*. at 4. Further, petitioner relied on a report from Dr. Dreyer, who diagnosed petitioner with PSS based on her deposition testimony, or her own word, rather than the medical records, and a finding may not be made based upon the claims of petitioner alone. *Id*.

In his January 22, 2024 status report, respondent stated that the "newly filed evidence," including articles and medical records, were duplicative of prior submissions and similarly lacked preponderant support for any residual effects lasting more than six months. Resp. Status Report at 1-2, ECF No. 29.

Respondent disagreed with petitioner's argument that the magnesium prescription she received at discharge was "open-ended" and asserted that the records also do not contain evidence that she continued to take the medication for six months after her hospitalization. Resp. Status Report at 4. He cited to the medical and pharmacy records to demonstrate that magnesium was prescribed at a dosage of 400 mg once daily, with a defined 10-day course beginning September 20, 2017, and no refills. *Id*.; *see* Pet. Ex. 21; Pet. Ex. 22; Pet. Ex. 23 at 4-7. This limited duration and the fact that no refills were prescribed contradict petitioner's claim of long-term use for residual effects. Resp. Status Report at 4-5. Further, a progress note from an October 11, 2017 neurology visit does not list magnesium oxide among petitioner's active medications. *Id*. at 5; Pet. Ex. 3 at 2382-83, 2388-89.

Respondent disagreed that the literature petitioner filed supported her case. Resp. Status Report at 6. He submitted that while the articles reference disabling muscle and joint pain as a long-term effect of PSS, she has not submitted any medical records to corroborate that she has PSS or the long-term effects thereof. *Id*. He further noted that the article petitioner filed on magnesium for muscle cramps concluded that the effectiveness of magnesium supplementation remains unclear, and petitioner conceded that it did not include muscle cramps as a result of a systemic disease like sepsis. *Id*. Even if the literature supported a connection between magnesium and post-sepsis cramping, it would still be insufficient to meet the statutory burden without corroborating medical documentation that petitioner suffered from muscle cramps related to her alleged vaccine-

related injury for more than six months and treated those with magnesium supplementation for more than six months following her alleged injury. *Id*.

B. Weighing Petitioner's Evidence

Following review of the evidence and arguments, I find that petitioner has not established by a preponderance of the evidence that she suffered a vaccine-related injury that satisfies the six-month severity requirement. Petitioner claims that she suffered from ongoing left arm cramping from vaccine-induced sepsis. However, there is nothing in the record to corroborate prolonged or recurring symptoms consistent with that assertion or that petitioner was prescribed magnesium to treat left arm cramping.

1. Relevant Medical Records

Petitioner argues that the magnesium prescribed in the hospital and at discharge to treat her left arm cramping. However, the medical record indicates she was prescribed magnesium oxide—a formulation generally used as a short-term laxative or to manage magnesium deficiency, not muscular symptoms.[6] Pet. Ex. 3 at 938-44, 2369. During her hospitalization, metabolic panels performed daily showed that petitioner's magnesium levels were abnormally low, and IV magnesium oxide was ordered and administered over the course of her inpatient care. *Id*. at 1043, 1071, 1155. A metabolic panel performed on the day of discharge showed her magnesium levels to be "abnormal" and low. She was prescribed oral magnesium oxide for ten days. *Id*. at 1073, 1088; Pet. Ex. 13 at 1. The discharge summary did not reference cramping or that the magnesium oxide was prescribed for muscle-related issues. *Id.* at 938-44, 2367. Further, the discharge summary lists all the medications to be started, those to be continued that have changed, those to be continued that have not change, and those to stop, with each entry noting the dosage and whether refills were ordered. *Id*. at 943-45. Magnesium oxide 400 mg tablets were to be taken once daily. Refills were noted as "0". *Id*. at 944.

There are no medical records filed following petitioner's discharge from the hospital that mention a diagnosis, treatment or complaints of PSS, left-arm cramping, or any related conditions. Petitioner resumed care only for her chronic right-sided neuritis and wrist-drop, which predated the vaccinations. Pet. Ex. 3 at 2425-2504. Petitioner attended multiple neurology and occupational therapy visits between October 2017 and May 2018, and did not report any left arm complaints. *See* Pet. Ex. 3 at 2374, 2385, 2425-27, 2450-55, 2502, 2522. While her discharge record reflects that magnesium oxide was prescribed for ten days, magnesium oxide or magnesium in any form was not listed on her medications in her medical records subsequent to her discharge from the hospital. *See id.* at 2382-84, 2389, 2397-99, 2403-04, 2411-12, 2415-16, 2419-20, 2428-29, 2434-36, 2443, 2448, 2460, 2487, 2493.

Petitioner filed a photo of the magnesium supplement bottle she alleges to take to treat her left arm cramping. It is not a prescription bottle, and only reflects "Magnesium" not "Magnesium Oxide" as prescribed. Pet. Ex. 10. As the medical records reflect, petitioner was administered magnesium oxide by IV for low magnesium levels during her hospitalization and prescribed oral

[6] Magnesium oxide is used "as an oral antacid and laxative, and as a preventative for hypomagnesemia." *Magnesium oxide*, DORLAND'S 1080.

magnesium oxide for ten days at discharge due to continued low levels of magnesium shown on discharge lab work. The record does not include any reference to magnesium oxide being prescribed to treat left arm cramping or that she was diagnosed with or suffered from PSS.

2. Petitioner's Testimony

Petitioner stated that she has experienced cramping in her left arm three to four times a week for five to 20 minutes at a time since her hospitalization, managed with over-the-counter magnesium which she claims "works". Pet. Ex. 8 at 83-88. Petitioner did not report or seek any medical treatment for left arm cramping after her discharge from the hospital. She could not identify the physician who she claimed recommended she take magnesium for left arm cramping. She offered no corroborating documentation to show that she was directed to take the magnesium supplement beyond the 10 days prescribed, or that her continued use of magnesium is medically required and/or supervised. She did not mention taking magnesium or having continued left arm cramping at any medical visits subsequent to her hospitalization. Petitioner's word alone is insufficient to satisfy her burden in proving that her symptoms lasted for more than six months. § 13(a)(1).

3. Dr. Dreyer's Opinion

Petitioner's expert, Dr. Dreyer, opines that she suffers from PSS with muscle cramping as a residual effect of vaccine-induced septic shock. Pet. Ex. 7 at 2. However, expert opinions are usually more persuasive when they rest on more than the expert's own assertions. *Prokopeas v. Sec'y of Health & Human Servs.*, No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019). Further, conclusory expert statements lacking reliable support are routinely rejected. *See Kreizenbeck v. Sec'y of Health & Human Servs*., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), *review denied, decision aff'd*, 141 Fed. Cl. 138 (2018), *aff'd*, 945 F.3d 1362 (Fed. Cir. 2020); see also *Burns*, 3 F.3d at 417 (holding that special master properly rejected the petitioner's medical expert testimony where the expert based his opinion on facts not substantiated by the record).

Dr. Dreyer's opinion lacks support from any medical documentation. Although Dr. Dreyer stated that petitioner suffers from PSS, which includes "long term physical effects like disabling muscle pain and joint pain," he offered no basis for how he diagnosed her with PSS or any literature that supports his assertion that muscle and joint pain are symptoms associated with PSS. Pet. Ex. 7 at 2. This is particularly problematic because none of petitioner's treating physicians diagnosed her with or even mentioned PSS or left arm cramping. Dr. Dreyer's report does not cite to any medical record in support of his opinions and appears to rely on petitioner's uncorroborated statements given at deposition in her civil case. The weight of his opinion is therefore significantly diminished.

4. Medical Literature

Petitioner submitted three articles discussing PSS and the related complications, as well as the role of magnesium in treating muscle cramping. Pet. Ex. 19; Pet. Ex. 20; Pet. Ex. 24. None of the literature establishes a causal relationship between vaccination and long-term cramping, nor

does it support the persistence of PSS symptoms beyond six months in the absence of clinical confirmation. Pet. Ex. 19; Pet. Ex. 20. Further, the authors of the article on magnesium concluded that magnesium supplementation "probably makes little to no difference" in reducing the frequency or severity of muscle cramps, particularly in older adults. Pet. Ex. 24 at 4. As such, the medical literature does not support petitioner's claim.

C. Analysis

Petitioner's claim rests on her personal account, unsupported by medical records. Her deposition testimony includes various beliefs associated with the vaccinations she received including that the vaccines caused sepsis, the injections were mishandled by the pharmacist, and that she should not have been given another pneumonia vaccine. Pet. Ex. 5 at 1; Pet Ex. 8 at 44-67, 95-100. None of her treating physicians persuasively linked her illness to the vaccines. There is no evidence to substantiate that magnesium was prescribed for left arm cramping or that it was to be continued beyond the prescribed ten-day window after discharge. Even if it was accepted that her left arm cellulitis was vaccine-related, it resolved with IV antibiotics and a ten-day course of oral medications following her discharge from the hospital with no further treatment required and no mention of any sequela in the medical records thereafter.

Moreover, petitioner's claim that magnesium was prescribed for cramping lacks clinical support. The specific formulation, magnesium oxide, is not standard for muscle cramps and is more commonly used as a laxative, antacid or for magnesium deficiency.[7] *See* Pet. Ex. 3 at 943-45. In fact, the medical records corroborate that petitioner was prescribed magnesium by IV due to low levels of magnesium, not cramping, during her hospitalization. Pet. Ex. 3 at 1043, 1071, 1073, 1155. A metabolic panel performed on the date of discharge showed that her magnesium levels were still low, and she was prescribed ten days of oral magnesium oxide. *Id*. at 1073, 1088; Pet. Ex. 13 at 1.

The Vaccine Act requires reliable, corroborative evidence of an injury lasting in excess of six months, and the word of petitioner alone is insufficient to satisfy her burden in proving that her symptoms lasted for more than six months. § 13(a)(1). Neither the medical records, expert report, or medical literature filed by petitioner provide any corroborating evidence that she continued to suffer any injury resulting from her vaccinations, that she was prescribed magnesium oxide for left arm cramping resulting from her vaccine injury, that the prescription for magnesium oxide was indefinite and to exceed the ten days following her discharge from the hospital on September 20, 2017, that she actually took magnesium oxide for longer than ten days, or that she continued to suffer any sequela from her vaccinations. Accordingly, petitioner has failed to satisfy the six-month severity requirement.

V. Conclusion

Upon careful review of the record and after assigning all evidence its appropriate weight, petitioner has failed to satisfy the severity requirement by preponderant evidence. Therefore, petitioner may not receive compensation under the Vaccine Act. The Clerk of Court shall enter judgment accordingly.

[7] *Supra* n.6.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master