# In the United States Court of Federal Claims

No. 17-1255 Filed: November 25, 2020 Reissued: February 26, 2021<sup>1</sup>

BREANA PORCELLO,	) )
Petitioner,	Vaccine Case; Motion for Review; Influenza Vaccine; Althen; Motion for Summary Judgment; Dismissal; Arbitrary and Capricious Standard; Ruling on the Record
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	) ) _)

#### **OPINION**

Michael G. McLaren, Black McLaren, et al., Memphis, TN, for petitioner.

Ryan Daniel Pyles, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

## **SMITH, Senior Judge:**

Petitioner, Breana Porcello, seeks review of a decision issued by Chief Special Master Brian H. Corcoran denying her petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on November 22, 2016. The Chief Special Master dismissed the petition for insufficient proof, finding that petitioner failed to offer preponderant evidence sufficient to satisfy all three of the *Althen* prongs. *Porcello v. Sec'y of Health & Human Servs.*, No. 17-1255, 2020 WL 4725507 (Fed. Cl. Spec. Mstr. June 22, 2020) ("*Porcello*"). Petitioner now moves for review of that decision. For the reasons that follow, the Court **DENIES** her motion.

## I. BACKGROUND

An unredacted version of this opinion was issued under seal on November 25, 2020. The parties were given an opportunity to propose redactions, but no such proposals were made.

A brief recitation of the facts provides necessary context.<sup>2</sup>

# A. Factual History

Ms. Porcello received the flu vaccination in her left shoulder on November 22, 2016. When Ms. Porcello received her vaccination, she was a twenty-year-old college student and field hockey player. She stated that her shoulder pain began immediately following vaccine administration, and, because she was away at college, she sought treatment from an athletic trainer with her campus's health services department. That athletic trainer, Hilary Ann Turner, stated in an affidavit that she spoke with Ms. Porcello regarding her shoulder pain in January 2017 and again in March 2017, and she noted that Ms. Porcello "asked about some left upper arm pain she had been experiencing" when lifting or doing pushups "after winter break."

On January 18, 2017, Ms. Porcello presented to Lawrence Memorial Healthcare Center with a cough, fever, and chills, at which time the medical note documented a "[r]ange of motion grossly normal. No pain with range of motion." Regardless, Ms. Porcello alleged that her range of motion was not examined during this appointment, and she further asserted that she informed her treating physician that she suffered from bothersome shoulder pain since she received her flu shot "a few months back."

On March 17, 2017, Ms. Porcello visited her primary care physician, Dr. Laura L. Carman, complaining of left arm pain since receiving her flu shot in November. Dr. Carman referred her to an orthopedist. On March 20, 2017, petitioner met with Dr. Marie Walcott at Agility Orthopedics, reporting that she developed "weakness in her left shoulder and difficulty doing her training for field hockey." Dr. Walcott found that Ms. Porcello had full supple range of motion of her left shoulder, as well as noting that she "had pain but intact strength with supraspinatus testing in the empty can position. She has pain and weakness with resisted external rotation." Dr. Walcott further remarked that "[i]t is unusual to have these symptoms after a flu shot and to last so long." She then recommended that petitioner get an MRI.<sup>3</sup>

As the basic facts here have not changed significantly, the Court's recitation of the background facts here draws from the Chief Special Master's earlier opinion in *Porcello*. *Porcello v. Sec'y of Health & Human Servs.*, No. 17-1255, 2020 WL 4725507 (Fed. Cl. Spec. Mstr. June 22, 2020) ("*Porcello*").

MRI is defined as "magnetic resonance imaging." *Dorland's Illustrated Medical Dictionary* 1167 (33rd ed. 2020) ("*Dorland's*").

Ms. Porcello underwent an MRI on her left shoulder on April 7, 2017, which revealed "bone marrow edema<sup>4</sup> in the superficial<sup>5</sup> distal<sup>6</sup> posterior aspect<sup>7</sup> of the left humeral greater tuberosity <sup>8</sup> with associated soft tissue and periosteal<sup>9</sup> edema worrisome for chronic osteomyelitis." <sup>10</sup> She returned to discuss her MRI results with Dr. Walcott on April 13, 2017, at which point Dr. Walcott observed that she "continues to have significant pain when reaching to the side and reaching overhead." She also noted that Ms. Porcello had full supple range of motion in her left shoulder, pain and weakness with supraspinatus testing and external rotation, and was tender to greater palpation <sup>11</sup> over greater tuberosity. Dr. Walcott concluded that Ms. Porcello likely suffered from "either a contusion or a chronic osteomyelitis," an assessment supported by the contemporaneous review of both a radiologist and a tumor specialist, and Dr. Walcott determined that a tagged white blood cell scan or a biopsy <sup>12</sup> would be needed to rule out infection.

On April 26, 2017, Dr. Walcott indicated that she reviewed Ms. Porcello's MRI results with "Dr. Olans from infection disease," who concluded that Ms. Porcello did not have osteomyelitis. Dr. Walcott also stated that she reviewed the results with an unnamed "colleague in Boston" who concluded that Ms. Porcello had SIRVA. At a follow-up appointment on May 9, 2017, Dr. Carman offered to refer Ms. Porcello to Dr. Lee, who was noted to be familiar with SIRVA, but Ms. Porcello declined the referral. Ms. Porcello completed six sessions of physical therapy for her left shoulder between July 31 and August 16, 2017. On her intake form, Ms. Porcello listed the date of onset of her shoulder injury as November 11, 2017—eleven days before she received the flu vaccination.

Edema is defined as "the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues." *Dorland's* 587.

Superficial is defined as "pertaining to or situated near or nearer the surface." *Dorland's* 1774.

Distal is defined as "remote; farther from any point of reference; opposed to proximal." *Dorland's* 549.

Posterior aspect is defined as "the surface of a body viewed from the back." *Dorland's* 162.

Also known as tuberbulum majus humeri and defined as "a large flattened prominence at the proximal end of the lateral surface of the humerus, just lateral to the highest part of the anatomic neck, giving attachment to the supraspinatus, the infraspinatus, and the teres minor muscles." *Dorland's* 1951.

Periosteal is defined as "pertaining to the periosteum." *Dorland's* 1396.

Osteomyelitis is defined as "inflammation of bone caused by infection, usually by a pyogenic organism, although any infectious agent may be involved." *Dorland's* 1328

Palpation is defined as "the act of feeling with the hand; the application of the fingers with light pressure to the surface of the body for the purpose of determining the consistency of the parts beneath in physical diagnosis." *Dorland's* 1345.

A biopsy is defined as "the removal and examination, usually microscopic, of tissue from the living body, performed to establish precise diagnosis." *Dorland's* 214.

At a visit with Dr. Walcott on September 28, 2017, Ms. Porcello was noted as having improved strength but residual pain in her shoulder. She underwent a second MRI and returned to Dr. Walcott's office on October 5, 2017 to discuss those results. At that time, Dr. Walcott noted that the MRI had "normalized," but that they "discussed the findings of a small partial-thickness infraspinatus tear" and "discussed treatment for her shoulder pain, which may be coming from the partial tear verses the residual SIRVA." Ms. Porcello forwent a cortisone<sup>13</sup> injection but agreed "to work with physical therapy and do [an] exercise program at home."

# B. Procedural History

Petitioner filed her petition, without medical records, with the Office of Special Masters on September 14, 2017. *See generally* Petition. On July 22, 2019, petitioner filed the expert report of Dr. Jeffrey A. Dlabach. The parties attempted settlement but were unsuccessful. On November 20, 2018, respondent filed a Rule 4(c) report, asserting that this case was not appropriate for compensation under the Vaccine Act. On May 22, 2019, petitioner filed a motion for summary judgment, arguing that she met her burden of proving she is entitled to compensation under the Vaccine Act. On January 6, 2020, respondent filed its response to petitioner's Motion, arguing that her Motion should be denied, and her claim dismissed for failure to demonstrate entitlement to compensation.

Under Vaccine Rule 8(d), a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in [Rule] 56 [of the Rules of the Court of Federal Claims] will apply." On June 22, 2020, without first holding an entitlement hearing, Chief Special Master Corcoran issued a decision denying petitioner's Motion for Summary Judgment and dismissing the claim for compensation. Decision (A) Denying Motion for Summary Judgment, and (B) Granting Dismissal of Claim [hereinafter Dec.]. In that decision, the Chief Special Master found that "[p]etitioner has failed to offer preponderant evidence sufficient to satisfy the third *Althen* prong." *Porcello*, 2020 WL 4725507, at \*10.

Petitioner filed her Motion for Review on July 22, 2020. See generally Petitioner's Motion for Review, ECF No. 67. In addition to her Motion for Review, petitioner filed three identical copies of her supporting Memorandum of Objections. See Petitioner's Memorandum of Objections, ECF No. 66; Petitioner's Memorandum of Objections, ECF No. 68; Petitioner's Memorandum of Objections, ECF No. 69 [hereinafter MFR]. That same day, petitioner filed a motion to strike the first two copies of her Memorandum of Objections, as she filed the first copy out of order and linked the second copy to the wrong document. Motion to Strike, ECF No 70. Respondent filed its Response to petitioner's Motion for Review on August 21, 2020. See generally Response to Motion for Review [hereinafter Resp. to MFR]. Petitioner's Motion is now fully briefed and ripe for review.

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Cortisone is defined as "a natural glucocorticoid that is metabolically convertible to cortisol." *Dorland's* 417.

#### II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In that instance, the Court may do the following:

(A) uphold the findings of fact and conclusions of law..., (B) set aside any findings of fact or conclusion of law... found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..., or, (C) remand the petition to the Special Master for further action in accordance with the court's direction.

*Id.* at § 300aa-12(e)(2)(A)–(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo. Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

This Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." Snyder ex rel. Snyder v. Sec'y of Dep't of Health & Human Servs., 88 Fed. Cl. 706, 718 (2009). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." Id. Under this standard, a special master's decision "must articulate a rational connection between the facts found and the choice made." Cucuras v. Sec'y of Dep't of Health & Human Servs., 26 Cl. Ct. 537, 541–42 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993) (citing Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)). This standard is "highly deferential." Hines v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Id.

## III. DISCUSSION

Althen v. Secretary of Health & Human Services provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. See generally Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). There are two means of proving causation under the Vaccine Act: (1) showing that the injury falls under the Vaccine Injury Table, which provides a presumption of causation; and (2) proving causation-in-fact for an injury not listed on the Vaccine Injury Table. See id. at 1278 (citing 42 U.S.C. §§ 300aa-14(a), -13(a)(1), -11(c)1(C)(ii)(I)). The latter applies to this case; thus, in order to prove causation-in-fact, a petitioner must

show by preponderant evidence that the vaccination brought about [petitioner's] 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.

*Id.* at 1278. For a petitioner to meet the preponderance standard and succeed on the claim, petitioners must provide a "reputable medical or scientific explanation" for their claim. *See id.* 

Within this framework, petitioner makes two numbered objections to the Chief Special Master's June 22, 2020 decision. *See* MFR at 1. First, petitioner asserts that "[t]he [Chief] Special Master erred in *sua sponte* converting [p]etitioner's Motion for Summary Judgment into one for a Ruling on the Record and weighing the evidence without providing [p]etitioner an opportunity to present evidence related to specific factual discrepancies relied upon by the [Chief Special Master] to ultimately dismiss [p]etitioner's claim." *Id.* at 4. Second, petitioner argues that "[t]he [Chief] Special Master erred in determining [p]etitioner had not met her burden for showing causation and entitlement." *Id.* at 6.

## A. Ruling on the Record

In her Motion for Review, petitioner alleges that "dismissal of her claim in the face of no procedurally correct motion from Respondent seeking such relief is arbitrary and capricious and not in accordance with the law." MFR at 4–5. In making this assertion, petitioner argues that she "did not have a full and fair opportunity to develop and present her evidence and arguments on the issue of timing of onset in relation to the issues that the Special Master found probative in his ruling." *Id.* at 5. Additionally, petitioner argues that "a ruling on the record was never contemplated amongst the parties before it was unilaterally made." *Id.* In response, respondent argues that there is no requirement that a party file a "procedurally correct motion" under the Vaccine Act. Resp. to MFR at 10. Rather, respondent argues, "a special master is only required to 'afford[] each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision," and by extension, determine that the record is "comprehensive and fully developed before ruling on the record." *Id.* at 10–11 (quoting *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (quoting Vaccine Rule 3(b)(2))).

Petitioner does not argue that, as a result of the manner in which the Chief Special Master procedurally managed this case, that she would have presented additional evidence that was never considered in the Chief Special Master's decision. Rather, the petitioner argues that she "merely seeks the opportunity with notice to present material evidence . . . that the [Chief Special Master] was going to and did eventually consider." MFR at 5. Alternatively, respondent argues at length that petitioner was afforded the opportunity to fully develop the record, as evidenced by the numerous evidentiary filings and record supplementations. Resp. to MFR at 11. Moreover, respondent alleges that petitioner "submits no specific proffer of evidence that would have materially changed the record if the Chief Special Master had explicitly filed notice that he intended to rule on entitlement on the record." *Id.* at 13. Finally, respondent contends that "*Kreizenbeck* makes clear that parties have no right to compel the special masters to hold hearings." *Id.* (citing *Kreizenbeck*, 945 F.3d at 1365–66).

While the Court acknowledges that the procedural path of this case does not fit the usual arc of a case emerging from the Office of Special Masters, the Court does not believe that the petitioner was in any way prejudiced by the manner in which the Chief Special Master reached its ultimate disposition. As the record makes clear, petitioner had multiple opportunities to provide evidentiary and affidavit support for her claim, all of which she took advantage. The Court cannot see how, if given the opportunity to present her case in a different way, petitioner's already-admitted evidence would change the ultimate decision of the Chief Special Master. As such, the Court declines to find that the Chief Special Master abused his discretion by issuing a ruling on the record. In fact, this procedure saved time and legal resources.

## B. Burden of Proof

Petitioner's second numbered objection alleges that the Chief Special Master erred in determining that petitioner had not met her burden for showing causation and entitlement. MFR at 6. In making this assertion, petitioner argues that "[t]he [Chief] Special Master erroneously failed to consider the totality of the records, basing his decision on improper weighing of evidence in support of positions not advanced by *either party*." *Id.* (emphasis in original). Specifically, petitioner objects to the Chief Special Master's determination regarding onset. *Id.* at 7. In response, respondent argues that "the record demonstrates that petitioner did not establish the onset of a shoulder injury in a time period proximate to vaccination, as contemplated under the Table, or during a timeframe that would establish the third prong of *Althen.*" Resp. to MFR at 15. Furthermore, respondent contends that the Chief Special Master reasonably concluded "that evidence of the onset of petitioner's shoulder injury was vague, and 'in some cases contradicted by evidence suggesting a pre-vaccination start." *Id.* at 16 (quoting Dec. at 12–13). Upon careful review, the Court does not believe that the Chief Special Master erred in determining that petitioner has not met the requisite burden of establishing a reasonable timeframe for a non-Table SIRVA injury.

In order to prevail under *Althen*, petitioner must establish by a preponderance of the evidence a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278. Finding such a proximate temporal relationship "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). In a causation-in-fact SIRVA claim, medical science has deemed persuasive the onset period of the Table version of such a claim, which requires the onset of symptoms within 48 hours or less of vaccination. *See Almanzar v. Sec'y of Health & Human Servs.*, No. 16-340V, 2018 WL 4042365, at \*7 (Fed. Cl. Spec. Mstr. April 20, 2018) (employing SIRVA Table criteria to find that the onset of symptoms within 48 hours of vaccination is a medically acceptable timeframe for which to infer causation); *see also* 42 C.F.R. § 100.3(c)(10). Moreover, as the Chief Special Master correctly pointed out, "timeframes for a non-Table SIRVA onset that are too long or too short, relying on the Table timeframe as a general 'yardstick,' have failed." Dec. at 11 (citing *Mack v. Sec'y of Health & Human Servs.*, No. 15-149V, 2016 WL 5746367, at \*11 (Fed. Cl. Spec. Mstr. July 14, 2016)

(finding an onset of six months is not evidence of a proximate temporal relationship for a non-Table SIRVA claim)).

The evidence and affidavits provided by petitioner paint, at best, a murky picture with regard to the onset date of petitioner's symptoms. Ms. Porcello alleges that the onset of her left shoulder pain occurred immediately after receiving the flu vaccination. Dec. at 12. However, a physical therapy intake form directly contradicts that statement, as Ms. Porcello self-reported on that form that the injury began on November 11, 2016, eleven days prior to her vaccination. *Id*. Moreover, petitioner did not begin to seek treatment for her left shoulder until March 2017, over three months after she received the vaccination. *Id*.

In determining whether a special master's finding of fact is arbitrary and capricious, this Court must look to plausibility, not to whether it is supported by a preponderance of the evidence. As long as the finding of fact is "based on evidence in the record that [is] not wholly implausible, [this Court is] compelled to uphold the finding as not being arbitrary or capricious." *Porter v. Sec'y of Health & Human Servs.*, 663F.3d 1242, 1249 (Fed. Cir. 2012) (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Upon careful review of the record, the Court finds that the finding of the Chief Special Master—that, based on the lack of reasonable timeframe and vague and inadequate evidence of petitioner's SIRVA onset date, he "cannot find that the timeframe for Petitioner's SIRVA was medically acceptable" to infer causation-in-fact—is neither arbitrary, capricious, nor contrary to law.

#### IV. CONCLUSION

The Court finds that petitioner has not met her burden of proof in alleging that her November 2016 influenza vaccine resulted in her SIRVA. For the foregoing reasons, the Court **DENIES** petitioner's Motion for Review. Additionally, petitioner's MOTION to Strike Document Number 66 and 68 is hereby **GRANTED**.

IT IS SO ORDERED.

s/ Loren H. Smith
Loren A. Smith,
Senior Judge