In the United States Court of Federal Claims

No. 20-625V

(E-Filed: June 13, 2022) ¹	
KATHERINE SHOEMAKER,	
Petitioner,) Influenza Vaccine; National Vaccine
v.) Injury Compensation Program, 42) U.S.C. §§ 300aa-10, et seq.; Review of
SECRETARY OF HEALTH AND HUMAN SERVICES,) Special Master's Decision.
Respondent.)) _)

<u>David A. Kulwicki</u>, Cleveland, OH, for petitioner.

<u>Christine M. Becer</u>, Trial Attorney, with whom were <u>Brian M. Boynton</u>, Principal Deputy Assistant Attorney General, <u>C. Salvatore d'Alessio</u>, Acting Director, <u>Heather L. Pearlman</u>, Deputy Director, <u>Alexis B. Babcock</u>, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

CAMPBELL-SMITH, Judge.

Petitioner filed the petition in this case on May 20, 2020. <u>See ECF No. 1</u>. The special master issued his entitlement decision on January 18, 2022. <u>See ECF No. 25</u>. On February 16, 2022, petitioner filed a motion for review with this court, <u>see ECF No. 26</u>, and respondent filed a response on March 18, 2022, <u>see ECF No. 28</u>. The court's rules do not require a reply, and petitioner did not seek to file one.

This opinion was filed on May 23, 2022, in accordance with Rule 18(b) of the Vaccine Rules, Appendix B to the Rules of the United States Court of Federal Claims. See ECF No. 29. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before June 6, 2022. No proposed redactions were submitted to the court.

The motion is now fully briefed and ripe for ruling. The court has considered all of the arguments presented by the parties and addresses the issues that are pertinent to the court's ruling in this opinion. For the following reasons, petitioner's motion for review is **DENIED**, and the special master's January 18, 2022 entitlement decision is **SUSTAINED**.

I. Background

In her petition, petitioner alleges that, "[o]n September 24, 2018, she received a vaccine administered in her right arm at Meijer Pharmacy in Marysville, Ohio." ECF No. 1 at 1. More specifically, petitioner alleges that she received "Flucivx Quad 18-19," or the "flu vaccine." <u>Id.</u> Petitioner claims that she suffered a shoulder injury related to vaccine administration (SIRVA), and that "the onset of symptoms immediately follow[ed] . . . administration of the vaccine." <u>Id.</u> Her injury has allegedly caused "difficulty with activities of daily living" for more than six months. <u>Id.</u> at 2.

Petitioner filed a personal affidavit and a variety of medical records along with her petition. See ECF No. 1-3 through ECF No. 1-8. Many of the records pre-date administration of the vaccine at issue. See ECF No. 1-5 at 11-93. The earliest record attached to the affidavit that post-dates administration of the vaccine is dated July 15, 2019, and documents a visit to a primary care doctor approximately ten months after vaccination. See ECF No. 1-5 at 8-10. The July 15, 2019 record reflects petitioner's complaint about shoulder pain as a result of receiving a "Flu shot in September." Id. at 8. Petitioner's primary care doctor recommended physical therapy (PT) to treat the pain, and notes that petitioner agreed to "start home PT," but that she "refuse[d] formal PT." Id.

Upon reviewing the petition and accompanying documentation, on May 27, 2020, the special master directed petitioner to file a "[v]accination record that includes a notation identifying the arm of administration of the vaccine at issue," as the record initially provided did not include that information. ECF No. 7 at 1. On June 4, 2020, petitioner filed a second personal affidavit in response, in which she states that she received the vaccination in her right arm, but did not provide any further documentation. See ECF No. 8-1 at 1.

The special master held an initial status conference on July 21, 2020. <u>See ECF No. 13</u> (July 24, 2020 scheduling order memorializing initial status conference). During the status conference, petitioner was advised that she needed to provide additional documentation with regard to the site of vaccination and an explanation for the ten-month delay in seeking treatment. <u>See id.</u> at 1. The special master directed petitioner to do so on or before October 21, 2020. See id. at 2.

On November 6, 2020, the special master entered an order stating that petitioner had failed to meet the October 21, 2020 deadline, and extending her time to file the documentation to February 9, 2021. See ECF No. 14 at 2. On February 10, 2021, petitioner filed a third personal affidavit in which she attributes the delay in seeking treatment to the press of school work and difficulty finding a primary doctor. See ECF No. 16-1 at 2. She further states that Meijer Pharmacy does not have records indicating the arm in which she received the flu vaccination at issue, see id. at 3, and she submitted medical records from gynecological exams dated August 2020, October 2018, October 2017, and August 2016, see ECF No. 16-2. None of the gynecologist's records address petitioner's alleged SIRVA injury. See generally id. As the special master notes in his decision, "[t]he medical records do show Petitioner failed to mention her right shoulder pain during an October 17, 2018 visit to her gynecologist, approximately three weeks post-vaccination." ECF No. 25 at 2; see also ECF No. 16-2 at 8 (noting that, as part of a review of systems, petitioner denied experiencing any joint or muscle pain).

On June 2, 2021, petitioner filed a motion for subpoena authority, seeking to subpoena Meijer Pharmacy for any records relating to her vaccination. See ECF No. 20. Petitioner was specifically seeking additional documentation identifying the arm in which she received the vaccine. See id. The special master granted the motion on June 2, 2021, see ECF No. 21, and petitioner filed the documents she received in response on July 14, 2021, see ECF No. 22. The documentation, however, did not identify the arm in which petitioner received the vaccine. See ECF No. 22-1 at 18.

The special master issued an order to show cause on August 10, 2021, in which he explained as follows:

In order[] to prevail in this case, Petitioner must provide preponderant evidence to support her assertion that she suffered a SIRVA as alleged. Petitioner's ten-month delay in seeking treatment and lack of evidence regarding the onset of her pain and alleged symptoms during this ten-month period suggest the claim cannot succeed unless Petitioner can offer other evidence, not yet filed in this case, to establish a vaccine-related injury as she alleges, and in the timeframe required by the Table. I am giving Petitioner a final chance to obtain and file such evidence—and it is important she take that chance seriously.

ECF No. 23 at 2. The special master then directed petitioner to submit any additional documentation on or before September 14, 2021. See id. at 2-3. Petitioner responded to the show cause order on September 9, 2021, but offered no new documentation or information about her injury or claim. See ECF No. 24.

On January 18, 2022, the special master issued his entitlement decision. <u>See ECF No. 25</u>. Therein, he explained that, the SIRVA for which petitioner seeks relief is a Table

injury, and therefore, causation will be presumed provided that a petitioner establishes that the injury "manifest[ed] within 48 hours of the administration of an influenza vaccine." See ECF No. 25 at 3 n.4 (citing 42 C.F.R. § 100.3(a)(XIV)). According to the special master, however, "the record lacks evidence needed to support her claims," and petitioner "failed to provide evidence to counter the inferences derived from her tenmonth delay in seeking treatment, or to show her condition during that time." Id. at 5.

The special master explained that "[n]arratives of post-vaccination pain provided closer in time to the vaccine's administration date would typically be afforded more weight than assertions made when filing the Petition." <u>Id.</u> at 6 (citing <u>Cucuras v. Sec'y of Health & Hum. Servs.</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993)). In this case, he stated, petitioner first reported her pain to her primary care doctor ten months after the alleged injury, but only four months before filing the petition in this case. <u>See id.</u>

The special master concluded that "Petitioner's ten-month delay in seeking treatment, and lack of evidence regarding the onset of her pain and alleged symptoms during this ten-month period, suggest the claim cannot succeed." <u>Id.</u> Because petitioner failed to present preponderant evidence of her claim, the special master dismissed the petition. <u>See id.</u>

Petitioner now seeks review of that decision. See ECF No. 26.

II. Legal Standards

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. See 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)).

This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny.

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of Dep't of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

As the United States Court of Appeals for the Federal Circuit has held, when reviewing a special master's decision, this court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011). "Rather, as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." Id. (quoting Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Under this standard "reversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Petitioner bears the burden of proving, by a preponderance of the evidence, that "the vaccination brought about her 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, 418 F.3d at 1278. "Because causation is relative to the injury, . . . petitioner[s] must provide a reputable medical or scientific explanation that pertains specifically to the petitioner[s'] case, although the explanation need only be 'legally probable, not medically or scientifically certain." Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)). If petitioner "satisfies this burden, she is 'entitled to recover unless [respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." Althen, 418 F.3d at 1278 (quoting Knudsen, 35 F.3d at 547).

III. Analysis

Petitioner assigns two categories of error to the special master's entitlement decision. First, she argues that the special master based his decision on clearly erroneous facts, see ECF No. 26 at 4-6; and second, petitioner argues that the decision was based on clearly erroneous law, see id. at 6-7. The court will address each argument in turn.

A. The Special Master Did Not Base His Decision on Clearly Erroneous Facts

Petitioner identifies six factual errors in her response. <u>See id.</u> at 4-6. As an initial matter, she takes issue with the special master's statement that "petitioner has provided no evidence to support her claim, such as affidavits from family, friends or co-workers or other documentation." <u>Id.</u> at 4 (quoting ECF No. 25 at 5). According to petitioner, her

"recitation of events is corroborated by the records of both shoulder specialists who examined her." <u>Id.</u> Petitioner, however, has taken the special master's statement out of context. That missing context is as follows:

The record in this case still shows that Petitioner did not seek medical care for her alleged SIRVA until almost ten months post-vaccination, on July 15, 2019. The purpose of the visit was to establish care and undergo an annual physical. While noting at the time of this visit that Petitioner complained of right shoulder pain which she attributed to the flu vaccine she received in September 2018, her primary care provider ("PCP") appeared to question that conclusion, given the length of time which had passed between vaccination and when Petitioner sought care. It was also noted that Petitioner was offered formal physical therapy which she refused in favor of a home exercise program.

Other than this record and later-provided histories, plus the allegations made in the Petition and her affidavit, <u>Petitioner has provided no evidence to support her claim</u>, such as affidavits from family, friends, or co-workers or other documentation.

ECF No. 25 at 5 (internal citations omitted, emphasis added). Read together with the preceding paragraph and the beginning of the sentence, the special master is clearly referring to the lack of contemporaneous documentation of petitioner's SIRVA. This is an appropriate consideration since petitioner bears the burden to prove that symptoms began within forty-eight hours of vaccination. See 42 C.F.R. § 100.3(a)(XIV). As such, the special master did not err in this regard.

Second, petitioner claims that the special master erred in stating that "the vaccine record did not indicate the site <u>or method of vaccination</u>." ECF No. 26 at 4 (quoting ECF No. 25 at 2). Petitioner then cites to petitioner's Exhibit 11 to demonstrate that the documentation, in fact, did indicate that the vaccine was administered by injection. <u>See id.</u> It is true that, in the beginning of the procedural history section of his entitlement decision, the special master states that the vaccine record initially filed with the petition "did not indicate the site or method of vaccination," citing petitioner's Exhibit 2. <u>See ECF No. 25 at 2 (citing ECF No. 1-4)</u>. At the end of the procedural history section, however, the special master noted that petitioner filed an additional document, petitioner's Exhibit 11, that still "failed to indicate the site of vaccination." <u>Id.</u> at 3. Petitioner seeks to assign error to the special master's decision based on the first statement, without acknowledging the second. <u>See ECF No. 26 at 4</u>. The finding to which petitioner objects is plainly an incomplete representation of the basis for the special master's decision, not clear error.

Third, petitioner argues that the special master erred in finding that petitioner "failed to provide evidence to counter the inferences derived from her ten-month delay in seeking treatment." Id. (quoting ECF No. 25 at 5). She claims that her affidavit effectively countered any such inferences by explaining her status as a student and her need to find a new doctor, which is corroborated by the doctor's note. See id. at 4-5 (quoting ECF No. 1-5 at 8, stating that one purpose of petitioner's July 15, 2019 visit was to "[e]stablish [c]are"). The special master clearly reviewed—and cited to—the page to which petitioner directs the court's attention on this point. See ECF No. 25 at 2 (citing ECF No. 1-5 at 8). That the special master did not credit these explanations as sufficient to demonstrate that plaintiff's claim meets the time limitations applied to SIRVA claims is not a basis for the court to overturn his decision. As noted above, this court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence." Porter, 663 F.3d at 1249. "Rather, as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." Id. (quoting Cedillo, 617 F.3d at 1338). Here, the special master considered the available records, and based on that evidence, he concluded that plaintiff had failed to adequately explain either the ten-month delay or her condition during that time. Because the special master's conclusion is not "wholly implausible," this court must sustain it. Id.

Plaintiff's final three assignments of error with regard to factual findings relate to inferences drawn by the special master. Petitioner contends that the special master "drew inappropriate negative inferences from neutral facts," when he noted that petitioner's primary care doctor "appeared to question" petitioner's conclusion that her shoulder pain resulted from a vaccine she received ten-months before the visit. ECF No. 26 at 5 (quoting ECF No. 25 at 5)). Petitioner does not disagree that the doctor appeared to question that conclusion; rather, she argues that "[t]he special master should know that not all physicians are versed in the relationship between vaccines and SIRVA injuries," and that such lack of knowledge was an "equally plausible inference." Id. The court cannot overturn the special master's finding on the basis that an equally plausible inference exists—his finding must be affirmatively implausible. See Porter, 663 F.3d at 1249 (stating that "as long as a special master's finding of fact is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious"). Petitioner has failed to demonstrate error on this point.

Petitioner next argues that the special master "drew an inappropriate inference from the fact that [p]etitioner did not report the shoulder injury to her obstetrician," stating that such a report would be "bizarre . . . given the nature of the obstetrician's focus." ECF No. 26 at 5. The court disagrees. The record indicates that petitioner's gynecologist performed a systems check during which she noted that petitioner denied experiencing any joint or muscle pain. See ECF No. 16-2 at 8. In the court's view it is entirely logical, not only plausible, to believe that a woman would report pain related to a

SIRVA when asked about joint or muscle pain by a doctor, regardless of that doctor's specialty.²

Finally, petitioner faults the special master for "giv[ing] no grace (i.e., positive inference) to the fact that [p]etitioner was a nursing student, not a lay person, who recognized immediately that the vaccine had caused a problem." ECF No. 26 at 6. The fact that petitioner disagreed with the manner in which the special master weighed the evidence is not a basis for the court to find the decision arbitrary or capricious. The special master was aware that petitioner was in nursing school, see ECF No. 25 at 2, but it is unclear to the court why petitioner's enrollment in a medical professional school should result in this court requiring the special master to more strongly credit her statements in this case. Petitioner offers no authority to support such a proposition, and thus, her argument on this point also fails.

B. The Special Master Did Not Apply an Erroneous Legal Standard

Petitioner also argues that the special master "misapplied the law" in his entitlement decision. ECF No. 26 at 6. Specifically, petitioner objects to the special master's statement that petitioner has failed to "provide evidence to counter the inferences derived from her ten-month delay in seeking treatment." ECF No. 26 at 6-7 (quoting ECF No. 25 at 5). Petitioner suggests that this sentence imposes a burden on petitioner to "report the injury to a healthcare provider within a specified period of time," a requirement not included in the Vaccine Act. See ECF No. 26 at 7.

Petitioner, again, has taken the special master's language out of context.

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In this section of her motion for review, petitioner also notes that the special master inappropriately considered the fact that petitioner did not participate in physical therapy, even though petitioner's primary care doctor noted that physical therapy was ineffective. See ECF No. 26 at 5. As is the case with many of petitioner's arguments, citation to the special master's decision is lacking. The court, in this instance, could not determine to which passage of the special master's decision petitioner was referring. The only mention of physical therapy in the decision appeared when the special master stated, in reference to petitioner's first visit to her primary care doctor, as follows: "It was also noted that Petitioner was offered formal physical therapy which she refused in favor of a home exercise program." ECF No. 25 at 5. This statement does not bear enough resemblance to petitioner's argument that the court can make the connection. As such, the court declines to further address this argument.

Petitioner represents in her motion that this statement appears in the special master's show cause order, ECF No. 23, which is dated August 10, 2021. See ECF No. 26 at 6-7. Petitioner does not provide a citation to the show cause order, and the quoted language does not appear in the August 10, 2021 order. See generally ECF No. 23. The court located the language in the entitlement decision, and therefore, assumes the reference to the show cause order in petitioner's motion was in error.

First, the statement as recited by petitioner is incomplete. The special master wrote that petitioner "has failed to provide evidence to counter the inferences derived from her tenmonth delay in seeking treatment, or to show her condition during that time." ECF No. 25 at 5 (emphasis added). The omitted portion of the special master's statement provides an explicit alternative to reporting the injury to a healthcare professional. In the court's view, neither this statement, nor any others in the entitlement decision indicate that the special master imposed a requirement that petitioner report her injury to a healthcare professional within a certain timeframe. See generally ECF No. 25. In fact, in the same passage referred to by petitioner, the special master notes that petitioner could have provided evidence in the form of "affidavits from family, friends, or co-workers" to support her claim. Id. at 5. Petitioner did not do so.

Petitioner admits that she bears the burden of establishing her claim "by showing that she received a vaccine listed on the Vaccine Injury Table and subsequently developed a corresponding injury within a corresponding period of time." ECF No. 26 at 7 (citing 42 U.S.C. § 300aa-13(c)). Petitioner's assertion that she has met this burden constitutes nothing more than a disagreement with the manner in which the special master viewed the relevant evidence. Because re-weighing the evidence falls outside of this court's remit, the special master's decision is sustained. See Porter, 663 F.3d at 1249 (stating that in reviewing a special master's decision, this court does not "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder").

IV. Conclusion

Accordingly, for the foregoing reasons:

- (1) Petitioners' motion for review, ECF No. 26, is **DENIED**;
- (2) The decision of the special master, filed on January 18, 2022, ECF No. 25, is **SUSTAINED**;
- (3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's January 18, 2022 decision, ECF No. 25; and
- (4) On or before **June 6, 2022**, the parties are directed to separately **FILE** any proposed redactions to this opinion, with the text to be redacted blacked out.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge