

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-990V

Filed: November 9, 2018

PUBLISHED

BARBARA STOLIKER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Ruling on Entitlement; Finding of
Fact; Administration Site; Evidence
of Vaccination; Table Injury; Influenza
(Flu) Vaccine; Shoulder Injury
Related to Vaccine Administration
(SIRVA)

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

Alexis B. Babcock, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT – SPECIAL PROCESSING UNIT¹

Dorsey, Chief Special Master:

On July 27, 2017, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) resulting from her September 30, 2014 influenza (“flu”) vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. The undersigned now resolves factual disputes regarding the site of administration of petitioner’s alleged injury-causing vaccination and the onset of

¹ The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

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).

petitioner's shoulder pain. For the reasons described below, the undersigned finds that petitioner's September 30, 2014 influenza vaccination was administered in her right deltoid and that the onset of the shoulder pain allegedly resulting from that vaccination occurred within 48 hours of vaccine administration.

I. Procedural History

On July 28, 2017, petitioner filed medical records marked as Exhibit 1 through 4 along with a statement of completion. (ECF Nos. 7-8.) On August 12, 2017, petitioner filed transcribed records from one of her medical providers (Dr. Sands) as Exhibit 5 and an affidavit as Exhibit 6. (ECF No. 9.)

Thereafter, an initial status conference was held with the staff attorney managing this case on September 7, 2017. (ECF No. 10.) Respondent was allowed 60 days to file a status report indicating how he intends to proceed. (*Id.*) However, citing high case volume, budget constraints, and hiring restrictions, respondent asked for additional time to determine his position on multiple occasions. (ECF Nos. 11, 15, 17.)

After six months, respondent advised on March 9, 2018, that he was willing to consider a reasonable settlement demand. (ECF No. 19.) Petitioner had previously presented respondent a demand for damages. (ECF No. 13.) However, settlement discussions did not commence. On June 19, 2018, the parties filed competing status reports explaining that respondent would not be responding to the demand because respondent had determined that the medical records in the case include two vaccination records which differ on the site of injection. (ECF Nos. 29, 30.)

Subsequently, on June 27, 2018, petitioner filed additional evidence. (ECF No. 34.) Specifically, petitioner filed a supplement affidavit (Exhibit 8) and a handwritten note from a CVS pharmacy manager, Sam Bright, Pharm.D. (Exhibit 7). (*Id.*) Respondent filed a motion for discovery seeking authorization to depose Dr. Bright along with Raed Ahmed, a CVS employee identified in Dr. Bright's note as the individual whose handwritten initials appear on one of the two vaccination records filed in the case. (ECF No. 33.)

The undersigned held a status conference on July 11, 2018. (ECF No. 37.) The undersigned addressed both respondent's motion for discovery and petitioner's concern that the case had been unreasonably delayed. (*Id.*) The undersigned granted respondent's motion for discovery, but time-limited the request due to respondent's delay in presenting the issue. (*Id.*) During the call, the parties agreed that Flores Orlando, listed as the administering immunizer on petitioner's vaccination record, would also be deposed. (*Id.*) The undersigned also ordered respondent to file his Rule 4 report. (*Id.*)

Subsequently, respondent filed transcripts of the depositions of Raed Ahmed and Samuel Bright as respondent's Exhibits A and B respectively. (ECF No. 46.) Respondent confirmed that he was unable to effectuate service of process upon Flores Orlando and he was not deposed. (ECF No. 49, p. 3, n. 2.)

Respondent filed his Rule 4 report on August 27, 2018. (ECF No. 47.) In his report, respondent indicated that petitioner has not met her burden to establish a table injury of SIRVA because there is not preponderant evidence that she received her vaccination in her right arm or that onset of her shoulder injury was within 48 hours of vaccination. (ECF No. 47, p. 5.) Additionally, on August 31, 2018, respondent filed a motion for a limited factual ruling. (ECF Nos. 47, 49.) In his motion, respondent indicated that “[a] determination as to the arm in which petitioner received her September 30, 2014 flu vaccination is a necessary factual predicate that will inform further proceedings on this petition.” (ECF No. 49, p. 6.) Accordingly, respondent requested that “based on the totality of the evidence, the Chief Special Master make a finding as to the site of petitioner’s September 30, 2014 flu vaccination.” (*Id.*)

Petitioner filed a response to the motion on October 1, 2018. (ECF No. 50.) Petitioner requested that the undersigned issue a ruling finding that petitioner received her September 30, 2014 flu vaccine in her right arm and further finding that the onset of her shoulder injury occurred within 48 hours of vaccination. (*Id.* at 2.)

Respondent filed no reply. Thus, this case is ripe for the undersigned’s finding of fact.

II. Factual History

On September 30, 2014, petitioner received an influenza vaccination at a CVS pharmacy. (Ex. 1; Ex. 2, pp. 2-3; Ex. 6, p. 1.) Petitioner averred that she received the vaccination in her right arm and that it was “uncomfortable.” (Ex. 6, p. 1.) She further indicated that by mid-day the following day her pain had increased to the point that she could not lift her arm. (*Id.*) Approximately two weeks later on October 15, 2014, petitioner was seen by her primary care physician, Dr. Sands, at which time she complained of right shoulder pain “since receiving the flu shot at pharmacy on 9/30/2014.” (Ex. 2, p. 12; Ex. 5, p. 8.) Dr. Sands attributed petitioner’s shoulder pain to her vaccination. (*Id.*) Petitioner subsequently returned to Dr. Sands on October 20, 2014, and December 15, 2014, continuing to complain of pain in the right shoulder “s/p” – status post – injection. (Ex. 2, pp. 10-11.) In subsequent medical records, petitioner’s right shoulder condition continued to be consistently attributed to her vaccination. (See, e.g. Ex. 2, pp. 8, 9, 37; Ex. 3, p. 2.)

Nonetheless, two conflicting copies of petitioner’s vaccination record have been filed. (Ex. 1; Ex. 2, pp. 2-3.) Petitioner’s medical records from Dr. Sands include a copy of petitioner’s Vaccine Consent and Administration Record. (Ex. 2, pp. 2-3.) Contrary to the above, it indicates petitioner received her vaccination in her left deltoid. (*Id.* at 3.) Additionally, petitioner separately filed as Exhibit 1 a copy of her vaccination record that she obtained herself. (Ex. 1; Ex. 8, p. 1.) That record indicates that petitioner’s vaccination was administered in her right arm. (Ex. 1.)

Petitioner averred that she obtained the record at Exhibit 1 directly from the CVS pharmacy on June 7, 2017. (Ex. 8, p. 1.) Upon reviewing the record, petitioner determined that the record incorrectly indicated that petitioner had received her vaccination in her left arm rather than her right arm. (*Id.*) She indicated that she returned to the pharmacy “a few days later” and that Raed Ahmed, the pharmacy

manager, amended her record to correct the site of administration. (*Id.*) The vaccination record at Exhibit 1 includes a handwritten notation striking out “left” deltoid as the site of administration and writing in “right.” (Ex. 1.) This alteration is initialed “R.A.” (*Id.*)

Petitioner further averred that she again returned to the CVS pharmacy on June 22, 2018, after respondent raised an issue regarding her evidence of vaccination in this case. (Ex. 8, p. 1.) At that time, she was informed by Samuel Bright that Mr. Ahmed no longer worked at that CVS location. (*Id.*) However, Dr. Bright provided a handwritten note authenticating Mr. Ahmed’s initials on petitioner’s vaccination form. (Ex. 8, pp. 1-2; Ex. 7.)

In deposition testimony, Mr. Ahmed confirmed that he was the manager at the CVS location where petitioner received her vaccination at the time she received her vaccination. (Ex. A, pp. 10-11.) Mr. Ahmed explained that at CVS documentation of the vaccinations administered, including the Vaccine Consent and Administration Record, are generated at the beginning of the technician’s encounter with the patient. (*Id.* at 14-15.) He indicated that these forms include a printed description of the site of administration (left versus right deltoid). (*Id.* at 15-16.) Mr. Ahmed further explained that, once collected, the electronic information cannot be changed or deleted at the pharmacy level. (Ex. A, p. 17.) However, it is the normal practice at CVS to determine the site of administration for a vaccination only after these forms have been generated. (*Id.* at 22-23.) As a result, Mr. Ahmed testified that it is common for CVS vaccination records to be altered by hand as to the site of administration. (*Id.* at 22-23, 27-28, 39-40.) He indicated that it happens “quite often.” (*Id.* at 28.)

Mr. Ahmed did not recall petitioner or ever talking with her. (Ex. A, p. 16-18, 28-29.) However, he indicated that the signature on her vaccination record is his own.³ (*Id.* at 21.) He also authenticated his handwritten initials on the vaccination record and confirmed that based on the record with his notation, he would have administered petitioner’s vaccination in her right deltoid. (*Id.* at 23.) Mr. Ahmed testified that this notation would have been made at the time of the vaccination and not subsequently. (Ex. A, pp. 23-24, 32-33.) He testified that he would not have changed the record after-the-fact even if asked. (*Id.* at 25, 32-34.)

Mr. Ahmed testified that the consent forms are not retained electronically, but that a physical copy is stored on site at the pharmacy. (Ex. A, pp. 30-31, 42.) He indicated that the pharmacy sometimes gets requests for records. (*Id.* at 35-36.) Record requests from physicians’ offices are handled by the CVS Privacy Office and not directly by the pharmacy. (*Id.*) Mr. Ahmed testified he is not familiar with that process. (*Id.* at 36.) However, with regard to the additional, unaltered copy of petitioner’s vaccination record contained in Dr. Sands’ records, Mr. Ahmed indicated that he is not surprised that it exists. (*Id.* at 37-38.) He explained that at the beginning of the encounter two copies of the document are produced, one for pharmacy records and one for the vaccinee to keep. (*Id.*) He reasoned, but could not confirm, that the additional

³ Despite the fact that Mr. Ahmed authenticated his own signature on the document, the vaccination lists Orlando Flores as the administering immunizer. Mr. Ahmed indicated that the fact of his signature on the document indicates that he certified that he had reviewed the form with petitioner and confirmed the lack of any contraindication, but that he could not tell from the signature whether he or Mr. Flores administered the vaccination. (Ex. A, pp. 21-22.)

copy is the patient copy and that he neglected to correct both copies of the form when petitioner was vaccinated. (*Id.*)

Dr. Bright testified in deposition that he took over management of the CVS location where petitioner was vaccinated in February or March of 2018. (Ex. B, p. 9.) He indicated that he was Mr. Ahmed's direct successor in the position. (*Id.*) He offered testimony regarding storage of the vaccine consent forms consistent with the description offered by Mr. Ahmed.⁴ (Ex. B, pp. 14-15.) Dr. Bright also testified that the process for amending vaccine records to change the site of vaccination as described by Mr. Ahmed is consistent with CVS policy. (*Id.* at 16-17.) He agreed that it is "not uncommon," estimating that it happens about ten percent of the time. (*Id.* at 21, 36.)

Dr. Bright recalled meeting petitioner on one occasion. (Ex. B, p. 17.) He explained that petitioner came to the pharmacy and asked him to authenticate Mr. Ahmed's initials on her vaccine record. (*Id.* at 17-18.) He authenticated the handwritten note filed at Exhibit 7. (*Id.* at 26.) He further testified that in his one meeting with petitioner he had agreed that, to the best of his knowledge, the initials on the document filed as Exhibit 1 were Mr. Ahmed's. (*Id.* at 18, 26-27.) Dr. Bright indicated that his authentication was based on his knowledge of Mr. Ahmed's handwriting and that he does not know when the notation was written. (*Id.* at 20, 22, 35.) He never spoke to Mr. Ahmed about the record. (*Id.* at 26.) Dr. Bright disclaimed any knowledge of whether the record was correct. (*Id.* at 26-29.) With regard to the additional, unaltered vaccination record within Exhibit 2, Dr. Bright did not know how that would have come into Dr. Sands' possession. He indicated that the patient copy of the form would not be an exact duplicate in that it would be blank, unlikely to have the immunizer's signature or the checkboxes completed. (*Id.* at 38-41.)

III. Party Contentions

In his motion for a finding of fact, respondent stresses the fact that petitioner's and Mr. Ahmed's accounts regarding the alteration of the vaccine record are in conflict. (ECF No. 49, p. 3.) While petitioner indicates the record was amended in June of 2017 (Ex. 8, p. 1), Mr. Ahmed testified that he only would have made the correction at the time of the vaccination. (ECF No. 49, p. 3 (citing Ex. A, pp. 21-22).) Respondent also cites Dr. Bright's testimony that he believes the record within Exhibit 2 would have been the original. (ECF No. 49, pp. 3-4.) Respondent stresses that both pharmacists testified that they would not change a vaccination record after the fact because they would not be able to recall the details. (*Id.*)

Respondent argues that "[a]side from the changed record, petitioner's only support for her allegation that the shot was administered in her right arm is her own affidavit. Because the [Vaccine] Act prohibits a special master from finding in favor of entitlement 'based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion,' 42 U.S.C. § 300aa-13(a)(1), petitioner must provide

⁴ Dr. Bright indicated, however, that he would fax a copy of a vaccine record directly to a physician's office. (Ex. B, p. 16.)

corroborating evidence to be entitled to compensation.”⁵ (ECF No. 49, p. 5.) In light of the conflicting vaccination records, respondent contends there is not adequate proof regarding the location of the vaccination. (*Id.* at 5.)

In his Rule 4 Report, respondent recommends against compensation in this case. (ECF No. 47, p. 6.) Respondent identifies the same injection site issue discussed in his motion as detrimental to petitioner’s case, suggesting that “the records do not establish by preponderant evidence that the flu vaccination at issue was given in petitioner’s right arm.” (*Id.* at 5.)

Additionally, respondent argues that “petitioner’s medical records do not establish that she suffered the onset of her alleged vaccine-induced injury within 48 hours of her vaccination.” (ECF No. 47, p. 5.) Respondent notes that “[a]t her first medical visit after receiving the flu vaccine, petitioner reported that her shoulder pain began “since receiving the flu shot at pharmacy 9/30/14.” (*Id.* (citing Ex. 2, p. 12).) Respondent characterizes such notations as offering “a relative time frame for the onset of shoulder pain,” but argues that they “do not clearly demonstrate that petitioner’s shoulder pain began within 48 hours of vaccine administration.” (ECF No. 47, p. 5.)

In response, petitioner argues that she explained the differing vaccine records in her supplemental affidavit. (ECF No. 50, p. 5.) She further notes that, but for the timing of the correction, her explanation is corroborated by Mr. Ahmed’s testimony authenticating his notations on the vaccine record. (*Id.* at 6.) Petitioner further stresses that her allegation that the vaccine was administered in her right shoulder is also corroborated by her other medical records. (*Id.* at 7.) Petitioner disputes respondent’s interpretation of the medical records as insufficient to place onset of petitioner’s condition within 48 hours of her vaccination. (*Id.* at 8-9.) Petitioner contends that the medical records are clear in indicating that petitioner’s pain began the day of her vaccination and further stresses that based on petitioner’s report of pain since vaccination, her physician attributed her condition to her vaccination. (*Id.*)

IV. Findings of Fact

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a “preponderance of the evidence.” § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

⁵ In fact, several prior decisions within this program have held that the fact of vaccination need not be supported by medical records or opinion pursuant to Section 13(a) of the Vaccine Act. See, e.g., *Centmehaiey v. HHS*, 32 Fed. Cl. 612 (1995), *aff’d* 73 F.3d 381 (Fed. Cir. 1995) (stating that “[t]he lack of contemporaneous, documentary proof of a vaccination, however, does not bar recovery.”); see also *Wonish v. HHS*, No. 90-667V, 1991 WL 83959 (May 6, 1991) (Fed. Cl.) (stating that “[v]accination is an event that in ordinary litigation could be established by lay testimony. Medical expertise is not typically required.”); *Woodson v. HHS*, No. 91-263V, 1992 WL 59707 (Mar. 5, 1992) (Fed. Cl.) (finding that “the petition should not be dismissed as a matter of law merely because there is no documentary evidence that the vaccination took place and [petitioner] is the only witness claiming personal knowledge of the vaccination. Her testimony on this point must be weighed in the context of the entire record.”). In any event, as described below the undersigned has found significant evidence corroborating petitioner’s allegation, including corroborating medical records.

a. Finding of Fact Regarding Injection Site

Upon review of the entire record and consideration of the parties' briefing, the undersigned finds that there is preponderant evidence that petitioner's September 30, 2014 influenza vaccination was administered in her right deltoid. Contrary to respondent's argument, petitioner has filed substantial evidence that the vaccine was administered in her right shoulder.

First, petitioner provided a vaccination record that so indicates. (Ex. 1.) Moreover, the notation of a right shoulder administration on that record has been authenticated by two individuals. (Ex A, p. 23; Ex. B, pp. 18, 26-27; Ex. 7.) And significantly, both pharmacists testified that notations such as those appearing on petitioner's vaccination record are routine.⁶ (Ex. A, p.28; Ex. B, p. 21, 36.) Additionally, based on that record, Mr. Ahmed testified that he administered the vaccination in petitioner's right shoulder. (Ex. A, p. 23.)

To the extent an additional unaltered record has been filed reflecting the left shoulder, Mr. Ahmed explained that he likely amended only the pharmacy's copy of the record (Ex. A, p. 37-38), potentially explaining the discrepant records. The undersigned does not find evidence in the record sufficient to explain how Dr. Sands obtained the unaltered copy of the vaccine record.⁷ Additionally, although Dr. Bright offered testimony opining on these questions, the undersigned does not find his testimony useful in resolving this issue because he testified that he had no personal knowledge of the accuracy of the records at issue in this case. (Ex. B, p. 26-29.)

Most significantly, however, petitioner's contemporaneous treatment records consistently attribute petitioner's right shoulder injury to the vaccination she received on September 30, 2018. This provides strong corroborating evidence that petitioner received her vaccination in her right arm. *See, e.g. Parker v. HHS*, No. 15-1331V, 2016 WL 3443929 (Fed. Cl. Spec. Mstr. May 13, 2016)(finding that a vaccine record recording administration in the left arm was incorrect based primarily on petitioner's consistent attribution of his right shoulder condition to his vaccination throughout his treatment). Upon the undersigned's review, petitioner linked her right shoulder condition to her vaccination the very first time she sought treatment and the remainder of petitioner's medical records consistently link petitioner's right shoulder condition to

⁶ Specifically, Mr. Ahmed characterized the practice as occurring "quite often" while Dr. Bright indicated that it is "not uncommon." (Ex. A, p. 28; Ex. B, pp. 21, 36.) Dr. Bright additionally estimated that it occurs about ten percent of the time. (Ex. B, p. 36.)

⁷ There were some questions during the depositions suggesting that a date stamp bannered across the top of the vaccine record at Exhibit 2, pages 2 and 3, may indicate that the record was faxed to Dr. Sands on March 8, 2017. Respondent again noted this potential transmittal date in his motion for a finding of fact. (ECF No. 50, p. 4, n. 3.) The undersigned notes, however, that this date stamp appears on all 51 pages of medical records from Dr. Sands' office and is not unique to the vaccine record. Nor does the date stamp indicate whether the fax was incoming or outgoing or even necessarily confirm that it is a fax transmittal date. Thus, it does not appear that the date stamp reflects a time at which the vaccine record was provided by fax to Dr. Sands. It likely suggests that Dr. Sands had the record in his possession no later than March 8, 2017.

the same vaccination. The undersigned found no notation in any of petitioner's treatment records that is contrary or inconsistent on that point.

Moreover, the first of these treatment records was generated only two weeks following the vaccination and long before petitioner reportedly returned to CVS to obtain a copy of her vaccination record. Specifically, on October 15, 2014, Dr. Sands wrote, not only that petitioner attributed her right shoulder condition to her vaccination, but also explicitly that "Pt. received flu shot 9/30/14 in R deltoid." (Ex. 2, p. 12; Ex. 5, p. 8.) For this reason, the undersigned does not find the timing of the amendment to petitioner's vaccine record to be a significant issue. Petitioner's consistent and contemporaneous treatment records would provide preponderant evidence overcoming the contrary or incorrect vaccination record (at Ex. 2, pp. 2-3) even in the complete absence of an amended record by Mr. Ahmed (at Ex. 1).

b. Finding of Fact Regarding Onset

Upon review of the entire record and consideration of the parties' briefing, the undersigned finds that there is preponderant evidence that petitioner's right shoulder pain began within 48 hours of her vaccination. Respondent argues that petitioner's records are insufficient to establish that onset of petitioner's condition was within 48 hours of vaccination; however, the undersigned disagrees.

As noted above, petitioner first sought treatment for her shoulder injury on October 15, 2014, just a little over two weeks following her vaccination. (Ex. 2, p. 12; Ex. 5, p. 8.) At that time, she presented with a chief complaint of "pain in R shoulder since receiving flu shot at pharmacy 9/30/14." (*Id.*) The undersigned disagrees with respondent's characterization of this notation as indicating "a relative time frame for the onset of shoulder pain." (ECF No. 47, p. 5.) To the contrary, the undersigned finds the notation to be an explicit statement that petitioner's shoulder pain began on September 30, 2014, which is within 48 hours of petitioner's vaccination.

Moreover, even if the notation at issue did constitute only a "relative time frame," the undersigned would still find preponderant evidence that the onset of petitioner's pain was within 48 hours of vaccination. *See, e.g. Cooper v. HHS*, No. 16-1387V, 2018 WL 1835179, at *5, n. 13 (Fed. Cl. Spec. Mstr. Jan. 18, 2018) (noting with regard to petitioner's medical records that "the undersigned recognizes that many of these records are imprecise regarding onset . . . It is sufficient that, petitioner's vaccination having occurred on October 30, the reported timeframe of early November reflected by the record as a whole does encompass the 48 hour post-vaccination period."). In this case, there is no suggestion that petitioner's history of onset was recorded in her medical records verbatim; however, the history she provided was sufficient for her physician to attribute her condition to her vaccination, characterizing it as an "adverse effect flu shot." (Ex. 2, p. 12; Ex. 5, p. 8.)

Additionally, petitioner averred that her shoulder pain began within 48 hours of vaccination, indicating that she was uncomfortable the day of her vaccination and that her pain increased the next day. (Ex. 6, p. 1.) This is also further corroborated by petitioner's subsequent treatment records. Respondent has not contended that any of

petitioner's medical records suggest that onset was *not* within 48 hours. Nor has the undersigned located any such record upon her own review.

V. Conclusion

In light of all of the above and in view of the record as a whole, the undersigned finds (1) that petitioner's September 30, 2014 influenza vaccination was administered into her right deltoid and (2) that the onset of petitioner's alleged shoulder pain resulting from her vaccination began within 48 hours of the administration of the September 30, 2014 influenza vaccination.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master