

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1341V

Filed: May 30, 2018

WOSSEN TARIKU,

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Petitioner,

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v.

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Douglas Lee Burdette, Burdette Law, PLLC, North Bend, WA, for petitioner.

Lara Ann Englund, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT ¹

Dorsey, Chief Special Master:

On October 14, 2016, Wossen Tariku (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et. seq, (the “Vaccine Act” or “Program”). Petitioner alleges that he suffered a shoulder injury related to vaccine administration (“SIRVA”), which was caused-in-fact by one or both of the vaccinations he received on September 8, 2015 – the Fluzone Quad or Flulaval quadrivalent influenza (“flu”) vaccine, and Tetanus Diphtheria acellular Pertussis (“Tdap”) vaccine. Petition at 1. The case was assigned to the Special Processing Unit (“SPU”).

I. Procedural History

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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). 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.

Following the filing of his petition, petitioner periodically filed supporting evidence including medical records (Pet.'s Exs. 2-4, ECF No. 7; Pet.'s Ex. 5, ECF No. 11; Pet.'s Exs. 6-8, ECF No. 14; Pet.'s Ex. 9, ECF No. 21) and his declaration (Pet.'s Ex. 1, ECF No. 7).²

Respondent filed a Rule 4(c) report on March 6, 2017. Resp. Report, ECF No. 25. In this report, respondent stated that the Division of Injury Compensation Programs ("DICP") at the Department of Health and Human Services had determined Mr. Tariku's case was not appropriate for compensation. Respondent argues that petitioner has not established that his injury was caused-in-fact by the vaccination(s) he received on September 8, 2015, specifically:

[P]etitioner has not provided evidence that satisfies his burden of proof under *Althen*. First, petitioner has not offered a persuasive medical theory linking the vaccinations to his condition. Petitioner has not submitted an expert report. Second, there is no evidence of a logical sequence of cause an effect showing that the vaccinations were the reason for the injury. There is no evidence in the contemporaneous medical records that the vaccines were given in petitioner's left arm. Third, petitioner has not shown a proximate temporal relationship between the vaccinations and his injury. Petitioner did not report any shoulder pain until November 3, eight weeks after the vaccinations. At that time, he did not attribute the pain to his vaccinations. Ex. 2 at 17-18. Petitioner first mentioned a vaccine as a possible cause of his injury on March 30, 2016, more than six months after vaccination. Ex. 5 at 1-4. He never reported that his pain began within forty-eight hours after he received the vaccines.

Resp. Report at 5 (citing *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005)).

Following respondent's report, the undersigned provided petitioner with an opportunity to file an affidavit explaining his delay in seeking treatment for his alleged injury. Order, ECF No. 26. Petitioner filed his affidavit on May 9, 2017. ECF No. 27.

A status conference was held on June 29, 2017, during which the parties stated a preference for proceeding with a fact hearing before the undersigned. Order, ECF No. 30. A fact hearing was thereafter scheduled for November 16, 2017. Order, ECF No. 32.

In preparation for the scheduled fact hearing, petitioner filed a witness affidavit from his friend, Samrawit Tesfaye. Pet.'s Ex. 10, ECF No. 34-1.

² Petitioner filed two exhibits designated as "Exhibit 1." The first, filed on October 20, 2016 (Pet.'s Decl., ECF No. 7-1), and another filed on October 21, 2016 (Pet.'s Record Request upon Neighborcare Health at Pike Place, ECF No. 8-1). The citations herein to "Pet.'s Ex. 1" refer to petitioner's October 20, 2016 declaration.

A fact hearing was held on November 16, 2017 in Washington, DC. Petitioner testified via videoconference. At the conclusion of the hearing, the undersigned made preliminary findings of fact regarding the shoulder location to which petitioner's vaccinations were administered, as well as the onset and causation of petitioner's injury. Order, ECF No. 37; Hr'g Tr. (Tr.), ECF No. 39, at 30-33. The undersigned's findings were informed by the SIRVA criteria as well as the medical articles referenced during the proposed rulemaking when SIRVA was incorporated into the Vaccine Table. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052) (filed as Court Exhibit I); and Bodor M, and Montalvo E, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007) (filed as Court Exhibit II)).

A schedule was set following the hearing to allow the parties an opportunity to file any additional relevant evidence and responses to Court Exhibits I and II. *Id.* The undersigned additionally notified the parties that the evidentiary record in regard to entitlement would close 30 days from the filing of the hearing transcript. *Id.*

The certified transcript of the November 16, 2017 fact hearing was filed on December 28, 2017, ECF No. 29. No additional evidence or responses to court's exhibits were filed and the record on entitlement closed on January 29, 2018. Order, ECF No. 37. The matter is now ripe for ruling.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen*, 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not

only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit held that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* These requirements were reiterated by the Circuit court in *Althen*:

to show by preponderant 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.

418 F.3d at 1278. All three prongs of *Althen* must be satisfied. *Id.*

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A),(B),(D) and (E). With regard to duration, a petitioner must establish she

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization **and** surgical intervention.

§ 11(c)(1)(D) (emphasis added).

III. Analysis - *Althen* Prongs

A. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. See *Pafford v. Sec’y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for review denied*, 64 Fed. Cl. 19 (2005), *aff’d*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. See, e.g., *Pafford*, 451 F.3d at 1355 (reputable); *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir.

2010) (reliable). Petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

1. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table (“Table”). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner’s claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned’s findings are informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

a) The elements of petitioner’s SIRVA claim

The undersigned’s findings and conclusions are as follows:

(1) Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Mr. Tariku’s medical history prior to his September 8, 2015 flu and Tdap vaccinations and found that petitioner did not have a history of pain, inflammation or dysfunction of his left shoulder prior to vaccination. Tr. 31. Thus, petitioner satisfies this criteria.

(2) Onset occurred within the specified time frame.

Respondent argues that petitioner “has not shown a proximate temporal relationship between the vaccinations and his injury” and “never reported that his pain began within forty-eight hours after he received the vaccines.” Resp. Rep. at 5.

At the conclusion of the November 16, 2017 fact hearing, however, the undersigned found that the onset of petitioner's left shoulder pain occurred within 48 hours of his September 8, 2015 vaccinations. Tr. 31. The undersigned based that finding on petitioner's testimony as well as the history documented by petitioner's physical therapist, Kevin Olson, on May 5, 2016, providing: "Mechanism of injury: Pain within 48 hours following flu and tetanus shot." *Id.* (citing Pet.'s Ex. 4 at 9). Further support for the undersigned's finding is summarized below.

Petitioner asserts that his left shoulder pain started within 48 hours after he received the flu and Tdap vaccinations on September 8, 2015. Pet.'s Ex. 1 ¶5 (Pet.'s Decl.); Tr. 9-10. Petitioner testified that the evening he received the vaccines he felt soreness and warmth in his left arm. Tr. 10. Petitioner recalls discussing his pain immediately following vaccination with his sister, friend, and consulting the internet. Tr. 10; Pet.'s Aff., ECF No. 27, at 1. Petitioner states his research led him to believe the pain was expected and could last 30 days. Tr. 10. Petitioner further recalls awakening with tremendous pain and stiffness in his left shoulder the morning after receiving the vaccinations. Tr. 12.

Petitioner's friend, Samrawit Tesfaye, avers that petitioner spoke with her about his left arm pain the same day he received the Tdap and flu vaccinations as well as the day after. Pet.'s Ex. 10 at 1-2. Ms. Tesfaye recalls telling petitioner the pain would go away over time. *Id.*

On November 3, 2015, petitioner reported to his primary care provider left shoulder pain lasting for two months which was assessed as shoulder tendonitis. Pet.'s Ex. 2 at 17-18. In continuing to seek care for his left shoulder pain, petitioner often attributed the start of his pain to receiving the Tdap and flu vaccinations. Pet.'s Ex. 5 at 1-4; Pet.'s Ex. 4 at 2-4, 9.

Although respondent asserts that petitioner's delay in seeking treatment for his left shoulder pain undermines a finding that his pain began within 48 hours, petitioner's affidavit and testimony provide a credible and persuasive explanation for this delay. Petitioner's account of the immediate onset of his left shoulder pain, in addition to being detailed, is supported by the recollection of his witness, Samrawit Tesfaye.

Based upon the totality of the evidence set forth in the medical records, affidavits, and testimony, the undersigned finds that the onset of petitioner's shoulder pain was within 48 hours of his September 8, 2015 flu and Tdap vaccinations, and therefore, is within the Vaccine Table specified time frame of ≤ 48 hours. § 13(a)(1)(A) (preponderant standard).

(3) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

Although petitioner's vaccination record (Pet.'s Ex. 2 at 4-6) does not indicate so, the undersigned previously found, based on the record as a whole, that the vaccinations

Mr. Tariku received on September 8, 2015 were administered to his left shoulder. Tr. 30. The undersigned likewise found that petitioner's pain and reduced range of motion were limited to the shoulder in which he received the September 8, 2015 flu and Tdap vaccinations. Tr. 31-32.

The undersigned's findings are supported by petitioner's submitted evidence including various medical records detailing the treatment Mr. Tariku sought for his *left* shoulder pain after his September 8, 2015 vaccinations through December 2016. Throughout these records, petitioner consistently seeks treatment for pain limited to his left shoulder. A summary of these records follows below.

Petitioner saw his primary care provider, Dr. Richard D. Kovar, on October 27, 2015 for a persistent cough and underwent a chest x-ray. Pet.'s Ex. 2 at 13-15. Although not noted in the visit record, petitioner insists he mentioned his left shoulder pain to his provider during this visit. Pet.'s Ex. 1 at ¶6; Pet.'s Aff. at ¶2; Tr. 13-14. Petitioner testified that at that appointment he refused a cortisone injection offered by Dr. Kovar and was given a sheet of exercises to perform. Tr. 14. Petitioner returned to Dr. Kovar a week later; the record of this visit indicates that petitioner sought treatment for left shoulder pain persisting for two months and he was assessed with left shoulder tendonitis. Pet.'s Ex. 2 at 17-18. Petitioner recalls that during this November 3, 2015 appointment with Dr. Kovar he specifically indicated his belief that the pain was caused by the vaccinations he received in September 2015. Tr. 15. There is no notation of this in the accompanying medical record. Petitioner described Dr. Kovar as dismissive of the suggestion that his shoulder injury was vaccine related. Tr. 14. Petitioner testified that he sought care for his left shoulder from another provider after being "frustrated" with Dr. Kovar. Tr. 17.

On March 30, 2016, petitioner saw a new primary care provider, Dr. Randy Wang. Pet.'s Ex. 5 at 1-4. At this visit, petitioner attributed his left shoulder pain to the Tdap and Flu vaccinations he received. *Id.* Dr. Wang assessed petitioner with adhesive capsulitis and referred him to an orthopedist. *Id.* Petitioner returned to Dr. Wang on April 29, 2016 for continued left shoulder pain and was referred to a neurologist. Pet.'s Ex. 5 at 7-10. Petitioner testified that he was unable to locate an available neurologist that accepted his insurance. Tr. 17.

Petitioner instead saw an orthopedist, Dr. Omar Bhatti, on May 2, 2016. At this visit, petitioner reported that his left shoulder pain began after receiving the flu and tetanus vaccinations in September 2015. Pet.'s Ex. 4 at 2-4. Dr. Bhatti's exam showed petitioner had a reduced range of motion in the left shoulder with positive impingement signs. *Id.* An x-ray was performed and evaluated to be normal. *Id.* Dr. Bhatti's impression was left adhesive capsulitis and he referred petitioner to physical therapy. *Id.* Petitioner attended eight physical therapy sessions between May 5, 2016 and September 15, 2016. Pet.'s Ex. 9 at 4-11.

Petitioner returned to Dr. Bhatti on November 21, 2016 reporting some improvement with his left shoulder range of motion since physical therapy, but continued

weakness when lifting objects. Pet.'s Ex. 9 at 12-16. Dr. Bhatti referred petitioner for an MRI and told petitioner to continue his at home exercises. *Id.*

Petitioner underwent a left shoulder MRI on December 2, 2016. Pet.'s Ex. 6. The results showed a partial thickness tear of the articular surface of the supraspinatus tendon; possible tears of the mid anterior labrum and inferior posterior labrum; and "possibly early adhesive capsulitis." *Id.* During a follow-up appointment with Dr. Bhatti on December 19, 2016, petitioner reported intermittent left shoulder pain and trouble performing daily activities such as reaching for objects, putting on his coat, and "general overhead activities." Pet.'s Ex. 8 at 4-6. Following Dr. Bhatti's evaluation, petitioner opted to continue with his home exercise routine rather than pursue a cortisone injection or surgical intervention. *Id.*

Based on petitioner's medical records, affidavit evidence, and hearing testimony, the undersigned finds that the pain and decreased range of motion petitioner experienced are limited to his left shoulder in which he received the September 8, 2015 flu and Tdap vaccinations. Thus, petitioner has satisfied this SIRVA criteria.

(4) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

The undersigned previously found that "there is no other condition or abnormality identified by Dr. Kovar, Dr. [Bhatti] or Dr. Randy Wang revealed in the medical records or the testimony given by Petitioner . . . which would explain [petitioner's] symptoms." Tr. 32.

Having satisfied each of the four SIRVA criteria, petitioner has therefore provided preponderant evidence to establish a medical theory of causation as required under the first prong of *Althen*.

B. Logical sequence of cause and effect showing the vaccine was the reason for the injury

The undersigned finds that since petitioner has satisfied all four Table SIRVA injury criteria (see section III.A.1), he has established, by preponderant evidence, a logical sequence of cause and effect showing that his September 8, 2015 flu and Tdap vaccinations were the reason for his left shoulder injury. Petitioner has thus satisfied *Althen* prong two.

Moreover, based on the undersigned's knowledge and experience reviewing a large number of SIRVA claims, petitioner's clinical course is consistent with SIRVA. The undersigned further bases this finding on the previously filed medical literature, Court Exhibit I (Atanasoff et al.) and Court Exhibit II (Bodor & Montalvo).

C. Proximate temporal relationship between vaccination and injury

“The proximate temporal relationship prong [under *Althen*] 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). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. See *Langland v. Sec’y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner’s shoulder injury must begin within 48 hours or less of the vaccination. The undersigned has found that the onset of petitioner’s shoulder injury began within 48 hours of the vaccination, and thus, petitioner has satisfied *Althen* prong three.

D. Duration of Injury

Under the Vaccine Act, a petition for compensation must contain “supporting documentation, demonstrating that the person who suffered [a vaccine related injury] ... suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa–11(c)(1)(D)(i). The burden of establishing, by a preponderance of the evidence, the persistence of a vaccine-caused injury for longer than six months is borne by petitioners. *Song v. Sec’y of Health & Human Servs.*, 31 Fed. Cl. 61, 65–66, *aff’d*, 41 F.3d 1520 (Fed.Cir.1994). However, dismissal is not appropriate if it appears the parties reasonably contest the length of time that petitioner has suffered from the effects of his alleged vaccine injury. See, e.g., *Faup v. Sec’y of Health & Human Servs.*, No. 12-87V, 2015 WL 443802, at *4 (Fed. Cl. Sepc. Mstr. Jan. 13, 2015).

Although a petitioner cannot establish the length or ongoing nature of an injury merely through his self-assertion, the fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from his or her alleged injury. See, e.g., *Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (finding that a petitioner suffered from residual symptoms that due to their mild nature did not require medical care).

Here, there is no dispute that petitioner received both the flu and Tdap vaccinations on September 8, 2015, and he must therefore show that his alleged injury lasted more than six months after administration of the vaccinations. *Herren*, 2014 WL 3889070, at *2; see also *Hinnefeld v. Sec’y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner’s Guillain-Barré syndrome resolved less than two months after onset). Thus, petitioner must demonstrate by preponderant evidence that his injuries continued through March 9, 2016.

The medical records submitted by petitioner show that he continued to seek treatment for his left shoulder pain throughout 2016. See e.g. Pet.'s Ex. 5 at 1-4 (Mar. 30, 2016 PCP assessment of left shoulder adhesive capsulitis); Pet.'s Ex. 4 at 2-4 (May 2, 2016 orthopedist record including impression of left shoulder adhesive capsulitis); Pet.'s Ex. 9 *passim* (Records of petitioner's left shoulder physical therapy from May 2016 through Sept. 2016); Pet.'s Ex. 6 (Dec. 2, 2016 left shoulder MRI). Thus, petitioner has satisfied the six month requirement under 42 U.S.C. § 300aa-11(c)(1)(D)(i).

IV. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records and hearing testimony, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master