

I. Facts

Ms. Sawvell received the Prevnar 13 vaccination at issue on April 10, 2015 from Dr. Robert Key at the Prairie Du Chien Mayo Clinic in Prairie Du Chien, Wisconsin. ECF No. 10 at 236. At the time of vaccination, Ms. Sawvell was 65-years old with hypertension and hypothyroidism. Id. She had a family history of prostate, skin, uterine, lung, breast, brain, and adrenal cancers. Id. at 11-17.

Petitioner was seen by Dr. Ryan Jawitz on November 25, 2015 for an evaluation of “suspicious growths” and skin lesions located on her chest and left shoulder. ECF No. 1-3 at 15. She reported that the lesions were asymptomatic, and had been present “for months.” Id. Dr. Jawitz’s exam revealed “light tan macules in sun distribution,” regular and symmetric even-colored macules and papules throughout petitioner’s body, bright red papules located on the body, and “stuck-on, warty, greasy brown papules with pseudo-horn cysts located on [petitioner’s left shoulder] and on the body throughout” Id. Dr. Jawitz diagnosed Ms. Sawvell with dermatoheliosis, or photo-aging from excessive sun exposure, benign nevi, acitinic keratoses, angioma, seborrheic keratoses, and neoplasm of uncertain behavior, classified as either a cyst, lipoma, nevus, or pilloleiomyoma. Id. at 15-16. Dr. Jawitz conducted a punch biopsy of petitioner’s left shoulder cyst because Ms. Sawvell reported that it was “itchy and painful.” Id. at 16.

Ms. Sawvell returned to Dr. Jawitz on December 9, 2015 to follow up on her biopsy. ECF No. 1-3 at 20. Dr. Jawitz noted that Ms. Sawvell’s wound was healing and that the results of her biopsy were negative, classifying her cyst as a “benign neoplasm.” Id.

Ms. Sawvell did not file any medical records documenting treatment during the years of 2016 and 2017; she was next seen by Dr. Stevel Halbreich on November 19, 2018 for a “left upper extremity mass.” ECF No. 1-3 at 22. Ms. Sawvell reported that the lump had been there for “about 2 years” and had become red and warm to the touch. She associated the lump with her flu shot², and explained that it continued to get larger as it went untreated. Id. Dr. Halbreich excised the mass and submitted it for analysis. Id. at 25. A November 21, 2018 surgical pathology report noted that the cyst was malignant, diagnosed as a “high grade myxofibrosarcoma,” and that Ms. Sawvell’s case would be forwarded to the

² Ms. Sawvell clarifies in her petition that she “may have unknowingly said flu instead of pneumonia vaccine or they recorded it incorrectly. I have never had a flu shot.” Pet. Filed May 11, 2020 at 13.

Soft Tissue Pathology department at Emory Hospital in Atlanta, Georgia. Id. at 28-30. Ms. Sawvel returned to Dr. Halbreich on November 28, 2018 where she was informed about the malignancy. It was recommended that further surgical excision be performed to clear the margins of the lesion as well as a lymph node biopsy to rule out any metastasis. Id. at 36-37.

Dr. Sharon Weiss of Emory Healthcare in Atlanta, Georgia returned a pathology report on Ms. Sawvell's cyst on December 4, 2018. ECF No. 1-3 at 39. Dr. Weiss wrote that the slides of petitioner's biopsy were consistent with a "sarcoma composed of fascicles of atypical spindle cells punctuated with large pleomorphic ones." Id. Dr. Weiss wrote that she would consider petitioner's lesion an "undifferentiated pleomorphic sarcoma with focal myxoid areas, also [referred to as a] high grade myxofibrosarcoma." Id.

Following her sarcoma diagnosis, Ms. Sawvell began treatment and monitoring at Moffitt Cancer Center ("Moffitt") on December 18, 2018. ECF No. 10 at 11. On her new patient questionnaire, Ms. Sawvell stated the sarcoma first appeared in April 2015 following a Prevnar 13 vaccination. Id. at 12. She listed a medical history of thyroid radiation treatments, polymyalgia rheumatica, and a family history of prostate, skin, uterine, lung, breast, brain, and adrenal cancers. Id. at 13, 15. At Moffitt, Ms. Sawvell was seen by Drs. Ricardo Gonzales and Arvind Sabesan who recommended an MRI and staging CT to identify any residual tumor tissue, preoperative radiation therapy, and a final excision of any residual tissue affected by the sarcoma. Id. at 19-20, 144-45.

Ms. Sawvell received a radiation oncology consult from Dr. Russell Palm for pre-operative radiation therapy on December 31, 2018. ECF No. 10 at 125-30. Later, she received a surgical consultation from Dr. Julian Pribaz who explained that petitioner will likely need reconstructive surgery, specifically, a flap repair, following the excision. Id. at 142-43. Ms. Sawvell received an additional opinion regarding her sarcoma from Dr. Marilyn Bui on January 8, 2019. Dr. Bui concurred with Dr. Weiss' December 4, 2018 pathology report. Id. at 39.

Petitioner continued to receive regular radiation therapy leading up to her excision on April 12, 2019. ECF No. 1-3 at 44-45, 50-55. Following the excision, petitioner received reconstructive surgery for her surgical scar on October 22, 2019 to provide greater mobility and relieve discomfort. Id. at 57. Petitioner continues to receive regular check ups to monitor her sarcoma for any signs of reoccurrence. ECF No. 10 at 32-36, 45, 74, 77, 158, 164.

II. Procedural History

Ms. Sawvell filed a petition for compensation and initial medical records on May 11, 2020. Pet., filed May 11, 2020, at 1. Following the court's pre-assignment review process, this case was assigned to Chief Special Master Corcoran on May 15, 2020 and subsequently reassigned to my docket on May 20, 2020. ECF Nos. 4, 6.

After this case was reassigned to the undersigned's docket, an order set an initial status conference and described various procedural considerations that should be kept in mind during the pendency of petitioner's claim. Initial Order, issued May 22, 2020. The initial status conference was held on June 9, 2020. During that conference, the undersigned spoke with petitioner regarding her representation, provided a list of attorneys who may be interested in taking her case, and discussed potential obstacles in her case including the statute of limitations and issues relating to causation. The undersigned also explained the need for petitioner to submit additional medical records or a medical opinion to support her theory of causation. The undersigned concluded the status conference directing petitioner to obtain all of the necessary medical records and explaining the process for filing as a *pro se* petitioner. Order, filed June 10, 2020.

Petitioner filed her medical records on August 7, 2020. ECF No. 10. I then ordered respondent to file a status report indicating whether he believed the medical records were complete. Order, filed Aug. 13, 2020. Respondent filed a status report on October 5, 2020 requesting additional vaccination and chiropractic records. Status Report, filed Oct. 5, 2020. The undersigned subsequently ordered petitioner to file the requested records on October 6, 2020. Order, filed Oct. 6, 2020. Petitioner filed her additional medical records on October 22, 2020. Notice of Filing, filed Oct. 22, 2020.

After petitioner filed her additional medical records, the undersigned ordered respondent to confirm whether he believed the record was complete and propose next steps in the case. Order, filed Oct. 23, 2020. Respondent filed a status report indicating that he believed the record was complete and requesting a 45-day deadline to file a Rule 4(c) report. Status Report, filed Nov. 12, 2020.

Respondent filed his Rule 4(c) report recommending that compensation be denied on January 8, 2021. Resp't's Rep., filed Jan. 8, 2021. In his report, respondent puts forth several arguments as to why petitioner should be denied

compensation. The first is that petitioner's claim was filed outside of the Vaccine Act's 36-month statute of limitations, noting that petitioner has cited a "lump" in her left arm that appeared on the day of her vaccination as the first sign of her sarcoma. Resp't's Rep. filed Jan. 8, 2021 at 6. Because this lump appeared in April 2015, and because petitioner did not file her claim until May 11, 2020, respondent argues that the statute of limitations should apply and bar petitioner's claim from moving forward. Id. Respondent also argues that petitioner's vaccination records documented an injection in the right arm, not the left, and therefore, the vaccination could not have caused a left-arm sarcoma. Id. at 7. Finally, respondent argues that in any event, petitioner has failed to carry her burden under Althen, specifically, that she has failed to provide evidence of a credible medical theory connecting the Prevnar 13 vaccination to sarcoma.

The undersigned next held a status conference on January 26, 2021 where he discussed respondent's Rule 4(c) report and explained to the parties that the next steps in this case would involve the presentation of expert reports. Order, filed Feb. 1, 2021.

On March 10, 2021, petitioner filed a response to respondent's report providing corrections to the factual record and raising objections to respondent's analysis of the case. Response to Resp't's Rep., filed Mar. 10, 2021. First, petitioner addressed several corrections to respondent's statement of facts. Id. at 6. Petitioner explains that her medical records incorrectly document the location of her vaccination, and that she did indeed receive the vaccination in her left arm. Id. Petitioner also notes that she never received a flu shot, and that her sarcoma did not appear until November of 2018. Id. at 7-8. Petitioner then suggests that she has carried her burden under Althen, invoking various medical institutions which she alleges claim that the aluminum adjuvant in Prevnar 13 is carcinogenic and can cause sarcomas.

On March 25, 2021, I ordered petitioner to file an expert report supporting her claim. Order, filed Mar. 25, 2021. Petitioner's deadline was extended first on August 17, 2021, and for a second time on October 29, 2021. Order, filed Aug. 17, 2021; Order, filed Oct. 29, 2021. Petitioner responded to the first extension order on October 7, 2021, arguing that expert reports are only required if the medical record is incomplete, or if the proposed medical theory is novel. Petitioner also provided a medical argument to support her claim, restating the assertions made in her petition and response to respondent's Rule 4(c) report, with an additional argument regarding Prevnar 13's link to chronic inflammation, and chronic

inflammation's link to DNA damage leading to cancers. Response to Scheduling Order, filed Oct. 7, 2021.

The undersigned subsequently issued an order explaining that because sarcoma is not listed as a table-injury associated with the Prevnar 13 vaccination, petitioner cannot use the vaccine injury table to support her claim, and will need to do so under a causation-in-fact theory. Order, filed Oct. 29, 2021. Petitioner filed another response to the undersigned's order, reiterating her previous arguments based on her own independent research, and explaining that despite diligent efforts, she had been unable to obtain an expert willing to opine in this case. Response to Scheduling Order, filed December 8, 2021.

The undersigned subsequently issued an order allowing for respondent to respond to petitioner's filing by January 14, 2022. Order, filed December 15, 2021. Respondent did not file any response, and this case was then submitted for adjudication on January 26, 2022. Order, filed, January 26, 2022. This case is now ripe for a ruling on entitlement.

III. Standards for Adjudication

Under the National Vaccine Injury Compensation Program, compensation awards are made to petitioners who suffer injuries after receiving vaccines. In order to receive compensation, a petitioner must establish several facts by a preponderance of the evidence, including that they received a vaccination listed on the vaccine injury table ("the table"); received it in the United States; suffered a serious, long-standing injury; and received no previous award or settlement on account of the injury. The final and often most disputed element in claims for entitlement is whether the petitioner can establish a causal link between the vaccine and the alleged injury. 42 U.S.C. § 300aa-13(a)(1)(A); 42 U.S.C. § 300aa-11(c)(1)(C)(i); 42 U.S.C. § 300aa-14(a); 42 U.S.C. § 300aa-13(a)(1)(B). If the vaccinee suffered an injury listed on the vaccine injury table and associated with the vaccination they received, he or she receives a presumption of causation if he or she can show that his or her injury occurred within the period of time specified by the table. See 42 C.F.R. § 100.3.

When a vaccinee suffers an injury not covered by the table, petitioners may pursue what is referred to as an "off-table" claim. 42 U.S.C. § 300aa-13(a)(1)(B); 42 U.S.C. § 300aa-11(c)(1)(C)(ii). In off-table claims, the vaccine injury table's presumption of causation is inoperative. Instead, the petitioner bears the burden of introducing preponderant evidence showing that the injury was caused-in-fact by the vaccination at issue. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274,

1278 (Fed. Cir. 2005); Hines v. Sec’y of Health & Hum. Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991). To carry their burden in these cases, petitioner must show that the vaccine “brought about [the vaccinee’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.” Althen, 418 F.3d at 1278.

The Althen court explained that petitioners are not required to provide medical literature supporting their theory of causation so long as they supply the medical opinion of an expert. Id. at 1279-80. The Court also indicated that program fact finders may rely upon “circumstantial evidence” to determine causation, reasoning that it was consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” Id. at 1280.

In both on-table and off-table claims, petitioners bear the burden of proving their case by a preponderance of the evidence. This standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Although medical certainty is not required, petitioners may not carry their burden based solely on their own assertions. Instead, the petitioner must be supported by either medical records, or by the opinion of a competent expert. 42 U.S.C. § 300aa-13(a)(1). This means that in order to establish an off-table claim, petitioners must provide an expert report that addresses each prong of the Althen test, or else provide medical records that do so.

A special master may not impose an evidentiary burden that is too high, thus, distinguishing between “preponderant evidence” and “medical certainty” is especially important. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

IV. Analysis

Here, Ms. Sawvell argues that she suffered a sarcoma caused by her April 10, 2015 Prevnar 13 vaccination. Because sarcoma is not listed on the vaccine injury table, Ms. Sawvell must establish her claim under a causation-in-fact theory. This section will first present each parties' arguments before proceeding to an analysis of each Althen prong.

A. Althen Prong One: A Causal Theory Connecting the Prevnar 13 vaccine to Ms. Sawvell's Sarcoma.

The first Althen prong requires the petitioner to provide a "sound and reliable" medical theory demonstrating that the vaccine can cause the alleged injury. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). Because the petitioner cannot rely on her assertions alone, she must also offer "a reputable or scientific explanation that pertains specifically to [her] case," in the form of medical records or an expert opinion. Moberly, 592 F.3d at 1322; see also 42 U.S.C. § 300aa-13(a)(1).

1. Parties' Arguments

Although petitioner did not submit any expert materials, she did submit several narratives within her petition, medical records, and status reports where she refers to publications from medical institutions which she argues supports her claim. Petitioner argues that "hundreds" of pets that received alum adjuvanted vaccines developed malignant tumors, which researchers refer to as "vaccine induced sarcomas." Pet., filed on May 11, 2020. She argues that these animal studies documented tumors of a yellowish color, and because her tumor was also a yellowish color, these animal studies are applicable to her case. Id. at 5-6.

In her second narrative, petitioner continues to reference publications by medical institutions, but again provides no record evidence nor citations to support her claims. Relevant to her medical theory of causation, petitioner argues that the International Journal of Cancer reported that "concentrations of aluminum in the range of those measured in human breasts fully transform cultural mammary epithelial cells, thus enabling them to form tumors and masticise (sic) in well-established mouse cancer models." Id. at K3. Petitioner also cites the Journal of Pediatrics which wrote that "persistent antigenic stimulation causing a chronic immune response, could eventually evolve into a lymph node malignancy." Id. at K4. According to Ms. Sawvell, the Cancer Treatment Centers of America reported

that chronic inflammation can cause or influence “1 in 5 cancers,” and the Mayo Clinic reported that aluminum “is a sarcoma causing agent by inflaming cells for a long period of time.” Id. Petitioner writes that “medical data shows that aluminum adjuvants leave a ‘depot’ . . . of antigens prolonging exposure . . . and can stimulate immune cells.” Id. She further refers to the National Cancer Institute and Fox Chase Cancer Center both of which reported that chronic inflammation can cause DNA cell damage and lead to cancer. Id. at K4-K5. Finally, petitioner refers to a study she says was conducted by the USDA which found a possible link between aluminum adjuvants and vaccine associated sarcomas in farm animals and pets. Id. at K5-K6.

Respondent argues that petitioner has failed to carry her burden under prong one because none of her medical records contain a causal theory, nor has she submitted an expert report providing a credible and reliable medical theory supporting her claim. Resp’t’s Rep., filed on Jan. 8, 2021 at 8.

2. Resolution

A petitioner may not receive compensation based solely on her assertions; instead, the petition must be supported by medical records or the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). As stated above, petitioner does not provide any record evidence or citations to the various assertions she attempts to put forth as medical evidence. The only submissions that resemble any sort of citation is a list of links to the websites of the institutions she mentioned in her narrative. However, these links only direct the Court to the institution’s home page, and not to any resource with which the undersigned is able to verify the data and reports mentioned in petitioner’s narratives. Ultimately, because she has provided no supporting documentation to verify the claims made in her narratives, I cannot credit petitioner’s claims as anything more than her own assertions.

Nothing in petitioner’s medical records suggest that any of her treating physicians concurred with her proposed medical theory that the aluminum adjuvant in the Prevnar 13 vaccine can cause malignant sarcomas. Petitioner has also failed to provide any expert opinions supporting her proposed medical theory. The only evidence petitioner has offered supporting her theory are uncited, unverified claims. However, even if petitioner provided sufficient citations requiring the undersigned to consider the data she refers to in her filings, her argument would still be unpersuasive because it has virtually no impact on whether the Prevnar 13 vaccination can cause sarcomas in human beings. Petitioner’s potentially most persuasive assertion shows a causal link between certain farm animals and pets who received aluminum adjuvanted vaccinations. However, petitioner’s burden

requires her to show that the biological mechanism at play in the case of farm animals and pets applies to humans who received the Prevnar 13 vaccine as well. Petitioner has offered no evidence suggesting that these biological mechanisms may occur in humans and cause similar injuries. Petitioner's argument ultimately asks the undersigned to assume, with no evidence, that this biological mechanism occurring in cats, dogs, or cows, can also occur in human beings. See Depena v. Sec'y of Health & Hum. Servs., 133 Fed. Cl. 535, 546 (2017) (ruling that special master was not arbitrary in noting that an expert did not provide a basis for extrapolating animal models to humans), aff'd 730 Fed. Appx. 938 (Fed. Cir. 2008).

The remainder of petitioner's medical theory relies on the idea that chronic inflammation may cause DNA damage that leads to cancer. Again, even if petitioner provided reliable citations supporting her assertions, she would nonetheless fail to carry her burden. This argument again asks the undersigned to assume without evidence. Petitioner's references make no mention of the Prevnar 13 vaccination, and only one mentions that aluminum can cause sarcoma, but makes no explanation as to how or why. There is nothing in petitioner's narratives that explains how the Prevnar 13 vaccine triggers chronic inflammation, whether it can trigger chronic inflammation, and under what circumstances it may trigger chronic inflammation. Thus, even if petitioner sufficiently supported her assertions with reliable evidence, that evidence would still fail to provide the necessary information linking the Prevnar 13 vaccination to sarcoma via petitioner's proposed medical theory. Consequently, petitioner's claim must fail on Althen prong one.

B. Althen Prong Two: A Logical Sequence of Cause and Effect

Because petitioner has failed to establish that the Prevnar 13 vaccine can cause a sarcoma, she necessarily must fail on Althen prong two. Where prong one requires the petitioner to show that the vaccine she received is capable of causing the injury she alleges, prong two requires the petitioner to show that the specific vaccination she received did most likely cause her alleged injury. Althen, 418 F.3d at 1278. However, because the undersigned is not persuaded that Prevnar 13 is capable of causing sarcoma, petitioner is unable to show that her specific Prevnar 13 vaccination caused her sarcoma.

C. Althen Prong Three: A Showing of a Proximate Temporal Relationship Between Vaccination and Ms. Sawvell’s Sarcoma

Finally, even assuming that petitioner carried her burden under Althen prongs one and two, petitioner did not present any argument or evidence whatsoever on the appropriate proximate temporal relationship. This prong is often defined as requiring the petitioner to establish a “medically-acceptable temporal relationship,” between the vaccination and the injury, and then show that her injury arose within that timeframe. Althen, 418 F.3d at 1281. Nothing in petitioner’s records mentions what the medically accepted timeframe between vaccination and sarcoma is. Thus, even if petitioner succeeded on prongs one and two, her completely lack of discussion regarding prong three would ultimately defeat her claim. As such, the undersigned must find that petitioner has failed to carry her burden.

V. A Hearing is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec’y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Ms. Sawvell has had a full and fair opportunity to present her case. She was provided ample time to collect and file her medical records, allowed to submit narrative arguments, affidavits, and seek expert reports. Ultimately, Ms. Sawvell was unable to secure an expert report, and unable to offer a persuasive theory by which the Prevnar 13 vaccine can cause a sarcoma. Therefore, a hearing would not resolve the failure to provide a sound and reliable medical theory.

VI. Conclusion

Ms. Sawvell has not met her burden of demonstrating that the Prevnar 13 vaccine was the cause-in-fact of her sarcoma. Accordingly, the Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court’s website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master