In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

* *
JANIE MILLER, * No. 18-327V
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Petitioner, *
* Special Master Christian J. Moran
v. *
* Filed: March 7, 2024
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
* *

Louis P. McFadden, McFadden Law Firm, Northfield, NJ, for petitioner;
Nancy O. Tinch and Zoe Wade, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Janie Miller alleged that an influenza ("flu") vaccine caused her to develop leukocytoclastic vasculitis. She seeks compensation through the National Childhood Vaccine Injury Compensation Program. Ms. Miller supported her claim with a series of reports from an immunologist she retained, Yehuda Shoenfeld. The Secretary denied that Ms. Miller was entitled to compensation and submitted reports from Olajumoke Fadugba, an immunologist, and Brendan Antiochos, an orthopedist. The parties advocated for their positions through memoranda.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

Ms. Miller has not established that she is entitled to compensation. The primary flaw is that she has not shown with preponderant evidence that she reacted in a way that was consistent with a theory Dr. Shoenfeld proposed.

I. Events in Ms. Miller's Life

Ms. Miller was born in 1952. Exhibit 1 (affidavit). According to a history given in January 2017, Ms. Miller had experienced a loss of appetite "for a long time." Exhibit 3 at 535.[2]

Ms. Miller saw a primary care physician, Carolyn Bullock, on July 14, 2016. Exhibit 4 (CM/ECF 8-5) at 53. Dr. Bullock works for "Ohio Health." It appears that Ms. Miller was primarily seeking treatment for ear pain. Id. Ms. Miller reported that she "Lost 7# in 1 yr." Id. During this appointment, Ms. Miller refused a colonoscopy and a mammogram. Id. Ms. Miller was advised to receive immunizations. Id.

Ms. Miller received the allegedly causal flu vaccination from a Kroger Pharmacy on October 1, 2016. Exhibit 5 at 6; see also Order issued, Aug. 29, 2019.

Approximately 12 days later, Ms. Miller noticed a sore on her right foot. Exhibit 1 (affidavit) ¶ 4. The sore became a rash and spread to both feet. Id.

Ms. Miller sought care from the Little Clinic and was seen by Lindsay Meggas, ARPN, on November 11, 2016. Exhibit 10 (CM/ECF 37-7) at 8. The chief complaint was "Rash on feet, onset 11/9/2016." Id. Ms. Miller weighed 248 pounds. Id. On examination, Ms. Meggas noted: "Numerous red/purple petechiae are present on bilateral feet and ankles." Id. Ms. Meggas recommended that Ms. Miller's husband drive her to the emergency room. Id. at 9. However, it appears that Ms. Miller did not go to the emergency room as medical records from an emergency room visit are not readily apparent.

Ms. Miller returned to the office of Ohio Health and saw Dr. Douglas Thompson on November 14, 2016. Exhibit 4 at 1. The "issues addressed" were "tiredness," "high cholesterol or triglycerides," "Type 2 diabetes mellitus with hyperglycemia, without long-term current use of insulin." Id. The reason for the visit was a rash on both feet for five days. Id. at 3. Ms. Miller was encouraged to

[2] Citations to Exhibit 3 refer to the page number of the PDF.

"continue to check her blood sugar in the mornings before eating." Id. at 1. Dr. Thompson also ordered a series of laboratory studies, which produced normal results. Id. at 4-5.

On November 18, 2016, Ms. Miller underwent a punch biopsy of her left forearm. Exhibit 10 at 1; Exhibit 4 at 40 (duplicate). A dermapathologist, Julia Cruz, stated the "findings are strongly suggestive of leukocytoclastic vasculitis." Id.[3] An immunofluorescence study was not performed. Id.

Following this diagnosis, Ms. Miller was prescribed prednisone. Exhibit 1 (affidavit); see also Exhibit 3 at 1 (medical record from December 11, 2016, containing a history of Ms. Miller being on prednisone "for about one month for vasculitis"). The remaining medical records are largely not relevant to determining whether the flu vaccine caused Ms. Miller's leukocytoclastic vasculitis. Thus, they are summarized briefly.

On December 11, 2016, Ms. Miller fainted and went to the emergency room. Exhibit 3 at 4. Ms. Miller's lesions were present but were healing. Id. at 55. She was admitted to the hospital.

While in the hospital, a rheumatologist, Kevin Schlessel, saw Ms. Miller for her leukocytoclastic vasculitis. Exhibit 3 at 118. In this appointment, Dr. Schlessel stated "there is no obvious etiology and no evidence to suggest systemic vasculitis." Id. Dr. Schlessel ordered laboratory studies. Id. He also recommended that Ms. Miller see him in his office. Id. The laboratory studies produced mostly expected results. See Id. at 42, 192-201; see also Exhibit A at 4 (discussing laboratory studies and noting "negative," "unremarkable," "not elevated," and "normal" results).

Follow up visits with Dr. Schlessel occurred on December 22, 2016, and December 4, 2017. Exhibit 4 at 6-12. In the next visit, which was on January 12, 2017, a certified physician's assistant in Dr. Schlessel's office, Candice M. Devol, ordered a test to rule out deep vein thrombosis. Id. at 16-17. An ultrasound detected extensive acute bilateral deep vein thrombosis.[4] Exhibit 3 at 266.

[3] Dr. Shoenfeld accepts the diagnosis of leukocytoclastic vasculitis. Exhibit 23 at 2-3. Dr. Fadugba concurs. Exhibit A at 6. It appears that Dr. Antiochos also agrees. Exhibit C at 2.

[4] Dr. Shoenfeld opined that "all thrombotic events were associated with her vasculitis." Exhibit 26 at 7. However, Dr. Fadugba and Dr. Antiochos questioned this connection. Exhibit A at 9, Exhibit C at 4. As explained in the decision, Ms. Miller has not established that she is

Ms. Miller was hospitalized again on January 12, 2017. See Exhibit 3 at 258. Upon admittance to the hospital, Ms. Miller weighed 218 pounds. Id. at 264. The clinical impression was acute pulmonary embolism and acute deep vein thrombosis of both lower extremities. Id. at 266. Ms. Miller informed hospital staff of her recent vasculitis diagnosis and stated that she experienced pain when walking or when touching the sites. Id. at 268. An IVC filter was placed on January 13. Id. at 384. Ms. Miller was discharged on January 20, 2017. Id. at 258.

On February 27, 2017, Ms. Miller had a radiology appointment with Dr. Joddi Neff-Massullo regarding her pulmonary embolism and retrieval of the IVC filter. Exhibit 4 at 41. Dr. Neff-Massullo recorded that Ms. Miller's bilateral deep vein thrombosis and pulmonary emboli "occurred in the setting of an acute inflammatory condition secondary to leukocytoclastic vasculitis and elevated BMI." Id. Dr. Neff-Massullo arranged for the IVC filter retrieval, and recommended weight reduction, increased activity level, and cancer screening including a mammogram and colonoscopy. Id. Ms. Miller's IVC filter was removed on March 10. Exhibit 7.

Ms. Miller returned to the radiologist on December 5, 2017. Exhibit 4 at 22. Dr. Neff-Massullo wrote: "Even though the PE/DVT [pulmonary embolism/deep vein thrombosis] occurred in the setting of an inflammatory process, the PE/DVTs were extensive. She was also noted to have deep vein reflux on US [ultrasound] bilaterally and continued to have chronic DVT." Id. Dr. Neff-Massullo again recommended cancer screening, which Ms. Miller declined. Id. at 23.

II. Procedural History

The course of this case in litigation has been relatively straightforward. Ms. Miller began the case by filing her petition on March 5, 2018. Periodically, she filed medical records.

The Secretary reviewed the material Ms. Miller submitted and recommended against compensation. Resp't's Rep., filed April 11, 2019. The Secretary

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entitled to compensation on her claim that the flu vaccine caused vasculitis. Therefore, whether her thrombotic events were sequalae to the vasculitis is not reached.

primarily argued that Ms. Miller had not shown that the flu vaccine caused her leukocytoclastic vasculitis. Id. at 5.[5]

To facilitate the process for obtaining valuable reports from experts, a set of draft instructions were issued on September 18, 2019. When the parties did not object, these instructions became final. Order, issued Oct. 10, 2019.

Complying with the instructions took a long time for Ms. Miller. She eventually relied upon a report from Dr. Shoenfeld, filed on February 23, 2021. Exhibit 26. Dr. Shoenfeld described this report as his primary report. Thus, the previous iterations are not described in this decision.

The Secretary, as previously noted, contested Dr. Shoenfeld's conclusion. The Secretary relied upon reports from Dr. Fadugba (Exhibit A, filed July 10, 2021) and Dr. Antiochos (Exhibit C, filed July 13, 2021). Ms. Miller replied with another report from Dr. Shoenfeld. Exhibit 28, filed Dec. 17, 2021. With this report, Ms. Miller also submitted another affidavit. Exhibit 27.

The case moved to the briefing phase. Order, issued Feb. 16, 2022. Ms. Miller filed her primary brief on June 4, 2022 and her reply brief on January 6, 2023.[6] In between, the Secretary filed his brief on October 24, 2022. With the submission of Ms. Miller's reply brief, the case is ready for adjudication.

Ms. Miller's claim can be resolved without a hearing. 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. Miller has had a fair and full opportunity to present her case. After Dr. Shoenfeld presented his initial opinion, Doctors Fadugba and Antiochos critiqued

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[5] Although the Secretary raised other arguments, they fell by the wayside. See Resp't's Status Rep., filed Aug. 19, 2019.

[6] Ms. Miller's briefs contain a great deal of rhetoric but were relatively short on analysis. As described below, Ms. Miller primarily argues that the Secretary has not established an alternative cause for her vasculitis. However, an issue regarding alternative cause may arise after a petitioner establishes the vaccine was the cause-in-fact of her illness. See 42 U.S.C. § 300aa–13(a)(1)(B).

it. Ms. Miller, then, had opportunities to respond to their criticisms. Therefore, a hearing is not needed.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence 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).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing 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 dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination 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 v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

Each of the Althen prongs are reviewed for completeness.

A. Althen Prong One – Theory

The record includes two types of evidence. The first is the set of medical articles regarding vaccinations causing vasculitis. The other type of evidence is opinion testimony from Dr. Shoenfeld.

1. Articles regarding Vaccinations and Vasculitis

Ms. Miller advances two articles as supporting her claim that the flu vaccine can cause vasculitis. First, is a case report in which an elderly woman experienced two episodes of leukocytoclastic vasculitis one year apart and both occurred 11 days after receiving a flu vaccine. Exhibit 13 (Monjazeb). Ms. Miller describes this article as the "most compelling" evidence. Pet'r's Br. at 7.

Second, Ms. Miller also relies upon the package insert. Id. at 11. This document, which is actually a "leaflet," includes "blood vessel inflammation" among "common side effects." Exhibit 12.

Ms. Miller submitted the Monjazeb case report and the package insert before Dr. Shoenfeld wrote his report. Dr. Shoenfeld did not cite either the Monjazeb case report or the package insert. Neither Dr. Fadugba nor Dr. Antiochos discussed either exhibit. Finally, although Ms. Miller cited this evidence in her primary brief, the Secretary did not refer to this evidence. See Resp't's Br.

Rather than addressing the evidence Ms. Miller advanced, the Secretary put forward an article by Bonetto and colleagues, filed as Exhibit C-9. Resp't's Br. at 18. These researchers searched for literature regarding reports of vasculitis developing in a temporal relationship with a vaccine published from January 1, 1994 to June 30, 2014. Exhibit C-9 (Bonetto) at 6641. They analyzed 75 studies, including six retrospective/observational studies and two randomized controlled trials. Id. at 6642. However, some of these studies investigated vaccines other than the flu vaccine. Id. at 6642-44. Ultimately, the authors concluded that: "Existing literature does not allow establishing a causative link between vaccination and vasculitides." Id. at 6649.

The Bonetto article merits consideration. See Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (discussing value of epidemiology), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020). However, epidemiology cannot establish that a vaccine cannot cause an injury. The limits to epidemiology are notable because the Monjazeb case report appears to present an example of challenge-rechallenge, which can be evidence of causation. See Stricker v. Sec'y of Health & Hum. Servs., No. 18-56V, 2024 WL 263189, at *25 (Fed. Cl. Spec. Mstr. Jan. 2, 2024), mot. for rev. filed (Feb. 1, 2024). Accordingly, the theories Dr. Shoenfeld offered are considered next.

2. Dr. Shoenfeld's Proposed Theories

With respect to disclosing theories by which the flu vaccine can cause vasculitis, Dr. Shoenfeld's report is not a model of clarity. See Exhibit 26 at 10-22. This lack of intelligibility carries over to Ms. Miller's brief, which did not explain why Dr. Shoenfeld's proposed theories are reliable or persuasive. See Pet'r's Br. at 5-7. In contrast, the Secretary did well to argue against every theory, but one, as discussed below.

At least measured by pages devoted to it, molecular mimicry appears to be Dr. Shoenfeld's primary theory. See Exhibit 26 at 14-22; see also Pet'r's Reply at 10-11. Dr. Fadugba and Dr. Antiochos criticized Dr. Shoenfeld's invocation of molecular mimicry. Exhibit A at 9-10, Exhibit C at 6-9.

A detailed explication of the criticisms is not required. Even at a superficial level, Dr. Shoenfeld's report leaves much to be desired and falls well short of presenting a reliable and persuasive medical theory. Dr. Shoenfeld lists a series of peptides, which are sequences of amino acids, that, according to Dr. Shoenfeld, are shared between the flu vaccine and human "constituents." Exhibit 26 at 16. However, Dr. Shoenfeld does not explain why the human peptide sequences contribute to the development of vasculitis. For example, Dr. Shoenfeld wrote that "Immune cross-reactions might attack ACE, ADA2, CO4A1 and RN213, alterations which are associated with intracerebral hemorrhage." Id. at 15. But, Ms. Miller is not seeking compensation for suffering an "intracerebral hemorrhage" and Dr. Shoenfeld has not explained how an intracerebral hemorrhage could lead to vasculitis. Thus, Dr. Shoenfeld's opinion regarding molecular mimicry is incomplete, unreliable, and unpersuasive.

Dr. Shoenfeld devoted much fewer pages to proposing theories other than molecular mimicry. See Exhibit 26 at 14. Ms. Miller's failure to advance these theories could be construed as a waiver. See Vaccine Rule 8(f). But, a resolution based upon a procedural failure is not needed. Even if Ms. Miller had advanced most of the theories that Dr. Shoenfeld offered, these remain unpersuasive.

Dr. Shoenfeld has advanced a theory based upon formaldehyde and Triton X-100. Exhibit 26 at 10-11. However, as the Secretary argued, the flu vaccine does not contain these adjuvants. Resp't's Br. at 20; see also Valeen v. Sec'y of Health & Hum. Servs., No. 16-390V, 2021 WL 6137878, at *4-5 (Fed. Cl. Spec. Mstr. Nov. 30, 2021).

Dr. Shoenfeld has proposed a theory based upon "viral invasion of endothelial cells." Exhibit 26 at 14. However, as the Secretary argued, the flu vaccine does not contain a live virus that replicates. Resp't's Br. at 21 n.5.

Finally, Dr. Shoenfeld suggested that the vaccination may cause harm because of "Immune mediated damage of the vessel walls due to deposition of immune complexes." Exhibit 26 at 14. Dr. Fadugba did not challenge this theory. Instead, Dr. Fadugba maintained that Ms. Miller did not have immune complexes. Exhibit A at 11; see also Resp't's Br. at 22 (repeating Dr. Fadugba's argument). However, whether a vaccine can cause a condition is analytically distinct from whether a vaccinee suffered from the condition. See Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012); Order for Briefs, issued Feb. 16, 2022, at 5 (stating that information about the petitioner should not be presented in the parties' prong 1 section). Special masters have found immune complexes can be the basis for a disease. G.C. by Contino v. Sec'y of Health & Hum. Servs., No. 15-773V, 2019 WL 4941087 (Fed. Cl. Spec. Mstr. Sept. 5, 2019); Fields v. Sec'y of Health & Hum. Servs., No. 02-311V, 2008 WL 2222141 (Fed. Cl. Spec. Mstr. May 14, 2008).

3. Summary regarding Theory

The Monjazeb case report of challenge-rechallenge and the package insert constitute some reliable evidence that vaccines can cause vasculitis. The Bonetto article does not completely diminish the strength of this evidence. Further, the immune complex theory was not rebutted as a theory. Under these circumstances, Ms. Miller can be assumed to have met her burden regarding Althen prong one.

B. Althen Prong Two – Logical Sequence

The second prong from Althen requires petitioners to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. In weighing whether the sequence of steps is "logical," special masters may consider whether the vaccinee responded in a way the theory predicted. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012); Baldwin v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 431, 447 (2020) ("Petitioner was required to prove by a preponderance of the evidence that one of her expert's theories actually occurred"); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 52-57 (2013); La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 205 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

Here, as explained in section IV.A above, the only even marginally passable theory from Dr. Shoenfeld involves immune complexes. The theory does little to enhance the overall value of Ms. Miller's claim because, as Dr. Fadugba contended, Ms. Miller did not have "evidence of immune complex deposition in [her] skin vessel walls." Exhibit A at 11. Although Dr. Shoenfeld had a chance to rebut this point, he did not. See Exhibit 28. Likewise, Ms. Miller did not argue against the Secretary's contention that she did not have evidence of immune complexes. See Pet'r's Reply.

Given this evidence, Ms. Miller has not shown a logical sequence of cause and effect. Although as a purely theoretical matter the flu vaccine might lead to the creation of immune complexes that cause vasculitis, the evidence does not support a finding that Ms. Miller had immune complexes. As such, she does not meet her burden regarding the second Althen prong. See Bourche v. Sec'y of Health & Hum. Servs., No. 15-232V, 2020 WL 571061 (Fed. Cl. Spec. Mstr. Jan. 7, 2020) (denying compensation because the vaccinee did not develop immune complexes).

C. Althen Prong Three – Timing

Because petitioners must establish each Althen prong to receive compensation, Ms. Miller's lack of persuasive proof on the second prong resolves her case. Nevertheless, the final Althen element is discussed, if simply to demonstrate that the entire record has been considered.

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

With respect to the appropriate interval, Dr. Shoenfeld states that "numerous case studies and other medical literature . . . agree with the date of onset being within a couple weeks of the vaccine as sufficient evidence (in the absence of other pre-existing conditions of potential causation) that the vaccine triggered the [leukocytoclastic vasculitis]." Exhibit 26 at 7. Dr. Fadugba's opinion seems to overlap partially: He wrote: "The time between cause and vasculitis development varies. Vasculitic rash tends to appear 7 to 10 days after exposure to a drug or infectious trigger and a mean of 6 months after the onset of an underlying medical condition." Exhibit A at 8. Thus, based upon the agreement of the experts, two weeks is an appropriate amount of time for vasculitis to appear after a vaccination.

Dr. Shoenfeld and Dr. Fadugba part company on the question as to when Ms. Miller began to experience vasculitis. Dr. Shoenfeld states that the vasculitis started 12 days after vaccination. Exhibit 26 at 4-5. But, Dr. Fadugba suggests that Ms. Miller had an undiagnosed pre-existing problem, such as some type of cancer, that could have caused her vasculitis. Exhibit A at 12; see also Resp't's Br. at 25-26.

Resolving this issue is not required. If Ms. Miller had established that her vasculitis started 12 days after the vaccination, she would not necessarily be entitled to compensation. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact.").

V. Conclusion

The episodes of vasculitis and thrombosis affect Ms. Miller and she deserves sympathy for suffering these health problems. However, she has not demonstrated that the flu vaccine caused her vasculitis.

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, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

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