

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

ALISHA N. PANKIW, *

*

Petitioner, *

No. 15-1082V
Special Master Christian J. Moran

v. *

SECRETARY OF HEALTH AND HUMAN SERVICES, *

Filed: March 9, 2021

Respondent. *

Entitlement; influenza ("flu") vaccine;
rheumatoid arthritis; diagnosis.

William E. Cochran, Jr., Black McLaren et al., P.C., Memphis, TN, for petitioner;
Sarah C. Duncan, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION^1

Alisha Pankiw alleges that an influenza ("flu") vaccination caused her to
suffer rheumatoid arthritis. She seeks compensation pursuant to the National
Childhood Vaccine Injury Compensation Program.

On December 21, 2020, Ms. Pankiw filed a motion for ruling on the record.
Respondent then filed his response to this motion on January 4, 2021, followed by
Ms. Pankiw's reply, filed on January 11, 2021. Thus, Ms. Pankiw's motion for
ruling on the record is now ripe for consideration. Ms. Pankiw has not
demonstrated: (1) a diagnosis of rheumatoid arthritis, or (2) that her alleged

^1 The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and
Promotion of Electronic Government Services), requires that the Court post this decision on its
website. This posting will make the decision available to anyone with the internet. Pursuant to
Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical
information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions
ordered by the special master will appear in the document posted on the website.

rheumatoid arthritis was caused by her flu vaccination. Thus, her petition is dismissed.

I. Factual Background

Ms. Pankiw received her flu vaccination on September 28, 2012. Exhibit 2 at 1. She then presented to her primary care physician, Dr. Heisel, 12 days later on October 10, 2012, complaining of “temporomandibular joint pain.” Exhibit 6 at 1. Dr. Heisel characterized Ms. Pankiw’s reported joint pain as “sharp in ankle,” “achy in knee,” “swollen knee,” and “most notable in the right ankle.” Id. at 5. However, Dr. Heisel noted that, while Ms. Pankiw did “have some arthritis,” that “[i]t is not a typical presentation for rheumatoid arthritis. It isn’t symmetric.” Id. Additionally, a squeeze was performed, which was negative. Id. Dr. Heisel noted a pain onset of “4 [months] ago 2 months postpartum.” Id. at 4. There are discrepancies in the doctors’ records regarding reported onset of Ms. Pankiw’s symptoms. However, the undersigned has found that her joint pain began on approximately October 1, 2012. See Pankiw v. Sec’y of Health & Human Servs., No. 15-1082V, 2017 WL 1376435, at *4 (Fed. Cl. Spec. Mstr. Mar. 21, 2017).

At a follow-up visit on October 15, 2012, Ms. Pankiw reported a worsening of her symptoms, which she characterized primarily as “stiffness.” Id. at 22. Dr. Heisel again noted that Ms. Pankiw exhibited “acute arthritis,” but that it was “[s]till not likely to be rheumatoid arthritis.” Id. at 23. He further noted that “[a]n inflammatory arthritis is suggested by her postpartum status and the presence of postpartum thyroiditis.” Id. Ms. Pankiw was put on prednisone at this visit.

On October 23, 2012, Ms. Pankiw reported to Dr. Heisel that her knee stiffness/pain had improved but was worsening again, that her right ankle was worse, and that there had been no change in the pain levels for her index finger and left third toe. Id. at 27-31. A few weeks later, on November 12, 2012, Ms. Pankiw visited her gynecologist for a prenatal visit, where she advised her gynecologist of her potential rheumatological diagnosis and stated that, due to the prednisone, she had experienced a “huge improvement in left knee stiffness.” Exhibit 8 at 8.

On December 4, 2012, Ms. Pankiw attended her first rheumatology visit with Dr. Thomas. Exhibit 7 at 3. She presented with “undifferentiated arthritis” and complained of pain in her left knee, right ankle, and right index finger. Id. Dr. Thomas noted the possibility of “seronegative [rheumatoid arthritis]” and the potential complicating diagnostic factor that Ms. Pankiw’s pregnancy presented. Id.

Between November 2012 and March 2013, Ms. Pankiw presented to multiple medical providers consistently complaining of pain and/or stiffness in her left knee, right ankle, wrist, and right index finger. These providers included infectious disease specialist Dr. Slama, a chiropractor, rheumatologist Dr. Thornberry, endocrinologist Dr. Asamoah, and OB/GYN Dr. Linn. See exhibit 9 at 20, 43-44 (Dr. Slama on December 18, 2012, and January 11, 2013); exhibit 11 at 5, 7 (chiropractor on January 4, 2013, and January 5, 2013); exhibit 9 at 16-19 (Dr. Thornberry on February 18, 2013); exhibit 16 at 21-24, 37-43 (Dr. Asamoah on November 20, 2012, and February 20, 2013); exhibit 8 at 29 (Dr. Linn on March 1, 2013).

During this time, Ms. Pankiw received various evaluations to determine whether her symptoms represented an onset of lupus; however, a diagnosis of rheumatoid arthritis was never made. On February 18, 2013, Dr. Thornberry recorded her impression of Ms. Pankiw's condition as "[a]symmetric inflammatory polyarthritis associated with positive ANA." Exhibit 9 at 18. She also noted that "[t]he distribution of [Ms. Pankiw's] articular disease is unusual for systemic lupus erythematosus (SLE) and rheumatoid arthritis. However we must consider that there is some influence upon her arthropathy by her pregnant state." Id.

On February 20, 2013, Dr. Asamoah noted normal thyroid tests, despite Ms. Pankiw's consistent complaints of joint pain and stiffness. Exhibit 16 at 37-43. On March 1, 2013, Dr. Linn characterized Ms. Pankiw's condition as "[p]ossibly arthritis/myalgias related to flu shot vs lupus." Exhibit 8 at 29. Dr. Linn listed systemic lupus erythematosus (SLE) as Ms. Pankiw's diagnosis. Id. at 41.

By May 2013, Ms. Pankiw began reporting significant improvement in her symptoms to her medical providers. In an appointment on September 5, 2013, Dr. Thornberry noted that, based on her evaluation, Ms. Pankiw's "pauciarticular inflammatory arthritis associated with positive ANA [has] resolved." Exhibit 9 at 9.² Dr. Thornberry later maintained this as the date of resolution of Ms. Pankiw's arthritis symptoms in a letter to Ms. Pankiw's attorney, stating that Dr. Thornberry "felt that the arthritis had resolved when [she] examined her on 09/05/2013." Exhibit 10 at 28.

On December 13, 2013, Dr. Thornberry responded to a request from Ms. Pankiw in which she asked for a note stating that she could not receive the flu vaccination in the future, stating that Ms. Pankiw "had a significant adverse reaction to an influenza vaccine administered in September, 2012, manifested by

² Pauciarticular means "pertaining to or involving only a few joints." Dorland's Illus. Med. Dictionary 1378 (33d ed. 2020)

arthritis.” Exhibit 10 at 41. Over a year later, Ms. Pankiw presented to Dr. Thornberry with joint pain. Dr. Thornberry characterized her condition as “joint pain without evidence of inflammatory arthritis” and noted that she “suspect[ed] that [Ms. Pankiw’s] discomfort [wa]s in part due to her deconditioned state and her overweight status.” *Id.* at 16-17. Ms. Pankiw did not complain of joint pain at any of her multiple subsequent medical appointments in 2015. In her letter to Ms. Pankiw’s attorney on January 8, 2015, Dr. Thornberry stated that “[w]ith the asymmetric and pauci-articular nature of her illness, consistent with viral arthropathy or vaccine-induced arthropathy, it was felt that there was a reasonable medical probability that her symptoms were caused by the influenza vaccination.” Exhibit 10 at 28.

II. Procedural History

Ms. Pankiw filed her petition on September 28, 2015. She asserted that the flu vaccination she received on September 28, 2012, caused her to suffer “arthritis of the joints.” Pet. at Preamble, ¶¶ 2, 9. Ms. Pankiw filed medical records along with her petition. She filed a statement of completion on December 18, 2015.

The Secretary filed his Rule 4(c) report on April 1, 2016, contesting Ms. Pankiw’s claim based on his view that Ms. Pankiw failed to present: (1) a reputable scientific or medical theory showing that the flu vaccine can cause arthritis (prong 1); (2) evidence showing that the flu vaccine actually caused arthritis of the joints in Ms. Pankiw’s case; and (3) evidence establishing that the time frame between Ms. Pankiw’s vaccination and onset of her injury fell within a medically acceptable time frame. Resp’t’s Rep. at 11-12. Additionally, the Secretary argued that Ms. Pankiw had not established a clear onset date for her arthritis and that she had “ignored potential alternative causes of the arthritis in her joints,” specifically the potential effects of her pregnancy on her joint pain. *Id.* at 12-13.

The parties discussed the factual issue of the onset of Ms. Pankiw’s joint pain in a status conference held on April 12, 2016. Eventually, a fact hearing regarding onset of Ms. Pankiw’s symptoms was set for October 18, 2016, in Indianapolis, IN. The undersigned found that Ms. Pankiw’s joint pain began on approximately October 1, 2012. See Pankiw v. Sec’y of Health & Human Servs., No. 15-1082V, 2017 WL 1376435, at *4 (Fed. Cl. Spec. Mstr. Mar. 21, 2017).

The parties then filed a succession of expert reports. Ms. Pankiw presented reports from Dr. Utz and the Secretary presented reports from Dr. Matloubian and Dr. Whitton. See exhibits 38-41, A, C-D, F-I. The Secretary filed the final expert report on December 9, 2019. The opinions from Dr. Utz and Dr. Matloubian on the topic of whether flu vaccine can cause rheumatoid arthritis largely matched the

reports they authored in another case, Tullio v. Secretary of Health & Human Services. Thus, at one point, the parties in Tullio and the parties in Pankiw considered holding one hearing. See order, issued Dec. 10, 2018, CM/ECF No. 83. However, the parties abandoned that effort largely due to the presence of experts other than Dr. Utz and Dr. Matloubian.

Dr. Utz and Dr. Matloubian presented testimony as to whether the flu vaccine can cause rheumatoid arthritis in a hearing held in Tullio on March 6-8, 2019. After considering this testimony as well as a series of medical articles including epidemiologic studies, the undersigned found that the petitioner in Tullio had not established that the flu vaccine can cause rheumatoid arthritis. Tullio v. Secretary of Health & Human Services on this case. No. 15-51V, 2019 WL 7580149 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020).

In a status conference held on February 18, 2020, the undersigned discussed with Ms. Pankiw and the Secretary the likely effect of the decision in Tullio. Ms. Pankiw's attorney stated that he would consult with Dr. Utz regarding potentially distinguishing factors between Ms. Pankiw's case and that of the petitioner in Tullio. He expressed a desire to wait on making any decisions about how to proceed in Ms. Pankiw's case until the Court of Federal Claims ruled on the motion for review in Tullio. Order, CM/ECF No. 104, issued Feb. 18, 2020.

On June 18, 2020, the Court of Federal Claims issued a decision denying the petitioner's motion for review in Tullio. 149 Fed. Cl. 448 (2020). The petitioner in Tullio did not appeal to the Federal Circuit.

After Ms. Pankiw's attorney requested additional time to review the Court's Opinion denying the motion for review in Tullio and consult with Dr. Utz and Ms. Pankiw, a status conference was held on September 29, 2020. Ms. Pankiw was ordered to submit additional proof to support her case and/or submit the case for a ruling on the record by October 29, 2020. Order, CM/ECF No. 111, issued Sept. 30, 2020. Ms. Pankiw filed additional medical literature on October 28, 2020, and filed a motion for ruling on the record on December 21, 2020. Pet'r's Mot., CM/ECF No. 113, filed Dec. 21, 2020. The Secretary filed a response on January 4, 2021, and Ms. Pankiw filed her reply on January 11, 2021. Resp't's Resp., CM/ECF No. 114, filed Jan. 4, 2021; Pet'r's Reply, CM/ECF No. 115, filed Jan. 11, 2021. Thus, Ms. Pankiw's reply makes the case ready for adjudication.

III. Standards for Adjudication

Petitioners are required to establish their cases 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 & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

To receive compensation, petitioners must establish five elements. 42 U.S.C. § 300aa–11(c)(1)(A) through (E); 42 U.S.C. § 300aa–13(a)(1)(A) (authorizing special masters to award compensation when petitioners establish items listed in section 11(c)(1)). To establish causation for off-Table injuries, 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 & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

IV. Analysis

Here, Ms. Pankiw has failed to meet her burden with respect to two aspects of her claims, which are dispositive. First, she has not shown by a preponderance of the evidence that she suffered from rheumatoid arthritis (“RA”), the diagnosis of which is the basis for Dr. Utz’s opinion supporting causation in her case. Second, even assuming a diagnosis of RA, she has not presented a persuasive medical theory to support that the flu vaccination can cause RA.

A. Diagnosis

A special master may make a preliminary determination regarding diagnosis before reaching the issue of causation, as proving a relevant injury is necessary to the success of a causation theory. See Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1345-46 (Fed. Cir. 2010). In his expert report, Dr. Utz presents an opinion that is very similar to his opinion in Tullio with respect to how

an influenza vaccination can cause rheumatoid arthritis. However, Dr. Utz admits that, while Ms. Pankiw did appear to suffer from arthritis, she definitively did not suffer from *rheumatoid* arthritis. See exhibit 38 (Dr. Utz report) at 8. Additionally, none of Ms. Pankiw’s medical providers diagnosed her with RA. In fact, Dr. Heisel rejected a diagnosis of RA. See exhibit 6 at 1 (noting that Ms. Pankiw did “have some arthritis,” but that “[i]t is not a typical presentation for rheumatoid arthritis”); id. at 23 (noting that Ms. Pankiw exhibited “acute arthritis,” but that it was “[s]till not likely to be rheumatoid arthritis”). Dr. Matloubian further argued that Ms. Pankiw’s arthritis was a manifestation of her thyroiditis, which existed pre-vaccination. Exhibit A at 23.

This conspicuous lack of a diagnosis or expert opinion identifying Ms. Pankiw’s symptoms as manifestations of RA is significant because Dr. Utz’s asserted medical theory relies on evidence produced to show that flu vaccinations can cause rheumatoid arthritis. Additionally, even though Dr. Utz states in his report that the flu vaccine can cause RA or inflammatory arthritis, see exhibit 38 at 17, Dr. Thornberry explicitly stated that Ms. Pankiw does not have inflammatory arthritis either. Exhibit 10 at 16-17. It follows that, even if the undersigned were to accept Dr. Utz’s medical theory, it is questionable how it would be applied to Ms. Pankiw’s specific case, given that she did not suffer from RA and that there is evidence against a diagnosis of inflammatory arthritis as well. Citing to studies relevant to the flu vaccine-RA link, Dr. Utz states that “[i]t is plausible, and I would argue very likely, that similar molecular mechanisms are at play in Ms. Pankiw’s case . . . causing inflammatory arthritis.” Exhibit 38 at 11-12. However, Dr. Thornberry stated that Ms. Pankiw did not suffer from inflammatory arthritis. Exhibit 10 at 16-17. Dr. Utz goes on to analogize various causal relationships with foreign antigens that involve conditions, none of which are Ms. Pankiw’s arthritis condition. Essentially, Dr. Utz’s medical theory is premised on research and medical literature involving RA. According to Dr. Utz and Ms. Pankiw’s medical providers, Ms. Pankiw never suffered from RA. Therefore, the evidence presented does not appear particularly informative, much less persuasive, with regard to Ms. Pankiw’s particular circumstances. See Broekelschen, 618 F.3d at 1345 (“[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case[.]”).

B. Althen Prong 1

Even if a determination were made that Ms. Pankiw suffered from rheumatoid arthritis or a condition sufficiently similar to make the asserted medical theory applicable, Ms. Pankiw has failed to provide a persuasive medical theory showing that a flu vaccination can cause arthritis. This finding is based primarily on the fact that Ms. Pankiw advances a virtually identical theory as was advanced

in Tullio, a case in which the undersigned rejected the molecular mimicry-based theory of flu-RA causation.

The petitioner in Tullio advanced the theory of molecular mimicry.³ Dr. Utz stated that “[i]n rheumatoid arthritis, the portion of the body that is attacked in the synovium. A constituent part of the synovium is collagen. . . . [A] sufficient degree of similarity between collagen and a portion of the flu vaccine such that T cells attack not only the flu antigens but also collagen.” Tullio, 2019 WL 7580149, at *12. In response, the Secretary’s expert Dr. Matloubian argued that the articles presented by Dr. Utz to support his theory “do not show a similarity between collagen and a portion of the flu vaccine.” Id.

Dr. Utz posits essentially the same theory of causation in this case. In his report, Dr. Utz states that:

It is well accepted in the field of rheumatology that Type II collagen is an autoantigen in RA. The Sun manuscript, as well as many other manuscripts referenced in their paper, demonstrate that the influenza antigen (HA) that is most important in generating an effective anti-viral response contains linear epitope(s) that can trigger a strong immune response that can cause inflammatory arthritis. Undoubtedly other environmental (nonself) vaccine antigens can trigger immune responses directed against self-molecules, leading to diseases, such as inflammatory arthritis, RA, and MS.

Exhibit 38 at 17. In response, Dr. Matloubian argued that there is no “scientific evidence to support molecular mimicry between influenza and collagen or other RA associated antigens” – an argument substantially similar to that of his responsive expert report in Tullio. Exhibit A at 22.

After the parties filed expert reports and the issue of Tullio’s probable effect on this case was discussed, Ms. Pankiw filed one additional piece of evidence in the form of a case report. See exhibit 52. The case report described a twelve-year-old girl who developed transient oligoarthritis after suffering from the influenza B infection. Id. at 1. As a preliminary matter, case reports hold relatively little weight in vaccine cases. W.C. v. Sec’y of Health & Human Servs., No. 07-456V, 2011 WL 4537887, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) (“[C]ase reports are generally weak evidence of causation because [they] cannot distinguish a temporal relationship from a causal relationship.”), mot. for rev. denied, 100 Fed. Cl. 440

³ For a detailed explanation of the molecular mimicry theory, see Tullio, 2019 WL 7580149, at *12.

(2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). Additionally, as the Secretary points out in his response, there are key distinguishing factors in this case report that make it unpersuasive for Ms. Pankiw's case – namely, that it involved (1) “possible” post-infectious arthritis, (2) an influenza infection, and (3) a child subject. Exhibit 52 at 1; Resp't's Resp. at 3. Additionally, the case report itself admits to a lack of reliability concerning causality. Exhibit 52 at 2. For these reasons, the lone piece of additional evidence Ms. Pankiw offered in response to concerns regarding the effect of the Tullio decision is unpersuasive as to the question of causation.

The undersigned rejected the theory of molecular mimicry as applied in the flu-RA context in Tullio, and does so here as well, given that there has been no substantial departure in this case from the theory originally advanced by Dr. Utz. See Tullio, 2019 WL 7580149, at *27. Furthermore, because Althen prong 1 is dispositive in this case, the undersigned does not reach the issues of specific causation or timing. It follows that, because the medical theory of causation is unpersuasive, that the application to Ms. Pankiw's circumstances would also be unpersuasive. The lack of diagnosis and questionability of the RA-related aspects of Ms. Pankiw's condition would add to the lack of persuasiveness with respect to specific causation or Althen prong 2.

C. Ruling on the Record is Appropriate

Special masters may rely on accumulated knowledge in the Vaccine Program to make entitlement decisions on the papers. Thus, special masters, “based upon their accumulated expertise in the field, judg[e] the merits of individual claims.” Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)). Additionally, special masters retain wide discretion in determining whether an evidentiary hearing is necessary. Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020) (citing 42 U.S.C. § 300aa-12(d)(3)(B)(v) (“In conducting a proceeding on a petition a special master . . . may conduct such hearings as may be reasonable and necessary.”)). The special master must only determine “that the record is comprehensive and fully developed before ruling on the record.” Id. at 1366 (citing Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1385 (Fed. Cir. 2012)).

The accumulated experience applied in this case includes the recent consideration by the undersigned of the precise issue as to whether the flu vaccine can cause rheumatoid arthritis. Ms. Pankiw submitted a motion for a ruling on the record. She has had a full and fair opportunity to present her case, including a

response to Tullio. Thus, a disposition on the papers is appropriate. See Kreizenbeck, 945 F.3d at 1365.

V. Conclusion

For the foregoing reasons, the undersigned finds that Ms. Pankiw has not met her burden to show by a preponderance of the evidence that the flu vaccination caused her arthritis. Accordingly, the claim for compensation is DENIED.

IT IS SO ORDERED.

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