In the United States Court of Federal Claims

No. 15-1302V
(Filed: January 16, 2019)
(Re-Filed: February 5, 2019)[1]

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JEFFREY PREPEJCHAL,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to -34 (2018); off-table claim; motion for review; *Althen* test; severity requirement; influenza vaccine.

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Mark T. Sadaka, Englewood, NJ, for petitioner.

Mollie D. Gorney, Trial Attorney, United States Department of Justice, Civil Division, Torts Branch, Washington, DC, with whom were *Joseph H. Hunt*, Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, and *Catharine E. Reeves*, Deputy Director, for respondent.

OPINION

BRUGGINK, *Judge*.

Pending is petitioner's motion for review of the Special Master's decision of October 5, 2018, denying compensation for an injury allegedly caused by the influenza ("flu") vaccine. The matter is fully briefed, and the court finds that oral argument is unnecessary. Because the Special Master was not arbitrary or capricious, did not abuse his discretion, and did not

[1] This opinion was held for fourteen days during which the parties were permitted to propose to chambers any appropriate redactions. The parties did not propose any redactions and thus we re-issue the decision without redactions. Rules of the United States Court of Federal Claims, App. B, Rule 18(b) ("Vaccine Rules").

otherwise act unlawfully in determining whether petitioner demonstrated that the flu vaccine caused his injury, we deny the motion for review.

BACKGROUND

On November 2, 2015, petitioner, Jeffrey Prepejchal, filed a petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to -34 (2018) ("Vaccine Act"). His petition alleged that, because of receiving the flu vaccine on November 7, 2012, he experienced "vaccine-induced soreness, swelling, phlebitis, and deep vein thrombosis" ("DVT"). Pet. at 1. The Special Master considered the petition on the record and concluded that Mr. Prepejchal did not establish entitlement to a damages award. *Prepejchal v. United States*, No. 15-1302V, 2018 WL 5782865 (Fed. Cl. Spec. Mstr. Oct. 5, 2018) (hereinafter "Decision"). We set out the background of Mr. Prepejchal's claim below, which is derived from the background set out in the decision.

Mr. Prepejchal is a fifty-year old medical charter pilot. He is on call in seven-day increments and generally flies a few days a week with flights usually lasting an hour or less. Mr. Prepejchal flew on four days during the two weeks preceding his vaccination. Prior to receiving the flu vaccine, his medical records reflect that he experienced right hip and left shoulder pain. Six months prior to his vaccine, May 7, 2012, he suffered from chronic left shoulder pain. His father had upper extremity DVT, but Mr. Prepejchal had not experienced DVT prior to his vaccination.

On November 7, 2012, petitioner received the flu vaccine in his left deltoid muscle. An hour later, he experienced "soreness and mild pain." Decision at 2 (quoting Pet'r's Ex. 18 at 2). Nine days after experiencing mild pain, Mr. Prepejchal visited his primary physician, Dr. Walter Meeker, to seek treatment for swelling in his left arm. Dr. Meeker wrote that Mr. Prepejchal's left arm was a "little sore." *Id.* at 3 (quoting Pet'r's Ex. 1 at 21).

Mr. Prepejchal underwent an ultrasound and the radiology report stated that he had "'near-complete occlusion' of the subclavian, axillary, and basilic veins." *Id.* (quoting Pet'r's Ex. 2 at 38). Dr. Meeker diagnosed him with left arm DVT and prescribed two anticoagulants. Dr. Meeker wrote that he was "unsure how this is related to recent flu shot." *Id.* (quoting Pet'r's Ex. 1 at 21).

On December 3, 2012, Mr. Prepejchal visited Darryl F. Lesoski, M.D., an occupational medicine specialist, to evaluate his DVT. The doctor noted that petitioner had a small bruise on his left bicep but no swelling in his left arm. Dr. Lesoski confirmed that Mr. Prepejchal had developed left upper extremity DVT of "questionable etiology," but "[b]ecause of the unusual nature of this it is unlikely that it was related to the influenza vaccine." Pet'r's Ex. 2 at 12.

Dr. Lesoski consulted a librarian, a hematologist, and an Occupational Health & Medicine practitioner list serv to conduct literature research and to determine whether there was a connection between upper extremity DVT and the flu vaccine. The literature research showed "that 'administration of the influenza vaccine was actually prophylactic or protective of DVTs.'" Decision at 3 (quoting Pet'r's Ex. 2 at 10) (emphasis omitted). The hematologist stated that "there was no association from her practice that was associated with this." Pet'r's Ex. 2 at 10. The practitioners' responses found "no association" between the vaccine and DVT. Decision at 3 (quoting Pet'r's Ex. 2 at 10).

Mr. Prepejchal routinely followed up with Dr. Meeker to test his blood's clotting tendency, beginning with tests multiple times a week and tapering off over time. His last test was on January 31, 2013, less than three-months post-vaccination.

Six months later, on June 6, 2013, Mr. Prepejchal completed anticoagulation therapy and Dr. Meeker did not recommend further therapy because the risk of further DVT was low. Dr. Meeker suggested that petitioner avoid flu shots in the future. In 2014, Dr. Meeker wrote that Mr. Prepejchal's DVT was "possibly related" to the flu vaccine. Decision at 4 (quoting Pet'r's Ex. 1 at 6.). Mr. Prepejchal has not had any recurrence of DVT since November 2012.

In 2015, Mr. Prepejchal filed his petition alleging that the flu vaccination caused soreness, swelling, phlebitis, and DVT. Mr. Prepejchal submitted three export reports from Dr. M. Eric Gershwin. Dr. Gershwin is a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California, Davis. He has been a resident at the Tufts-New England Medical Center and served at the National Institutes of Health as a Clinical Associate in Immunology. He has seen one case of Nicolau Syndrome and has testified in one case regarding Nicolau Syndrome.

Dr. Gershwin's first report began, "I do not believe that there is any component of the influenza vaccine that would produce venous thrombosis. In other words, there is no immunological basis to associate the vaccine components with a clotting abnormality." Pet'r's Ex. 5 at 1. Instead, Dr. Gershwin "believe[d] that a mechanical injury from the injection led directly to the swelling and subsequent deep venous thrombosis." *Id.* He continued, "The best analogy of this is a rare and diverse syndrome, which has been coined Nicolau Syndrome." *Id.* He explained that Nicolau Syndrome ("NS") is a rare reaction to an intramuscular injection that "is characterized by pain at the site of injection and including erythema and possibly even the chronic ulcers and scarring." *Id.* He stated that it can affect deeper tissue and that it has been associated with all types of medicine, including vaccines. He referred to NS first as an analogy to Mr. Prepejchal's injury, but later stated, "I believe Mr. Prepejchal's thrombosis is most consistent with a local reaction similar to Nicolau Syndrome." *Id.* Mr. Prepejchal was not diagnosed with NS.

The report did not define DVT, explain how a mechanical injury during the flu vaccine administration would occur and lead to DVT, or draw a comparison between DVT and NS. Dr. Gershwin stated his opinion that NS can affect deep veins, but the Special Master did not find this to be supported by the literature.

The supporting literature explained that NS "is a rare dermatological condition associated with intramuscular injections," which "begins with instantaneous, severe pain at the site of injection, followed shortly thereafter by development of skin lesions." Decision at 5-6 (citations omitted). It generally presents with "large areas of purplish plaque on the skin, and can include erythema (skin redness caused by capillary congestion), chronic ulcers, and scarring." Decision at 6 (citations omitted).

The Special Master requested clarity as to what type of specialists would be best-suited to speak to the presentation of NS. Dr. Gershwin's second report responded that, because NS presents in a variety of ways, it may be referred to many practitioners, but that internists, such as Dr. Gershwin, and allergists are particularly qualified to discuss the syndrome.

Respondent filed one expert report from Dr. Megha Tollefson. Dr. Tollefson is a board-certified Pediatric Dermatologist at the Mayo Clinic in Rochester, Minnesota. She completed residencies in both General Pediatrics

and Dermatology at the Mayo Clinic. She was a one-year fellow in Pediatric Dermatology at Stanford University.

Dr. Tollefson agreed that the flu vaccine has never been associated with DVT, but she disagreed that Mr. Prepejchal's DVT was consistent with NS. She noted that NS generally involves immediate pain and skin changes either during or just after the injection. She cited supporting materials that NS generally occurs directly at the site of the injection. Dr. Tollefson distinguished Mr. Prepejchal's experience by noting that he did not experience pain during or immediately after the injection, did not develop skin changes, and that his DVT did not involve the skin or muscle layers where the vaccination was administered. Dr. Tollefson also highlighted that Mr. Prepejchal's medical records did not state a clear cause of his DVT and that both Mr. Prepejchal's family history and profession created risk for the development of DVT.

Dr. Gershwin began his response by arguing that Dr. Tollefson had placed too much weight on Mr. Prepejchal's piloting because his air travel was not prolonged, the DVT was in an upper extremity rather than lower extremity, and the DVT developed on the same side on which the flu vaccine was administered. Dr. Gershwin noted that NS has several variations and provided a citation to a NS patient experiencing thrombosis. Dr. Gershwin pointed to Mr. Prepejchal's 2018 affidavit in which he stated that he "experienced soreness and mild pain an hour after the injection." Pet'r's Ex. 18. Dr. Gershwin agreed that Mr. Prepejchal may be predisposed to DVT based on his family history, but argued that his predisposition would make DVT more likely following an injury.

After reviewing the record, including the medical history, experts' reports, and literature, the Special Master found that petitioner did not prove by a preponderance that his injury was caused by the flu vaccine. He determined that Mr. Prepejchal failed to provide a plausible medical theory causally connecting the vaccination to his injury and to show a logical sequence of cause and effect between the flu vaccine and his injury, as required by the test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

On *Althen* prong one, the Special Master found that petitioner "failed to offer a cogent and reliable theory of causation." Decision at 18. The Special Master based this conclusion on four contributing factors. First, petitioner conceded that there is no immunological connection between the

flu vaccine and DVT. Second, although Dr. Gershwin had some familiarity with NS, accepting the causation theory would require accepting a mechanical injury theory on which Dr. Gershwin was not an expert. The Special Master acknowledged that Dr. Gershwin was well-credentialed, but that his credentials were not relevant to mechanical injuries giving rise to either NS or DVT.

Third, the comparison to NS was faulty. The Special Master noted that petitioner was not diagnosed with NS and that no treater had ever mentioned NS. Also, NS and DVT are sufficiently different to make the comparison too tenuous. For instance, petitioner's literature stated that NS presents with immediate and severe pain at the site of the injection, which Mr. Prepejchal did not allege he had experienced. Petitioner's literature also stated that NS typically presents with death of tissue, which Mr. Prepejchal did not experience. Finally, the literature did not support a conclusion that the vaccination caused DVT, because the literature only addressed NS. Fourth, the Special Master found that petitioner's argument that DVT is caused by a triggering event was unpersuasive.

Regarding *Althen* prong two, the Special Master was unable to find by a preponderance of the evidence that Mr. Prepejchal's DVT was caused by a vaccine. First, his treaters' records were contradictory. The Special Master gave some weight to Dr. Meeker's opinion that the vaccine may have been related to DVT, despite that Dr. Meeker's earlier conclusion that he was unsure how the two were connected. The Special Master found Dr. Lesoski's opinion that the vaccine and DVT were unconnected was more credible, because it was founded on independent research and consultation. Furthermore, the Special Master found that the record did not otherwise support the vaccination triggering DVT, akin to NS or not. Petitioner experienced some soreness after vaccine administration, but the extent of any pain or swelling immediately or in the nine days after vaccination was unclear. The Special Master conceded that there was temporal association between the vaccination and injury, but he found that the temporal association was not sufficient to demonstrate causation in fact. Because petitioner failed to demonstrate prongs one and two, showing a temporal relationship sufficient to prove prong three of the *Althen* test could not save the claim.

Although the Special Master found that petitioner's "failure to offer a plausible causation theory is a more fundamental failure in his evidentiary showing, his insufficient showing on the severity requirement is another

basis for the claim's dismissal." Decision at 22. The Special Master applied the standard found in 42 U.S.C. § 300aa-11(c)(1)(D), which states that claimants must show that they suffered from the "residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." The Special Master found that Mr. Prepejchal's condition "had mostly resolved by January 31, 2013—less than three months after vaccination." Decision at 21. Despite the petition stating that Mr. Prepejchal continued to experience symptoms through the time of filing, no evidence of such symptoms was included in the record. The Special Master compared Mr. Prepejchal's petition to three other cases filed under the Vaccine Act in which petitioners received treatment after injury. The Special Master concluded that past cases found "that taking medication over a period of time, without evidence of other noticeable effects of an alleged vaccine-caused injury, only satisfies the six-month severity requirement when the medication treats symptomology that would otherwise be present over that time period." *Id*. The Special Master found that petitioner did not meet the severity requirement, relying on the dates in the record and that the purpose of petitioner's medication was stop future clots rather than to treat the existing clot.

Finally, the Special Master found that, despite petitioner suggesting that a hearing would be useful, the matter could be decided on the record. The Special Master explained that the causation theory was self-evident from the expert reports and that live testimony from either the experts or Mr. Prepejchal was not necessary. The Special Master concluded that Mr. Prepejchal did not establish entitlement to compensation and dismissed his claim.

DISCUSSION

This court has jurisdiction to review the Special Master's decision in accordance with 42 U.S.C. § 300aa-12. Our review is deferential, only setting aside decisions when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." *Id.* § 300aa-12(e). When the Special Master has considered the relevant evidence and articulated a rational basis for the decision, reversible error is "extremely difficult to demonstrate." *Hines v. Sec'y Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). This court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the

witnesses–these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

A petitioner may seek compensation for "any illness, disability, injury, or condition" sustained or significantly aggravated by a vaccine. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)(A). When a petitioner seeks compensation for an injury caused by a vaccine other than those injuries listed on the Vaccine Injury Table, an off-table injury, petitioner must prove causation in fact. *Althen*, 418 F.3d at 1278 (citing 42 U.S.C. § 300aa-13(a)(1)(A)). Petitioner must show that the vaccination caused the injury by proving three elements by a preponderance of the evidence: "(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." *Id.*

A different showing corresponds to each of the elements, but the same evidence may be used to prove more than one element. *Id*. First, petitioner must provide a reputable medical theory that demonstrates that the vaccine can cause the alleged injury. *Althen*, 418 F.3d at 1278. A petitioner is not required to submit medical literature, propose a generally accepted theory, or demonstrate proof of scientific certainty. *See Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009). Yet petitioner cannot prevail on "a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352,1356 (Fed. Cir. 2013) (citing *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1332 (Fed. Cir. 2010)). "[A] mere showing of a proximate temporal relationship between vaccination and injury" is insufficient to prove actual causation. *Althen*, 418 F.3d at 1278.

To demonstrate a logical sequence of cause and effect, petitioner may use reputable medical or scientific evidence, including medical records. *See Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citations omitted). Additionally, the treating physician's opinion is entitled to weight, particularly because it was created contemporaneously. *Id.* Finally, petitioner must establish that there is a "medically-acceptable" timeframe between the vaccination and alleged injury that is consistent with the theory of how the vaccine could cause the injury. *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Mr. Prepejchal raises three arguments: that the Special Master was arbitrary and capricious or abused his discretion by ignoring aspects of the expert reports and evidence submitted; that the Special Master improperly raised the six-month severity requirement; and that the Special Master should have held a hearing. For the reasons set out below, we find that the Special Master's decision considered the evidence presented, applied the proper standard, and articulated why Mr. Prepejchal did not meet his burden.

Petitioner asserts that the Special Master placed a higher burden on him than a preponderance of the evidence by ignoring aspects of the expert reports and evidence submitted. Petitioner does not state which literature or aspect of the reports that the Special Master ignored, but, in any event, the Special Master is not required to mention each piece of literature or to recite the theory word-for-word. *See Moriarty v. HHS*, 844 F.3d 1322, 1328 (Fed. Cir. 2016). Furthermore, the Special Master expressly referenced the NS literature that petitioner filed and considered whether NS and Mr. Prepejchal's DVT were analogous. Decision at 18-19.

It appears that petitioner's expert's theory reasonably could have been understood in two ways: either a mechanical injury during vaccination led to the DVT, akin to the way NS presents, or a mechanical injury during vaccination in fact caused NS and the DVT is evidence of NS. This ambiguity could have been problematic, but respondent's expert addressed both interpretations and the Special Master considered both viewpoints. Dr. Tollefson noted that the literature filed by both parties indicated that persons suffering from NS will experience pain during or immediately after the injection; contrary to the literature, Mr. Prepejchal did not suffer pain during or immediately after the injection. Moreover, he did not develop skin changes at the site of injection and his DVT did not involve the skin or muscle layers where the flu vaccine was given. Thus, respondent's expert concluded that petitioner's injury did not appear to be NS and the DVT also did not occur in the same way NS would occur. The Special Master drew similar distinctions between petitioner's injury and NS, also noting that petitioner's theory was not clear regarding a triggering event for the DVT: what was the mechanical injury and how did that lead to petitioner's DVT? The Special Master had a rational basis for concluding that Mr. Prepejchal did not make the necessary showing under *Althen* prong one.

Furthermore, pursuant to *Althen* prong two, the Special Master considered the treating doctors' opinions and found that Dr. Meeker's opinion was somewhat contradictory and ill-researched and that Dr.

Lesoski's opinion did not support petitioner's theory. Dr. Meeker was unsure how Mr. Prepejchal's DVT was related to the flu vaccine during the first visit; he later revised that opinion, without outside consultation, to recommend that Mr. Prepejchal avoid the flu vaccine in the future. Dr. Lesoski, on the other hand, conducted research before reaching the conclusion that Mr. Prepejchal's DVT was unrelated to the flu vaccine. Neither treater referenced a mechanical injury.

The Special Master's decision reflects a close reading of the record followed by the drawing of conclusions; he did not insert himself as a medical expert or ignore some aspect of the record. In sum, the Special Master applied the appropriate burden and rationally found that petitioner did not make a sufficient showing under the first two *Althen* elements.

Mr. Prepejchal also argues that it was inappropriate for the Special Master to raise the six-month severity requirement found in 42 U.S.C. § 300aa-11(c)(1)(D) when respondent did not bring up the issue in its Vaccine Rule 4(c) report. The government argues that the Special Master permissibly raised the issue because Vaccine Rule 4(c) does not state that respondent waives arguments not raised and the severity standard is a statutory requirement that petitioner must meet. Vaccine Rule 4(c) states,

> [R]espondent must file a report setting forth a full and complete statement of its position as to why an award should or should not be granted. The report must contain respondent's medical analysis of petitioner's claims and must present any legal arguments that respondent may have in opposition to the petition.

Although the rule does not state that arguments not raised are waived, respondent's responsibility is to raise its arguments such that petitioner and the special master have notice of the details of its argument and the opportunity to review them and respond. We agree with the government that it was not inappropriate for the Special Master to raise the requirement, nor was it arbitrary and capricious, because the severity requirement is a statutory element that petitioner must meet prior to being awarded compensation. Given the lack of notice of this argument, however, the Special Master could have sought explanation or testimony from Mr. Prepejchal on this issue.

Even if the Special Master should have sought more explanation of the role petitioner's medication played in resolving his DVT rather than

relying on inferences, the Special Master expressly stated that the insufficient causation evidence was the fundamental reason for denying petitioner's claim. The severity requirement was an alternative basis for denying Mr. Prepejchal's petition. Furthermore, petitioner's argument that it was improper for the Special Master to conduct his own research is incorrect. The Special Master recited facts from the medical record and compared those facts to other decisions dealing with the severity requirement; such research is a basic aspect of legal reasoning. Thus, we will not disturb the Special Master's conclusion.

Finally, Mr. Prepejchal asserts that the Special Master abused his discretion by declining to hold a hearing despite questioning petitioner's expert's theory. Respondent correctly points out that the Special Master is not required to hold a hearing. The Vaccine Act provides that the Vaccine Rules should include a provision allowing for decision on the record, and the Vaccine Rules in fact state that the Special Master's authority to hold a hearing is permissive, not mandatory. 42 U.S.C. § 300aa-12(d)(2)(D); Vaccine Rule 3(b)(2), 8(d); *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The Special Master found the Dr. Gershwin's theory did not require further explanation, that he did not require live testimony to weigh credibility, and that petitioner's medical record spoke for itself. The Special Master was not required to hold a hearing and reasonably explained his reasoning for declining to do so.

CONCLUSION

In sum, because the Special Master rationally determined that petitioner did not demonstrate the first two prongs of the *Althen* test and the Special Master did not otherwise act arbitrarily or in violation of law, we affirm his decision. Accordingly, we deny petitioner's motion for review. The clerk is directed to enter judgment accordingly. No costs.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge