In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

SCOTT VALEEN,	*	
	*	No. 16-390V
Petitioner,	*	Special Master Christian J.
	*	Moran
	*	
v.	*	
	*	Filed: November 30, 2021
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement; flu vaccine;
	*	GPA; prong one.
Respondent.	*	

Renée J. Gentry, Vaccine Injury Clinic, George Washington University School of Law, Washington, DC, for petitioner;

Naseem Kourosh, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Scott Valeen alleges that an influenza ("flu") vaccine caused him to suffer granulomatosis with polyangiitis ("GPA"). The parties have submitted reports from experts and argued their positions through legal briefs. An assessment of this information shows that Mr. Valeen has not met his burden of establishing that the flu vaccine can cause GPA. Thus, his case is dismissed.

[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. 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.

I. Facts[2]

Before the vaccination, Mr. Valeen worked at an oil refinery. Exhibit 78 at 2. He suffered from diabetes type 2 and hypothyroidism. Exhibit 10 at 1. Mr. Valeen received a flu vaccination on October 17, 2012, and he did not report any adverse reactions. Exhibit 2 at 30.

Almost one year later, Mr. Valeen received another flu vaccination. Exhibit 2 at 30 (September 11, 2013). He alleges this September 11, 2013 vaccination caused his GPA.

Mr. Valeen sought medical care from his primary care doctor, Dennis Tang, on October 7, 2013. Mr. Valeen complained about nasal congestion, nosebleeds, runny nose, postnasal drip, and sneezing for about 3 to 4 weeks. Exhibit 2 at 17. While the estimate of 3 to 4 weeks places the onset of these problems either a few days before or a few days after the vaccination (September 9-16, 2013), Mr. Valeen averred that he began experiencing the symptoms on either September 21, 2013 or September 25, 2013. Exhibit 10 (affidavit, dated Apr. 7, 2016) and Exhibit 14 (affidavit, dated June 16, 2016).

Following this October 7, 2013 appointment with Dr. Tang, Mr. Valeen saw doctors over the next weeks. Eventually, in December 2013, Mr. Valeen was hospitalized during which various tests were performed. He was diagnosed with GPA. Exhibit 17 at 1 (discharge report). A pulmonologist (Dr. Maksoud) and a rheumatologist (Dr. Elkhalili) also confirmed the GPA diagnosis. Exhibit 5 at 13-14; exhibit 6 at 30-31.

The parties agree that GPA is an appropriate diagnosis for Mr. Valeen. GPA is "a multi-system disease chiefly affecting males, characterized by necrotizing granulomatosis vasculitis involving the upper and lower respiratory tracks, glomerulonephritis, and various degrees of ANCA-associated type of small vessel vasculitis. Most authorities consider this condition to be an aberrant hypersensitivity reaction to an unknown antigen." Dorland's Illustrated Medical Dictionary 796 (32d ed. 2012).

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[2] The recitation of events in Mr. Valeen's life is abbreviated because the outcome of this case largely turns on Althen prong one.

After the GPA diagnosis at the end of 2013, Mr. Valeen has continued to receive treatment for GPA periodically. However, the details of the 6 years of medical history do not affect the outcome of the case.[3]

II. Procedural History

Mr. Valeen initiated this case on March 28, 2016. By August 22, 2016, Mr. Valeen had filed his medical records.

The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., filed Oct. 31, 2013. The Secretary reasoned that Mr. Valeen failed to provide a credible theory of causation connecting his vaccine to his GPA. Id. at 8. Additionally, the Secretary noted that none of Mr. Valeen's treating physicians associated his vaccine with his condition. Id. Finally, the Secretary argued that Mr. Valeen failed to offer a medically acceptable timeframe between the date of his vaccination and the onset of his symptoms. Id.

The parties filed a series of reports from experts. To advance his case, Mr. Valeen submitted a report of Yehuda Shoenfeld, an immunologist, on March 17, 2017. Exhibit 28.[4] The Secretary presented a report from Lindsay Whitton, a medical researcher with a Ph.D. whose license to practice medicine is not in the United States, and a report from Robert Lightfoot, a rheumatologist. Exhibit A; exhibit C. Dr. Shoenfeld presented another report. Exhibit 77. Dr. Whitton wrote a second report as well. Exhibit E. The parties also filed various medical articles their experts cited.

The case was assigned to the undersigned on March 5, 2021. Mr. Valeen filed updated medical records in April and May 2021. Because the parties had submitted complete reports from their experts, the parties were instructed to advocate for their positions in briefs. Order, issued May 21, 2021.

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[3] The parties summarized Mr. Valeen's medical course in their briefs. See Pet'r's Br. at 2-4; Resp't's Br. at 2-12.

[4] Mr. Valeen also submitted a report by Judy A. Mikovits and Francis W. Ruscetti. However, Mr. Valeen later struck this report from the record. Pet'r's mot. to strike, filed Apr. 1, 2021; order, issued Apr. 6, 2021.

Mr. Valeen filed a primary brief on July 15, 2021, and a reply brief on October 21, 2021. With the primary brief, Mr. Valeen submitted a short report from Dr. Shoenfeld. Exhibit 87. Between Mr. Valeen's primary brief and reply brief, the Secretary submitted his brief as well as brief statements from Dr. Whitton and Dr. Lightfoot. Exhibit F and I. With the submission of Mr. Valeen's reply brief, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his 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 the 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).

In a case, such as this case, in which a petitioner seeks compensation for an injury not listed on the Vaccine Table, the Federal Circuit has defined the elements of petitioner's case. 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

Mr. Valeen's case fails at least two of the three Althen prongs. This lack of persuasiveness is most apparent for the first prong. Thus, the analysis begins there.

A. Althen Prong One: A Causal Theory Connecting the Vaccine and GPA

Through Dr. Shoenfeld, Mr. Valeen has attempted to present a theory by which the flu vaccine can cause GPA. However, Mr. Valeen's claim that a flu vaccine can cause GPA lacks persuasiveness in at least two respects.

1. Dr. Shoenfeld offers a theory based upon adjuvants but the vaccine Mr. Valeen received does not contain adjuvants.

The March 21, 2021 order directed Mr. Valeen to set forth the theory by which a flu vaccine can cause GPA. Order, issued Mar. 21, 2021, at 5-6. In response to the order, Mr. Valeen explained Dr. Shoenfeld's proposed mechanism as "the influenza vaccination received by Mr. Valeen contained adjuvants, which are not only capable of eliciting a hyperactivated immune response, they are designed to do that very thing. This hyperactivated immune response increases the likelihood of cross-reacting with human proteins . . . and . . . Mr. Valeen's GPA is the result of that autoimmunity." Pet'r's Br. at 17. After the Secretary challenged Mr. Valeen's proof on this element, Mr. Valeen again defined Dr. Shoenfeld's theory beginning with the assertion that "Mr. Valeen's influenza vaccination contained adjuvants." Pet'r's Reply at 2.

The brand of influenza vaccine that Mr. Valeen received is Fluzone. Exhibit 2 at 30. The experts dispute whether Fluzone contains any adjuvant.

Dr. Shoenfeld's first report was inconsistent on this topic. At the beginning, Dr. Shoenfeld stated that all seasonal flu vaccines administered in the United States do not contain adjuvants. Exhibit 28 at 8. However, later, Dr. Shoenfeld maintained that all vaccines need adjuvants. Id. at 24.[5]

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[5] Dr. Shoenfeld reasoned that because the immune system's first exposure to any antigen produces only a weak immune response, an adjuvant is needed to boost the strength of the immune response. Exhibit 28 at 24. This reasoning is flawed because, in part, Dr. Whitton persuasively explained that some antigens

In contrast, Dr. Whitton stated that Fluzone does not contain an adjuvant. Exhibit A at 7.[6] Dr. Whitton cited the earlier portion of Dr. Shoenfeld's report in which Dr. Shoenfeld maintained that Fluzone does not contain an adjuvant. Id. at 9 (citing exhibit 28 at 8). Dr. Whitton later also noted that Dr. Shoenfeld was mistaken when Dr. Shoenfeld asserted that all flu vaccines given in the United States are not adjuvanted because one brand of flu vaccine, Fluad, does contain an adjuvant. Exhibit E at 5-6.

Dr. Lightfoot did not discuss the presence (or lack) of adjuvant extensively. At most, Dr. Lightfoot noted the inconsistency in Dr. Shoenfeld's first report. Exhibit C at 8-9 (citing exhibit 28 at 8, 24).

When given a chance to respond, Dr. Shoenfeld pointed to two components of the Fluzone vaccine, formaldehyde and Triton X-100. To Dr. Shoenfeld, these substances could function as an adjuvant. Exhibit 77 at 2-3.

Dr. Whitton, in turn, explained why formaldehyde and Triton X-100 are not adjuvants. Exhibit E at 5-6. In support, Dr. Whitton submitted guidance from the Centers for Disease Control and Prevention ("CDC") that states that Fluzone does not contain adjuvants. See exhibit E, tab 2, at 14 (Lisa A. Grohskoph et al., Ctrs. for Disease Control & Prevention, Prevention and Control of Seasonal Influenza with Vaccines 14 (2017)).

The parties' briefs draw upon these portions of the expert reports. See Resp't's Br. at 34; Pet'r's Reply at 2.

Mr. Valeen has not presented persuasive evidence that Fluzone contains an adjuvant. The strongest reason for finding that Fluzone does not contain an adjuvant is the statement from the CDC. The CDC characterizes Fluzone as unadjuvanted. See exhibit E, tab 2, at 14. This evidence is clear and convincing.

The finding that Fluzone does not contain an adjuvant is consistent with statements involving Fluzone in other cases. A primary example is Dougherty v.

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cause a strong immune response on their first interaction with a human being. Exhibit A at 12.

[6] Technically, in this portion of Dr. Whitton's report, he was responding to Ms. Mikovits's assertion that Fluzone contains an adjuvant.

Secretary of Health & Human Services, No. 15-1333V, 2018 WL 3989519 (Fed. Cl. Spec. Mstr. July 5, 2018), mot. for rev. denied, 141 Fed. Cl. 223 (2018). In Dougherty, the petitioner alleged that a Fluzone vaccine caused her to suffer narcolepsy with cataplexy. Id. at *1. Ms. Dougherty maintained that the Fluzone vaccine can cause narcolepsy just as a different vaccine, Pandemrix, can cause narcolepsy. Id. at *42. However, the special master did not agree with that comparison because Fluzone is not adjuvanted. Id.

While the unadjuvanted nature of Fluzone was a key part of the special master's analysis in Dougherty, portions of other decisions have mentioned that Fluzone lacks an adjuvant. See Halverson v. Sec'y of Health & Hum. Servs., No. 15-227V, 2020 WL 992588, at *18 (Fed. Cl. Spec. Mstr. Feb. 4, 2020) (testimony of respondent's expert, Dr. Rose); Bantugan v. Sec'y of Health & Hum. Servs., No. 15-721V, 2019 WL 7602581, at *11 (Fed. Cl. Spec. Mstr. Dec. 20, 2019) (testimony of respondent's expert, Dr. Whitton); McCabe v. Sec'y of Health & Hum. Servs., No. 13-570V, 2018 WL 3029176, at *30-31 (Fed. Cl. Spec. Mstr. May 17, 2018) (testimony of respondent's expert, Dr. Matloubian).

In light of this strong evidence, Dr. Shoenfeld faced a challenge to establish, more likely than not, that Fluzone contains an adjuvant. Dr. Shoenfeld fell well short of meeting this burden of presenting preponderant evidence on this point.

Dr. Shoenfeld identified two components of Fluzone that function as adjuvants, formaldehyde and Triton X-100, which is also known as octylphenoxy polyethoxyethanol. Pet'r's Reply at 2. Formaldehyde is "added to inactivate (kill) the virus." Exhibit E at 6 (Dr. Whitton's report). Then, the formaldehyde is filtered from the vaccine, leaving (perhaps) a de minimis residue. Id. at 3. Dr. Whitton's discussion of formaldehyde's use in vaccines is consistent with expert testimony from other cases. See Murphy v. Sec'y of Health & Hum. Servs., No. 05-1063V, 2016 WL 3034047, at *19 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) (the DTaP vaccine is "chemically inactivated using formaldehyde"); Sucher v. Sec'y of Health & Hum. Servs., No. 07-0058V, 2010 WL 1370627, at *27 (Fed. Cl. Spec. Mstr. Mar. 15, 2010) ("A number of methods have been used for toxoiding including . . . chemical treatments of the toxin or whole cells with formaldehyde . . . ."); James ex rel. Chee v. Sec'y of Health & Hum. Servs., No. 09-284V, 2010 WL 4205699, at *10 (Fed. Cl. Spec. Mstr. Sept. 30, 2010) ("[The] pertussis toxin is inactivated either through the use of glutaraldehyde or formaldehyde or other chemicals to produce a toxoid."). Additionally, Dr. Whitton's findings on the use of formaldehyde in vaccines is in accord with

testimony the undersigned has received in other cases. See Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (indicating that special masters may draw upon their "accumulated expertise" in resolving cases).

The undersigned has heard much less, if any, testimony about Triton X-100 or octylphenoxy polyethoxyethanol. According to Dorland's, octylphenoxy polyethoxyethanol, which is also known as octoxynol 9, is "used as a surfactant in pharmaceutical preparations." Dorland's at 1294. Dr. Whitton explained that Triton X-100 disrupts the inactivated virus, causing a "'split virus' vaccine." Exhibit E at 3. This description resembles Dr. Shoenfeld's description of the purpose of Triton X-100: Triton X-100 is used "to both lyse cells to extract proteins or organelles and to permeabilize cell membranes." Exhibit 77 at 3.[7] In this context, Dr. Shoenfeld cites an article as reference 7, but Mr. Valeen neither filed this article nor discussed it his briefs.

While Dr. Shoenfeld and Dr. Whitton agree that Triton X-100 is used as part of the process of making the flu virus safe in the vaccine, they disagree over what happens next. Dr. Shoenfeld states that "When mixed with the antigen, formaldehyde-Triton X100 help to deposit and sequester the injected antigen. This causes a dramatic increase in the antibody response." Exhibit 77 at 3. In contrast, Dr. Whitton states any Triton-X 100 is removed in the manufacturing process by passing the mixture over a Triton-binding column. Exhibit E at 3. Neither Dr. Shoenfeld nor Dr. Whitton cited any articles about the persistence or removal of Triton-X 100 as Fluzone is manufactured. However, Dr. Whitton's explanation is persuasive because, in part, it implicitly matches the CDC's statement that Fluzone does not contain an adjuvant.

Consequently, Mr. Valeen has failed to establish, by preponderant evidence, that Fluzone contains an adjuvant. Because Dr. Shoenfeld's theory for how Fluzone can cause GPA presupposes the presence of an adjuvant, the finding that Fluzone is not adjuvanted eliminates the reliability of Dr. Shoenfeld's opinion.

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[7] "Lyse" means "to cause or produce disintegration of a compound, substance, or cell." Dorland's at 1074.

2. Even if Dr. Shoenfeld's theory did not depend upon adjuvants, his theory remains unpersuasive.

Although Mr. Valeen has twice described Dr. Shoenfeld's theory as based upon an adjuvanted vaccine, Pet'r's Br. at 17 and Pet'r's Reply at 2, conceivably, Dr. Shoenfeld's opinion could be stretched to present the theory of molecular mimicry without requiring an adjuvant. "Petitioner's theory of causation is the influenza vaccine, specifically the antigens in the vaccine triggered multiple cross-reactions with human proteins that resulted in Mr. Valeen developing GPA . . . . Dr. Shoenfeld's proposed biological mechanism is molecular mimicry." Pet'r's Br. at 10-11.

Experts for petitioners often advance molecular mimicry as a theory to explain how a vaccine can cause a variety of injuries. See, e.g., E.M. v. Sec'y of Health & Hum. Servs., No. 14-753V, 2021 WL 3477837, at *18 (Fed. Cl. Spec. Mstr. July 9, 2021). In the context of attempting to explain how the flu vaccine can cause GPA, Dr. Shoenfeld's use of molecular mimicry is underdeveloped, vague, and, ultimately, unpersuasive.

The experts discussed molecular mimicry in their reports. In Dr. Shoenfeld's first report, he asserted that "hemagglutinin from Influenza A virus . . . shares a conspicuous number of minimal immune determinants (i.e. pentapeptides) with human proteins that are expressed in cilia or ciliated cells and that, when altered, are involved in ciliary dyskinesia, a disorder characterized by abnormalities and malfunction of motile cilia." Exhibit 28 at 17.

The Secretary's experts disagreed. Dr. Whitton stated that sequences of five amino acids are "predictable and commonplace." Exhibit A at 12. Dr. Whitton also noted that Mr. Valeen was not diagnosed with ciliary dyskinesia. Id. at 11. Referring to the opinion Ms. Mikovits and Mr. Ruscetti presented, Dr. Lightfoot stated that "While it is likely that many vaccines contain amino acid sequences found in human tissue, that does not indicate that immune cross-reactivity occurs." Exhibit C at 8. Dr. Lightfoot added that the basis for extrapolation from ciliary dyskinesia to GPA is not clear. Id. at 9.

In response, Dr. Shoenfeld defended his position. He asserted "as few as four or five homologous amino acids can constitute a crossreacting antigenic determinant with pathologic consequences." Exhibit 77 at 5. Dr. Shoenfeld also stated that the "crossreactions induced by Fluzone hit multiple targets in the organism's DNA." Id. at 7.

Dr. Whitton pointed to flaws in Dr. Shoenfeld's opinion. Dr. Whitton discussed the significance (or lack of significance) of strings of five amino acids. Exhibit E at 7-8. In response to Dr. Shoenfeld's comparison to ciliary dyskinesia, Dr. Whitton maintained that this condition "is irrelevant to the case." Id. at 9.

Both critiques seem to reduce the persuasive value of Dr. Shoenfeld's opinion. Dr. Whitton's discussion that marching pentapeptides are common and do not necessarily carry any immunologic significance seems credible. Exhibit A at 11-12; see also T.M. v. Sec'y of Health & Hum. Servs., No. 08-284V, 2016 WL 11087157, at *17, 29 (Fed. Cl. Aug. 9, 2016), mot. for rev. denied, 133 Fed. Cl. 78, 90-91 (2017).

However, an extensive discussion of the value of pentapeptides is not the primary reason for finding Dr. Shoenfeld's use of molecular mimicry not credible in this case. Even if Dr. Shoenfeld were correct that pentapeptides can be the basis for a cross-attack, Dr. Shoenfeld has, at best, linked the matching amino acid sequences to proteins "involved in ciliary dyskinesia." Exhibit 28 at 17. Mr. Valeen attempts to reinforce this connection by citing multiple articles about ciliary dyskinesia. Pet'r's Br. at 13-15.

However, neither Dr. Shoenfeld nor Mr. Valeen have explained how ciliary dyskinesia, a disease with which Mr. Valeen was not diagnosed, resembles GPA, the condition affecting Mr. Valeen. The only comparison Mr. Valeen draws between GPA and ciliary dyskinesia is that Mr. Valeen's symptoms "fit the destruction or dysfunction in the cilia." Pet'r's Br. at 20. This gap is particularly noticeable because Dr. Whitton and Dr. Lightfoot have pointed it out. The Secretary echoed their contentions, arguing that a discussion of ciliary dyskinesia "is irrelevant at best, given that petitioner's alleged injury in this case is GPA, not ciliary dyskinesia." Resp't's Br. at 32. When given a final word, Mr. Valeen presented no argument about how a process arguably leading to ciliary dyskinesia would resemble a process leading to GPA. See Pet'r's Reply at 5 (stating that hemagglutinin shares peptides with human proteins that are expressed in cilia or ciliated cells). Accordingly, Mr. Valeen has failed to present "a reputable medical or scientific explanation that pertains specifically to the petitioner's case." Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010).

Beyond the sequences of matching peptides, Dr. Shoenfeld identifies a series of articles in which a person received a vaccine (often an influenza vaccine) before developing a form of vasculitis. See Pet'r's Br. at 11-13. Of this group, the

potentially most persuasive are a book chapter on vasculitides and an article about giant cell arteritis and polymyalgia rheumatica. See exhibit 59 (Alessandra Soriano et al., Vasculitides, in Vaccines and Autoimmunity (Yehuda Shoenfeld, Nancy Agmon-Levin, and Lucija Tomljenovic eds. 2015)) and exhibit 37 (A. Soriano et al., Giant Cell Arteritis and Polymyalgia Rheumatica After Influenza Vaccination: Report of 10 Cases and Review of the Literature, 21 Lupus 153 (2012)).

The chapter and the article resemble each other. The lead author appears to be the same. The basic methodology is identifying case reports in which vaccines preceded the development of certain conditions. Compare exhibit 59 (chapter) at 223, with exhibit 37 (article) at 154. The authors appear to endorse the concept "autoimmune syndrome induced by adjuvant" also known as ASIA. Exhibit 59 at 224-25 and exhibit 37 at 156.[8] The authors suggest mechanisms by which vaccines might possibly cause conditions.

The similarities continue in how the pieces conclude. In the earlier work, the article published in the journal Lupus, the authors "recommend a systemic research of previous vaccination in patients with recent onset of [giant cell arteritis/polymyalgia rheumatica]." Exhibit 37 at 156. The latter work, the book chapter, repeats this recommendation: "Further investigations are needed to clarify the biologic plausibility of post-vaccination phenomena. Thus, surveillance systems and registries can be important tools for retrospective as well as prospective evaluations of all cases." Exhibit 59 at 229.

However, the book chapter goes a little further: "The lack of evidence for other causes of the symptoms and the coincidence regarding the vaccination in most of the cases analyzed here strongly supports a causal relationship between the vaccination and vasculitis onset, especially where a plausible temporal association exists." Id. Mr. Valeen relies upon this passage. Pet'r's Br. at 11.

Neither the Soriano book chapter nor the Soriano article make Dr. Shoenfeld's opinion persuasive. See exhibit A at 10 (Dr. Whitton's critique of the Soriano article). In essence, both are collections of case reports. Case reports

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[8] Special masters have consistently rejected ASIA. E.g., Pearson v. Sec'y of Health & Hum. Servs., No. 16-9V, 2019 WL 3852633, at *13 (Fed. Cl. Spec. Mstr. July 31, 2019).

provide little, if any, reliable information for determining causation. See K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports). Because they present a sequence of events in which a vaccine occurred before the onset of the disease, case reports cannot rule out the possibility of a coincidental (not causal) relationship.

In sum, regardless of whether Dr. Shoenfeld's theory requires an adjuvanted vaccine, his opinions regarding the means by which a flu vaccine can cause GPA are not persuasive. For these reasons, Mr. Valeen has not met his burden of proof regarding the first Althen prong. Because the finding that Mr. Valeen has not presented a reliable basis for concluding that the flu vaccine can cause GPA resolves the case, the remaining Althen prongs can be discussed briefly.

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

With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, statements from treating doctors do not assist Mr. Valeen. The May 21, 2021 Order directed him to identify any passages in which a doctor associated his GPA with the vaccination. Order, issued May 21, 2021, at 7. However, Mr. Valeen has not presented any such evidence from treating doctors in his brief. Pet'r's Br. at 18-20; see also Resp't's Br. at 38 ("[N]one of petitioner's treating physicians – including various specialists who treated him for several years – drew a causal connection between his flu vaccination and his GPA."). Mr. Valeen merely argues that the nature and onset of his symptoms align with Dr. Schoenfeld's theory of causation. Pet'r's Br. at 20.

C. Althen Prong Three: A Showing of a Proximate Temporal Relationship Between Vaccination and GPA

The timing prong of Althen 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).

The medically acceptable timeframe depends, at least in part, on the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013). Here, as explained in section IV.A. above, Mr. Valeen has not presented a persuasive medical theory to explain how the flu vaccine can cause GPA. Thus, analyzing the medically acceptable amount of time becomes somewhat fanciful.

With respect to the interval of time for which an inference of causation is medically appropriate, Dr. Shoenfeld's opinion is confusing. Dr. Shoenfeld seems to suggest that the onset of GPA after a second flu vaccination should be rapid. Exhibit 28 at 24; see also Pet'r's Br. at 21 (stating that "the rapidity of onset is particularly compelling"). Yet, at the same time, Dr. Shoenfeld suggests that an onset of symptoms two weeks after vaccination would also be appropriate. Exhibit 28 at 13; Pet'r's Br. at 21. In response, the Secretary noted that Mr. Valeen provided no support for his assertion that two weeks is a medically acceptable timeframe for onset of symptoms. See Resp't's Br. at 39.

While Dr. Shoenfeld might clarify his opinion on timing at a hearing, this clarification would be academic. Even if Mr. Valeen presented preponderant proof that his GPA developed within the time for which an inference of causation is appropriate, establishing this sequence of events would not necessarily mean that Mr. Valeen is 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."). The lack of preponderant evidence regarding the other Althen prongs would still prevent Mr. Valeen from receiving compensation.

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).

Mr. Valeen has enjoyed a fair and full opportunity to present his case. After Dr. Shoenfeld presented his opinion initially, Dr. Whitton and Dr. Lighthouse critiqued it, persuasively pointing out gaps and flaws in Dr. Shoenfeld's opinion. Dr. Shoenfeld was then given an opportunity to respond but did not repair those deficiencies. Mr. Valeen was given a further chance to shore up Dr. Shoenfeld's opinion during the briefing process, but any such efforts were not persuasive.

VI. Conclusion

After receiving a flu vaccination, Mr. Valeen developed GPA. However, Mr. Valeen has not met his burden of establishing, more likely than not, that the flu vaccination caused his GPA. 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