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

DUSTIN HARLOW,	*	
	*	No. 20-550V
Petitioner,	*	
	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: November 13, 2023
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Edward Kraus, Kraus Law Group, LLC, Chicago, IL, for Petitioner; Sarah Black Rifkin, United States Dep't of Justice, Washington, D.C., for Respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Dustin Harlow alleges that an influenza ("flu") vaccine caused him to develop a rare condition affecting his face, Melkersson-Rosenthal syndrome ("MRS"). The Secretary disputes this claim. The parties developed their positions by submitting reports from doctors retained for this litigation and by arguing their cases through legal 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.

As explained below, Mr. Harlow is not entitled to compensation. He has not established with preponderant evidence a theory by which the flu vaccine can cause MRS. Thus, his case is DENIED.

I. Background about MRS

Clinical manifestations of MRS include "oro-facial swelling, relapsing facial palsy and fissured tongue." Exhibit 14 (Mauro Cancian et al., "Melkersson-Rosenthal syndrome: a case report of a rare disease with overlapping features," 15 Allergy Asthma Clin Immunol 1 (2019)) at 2.

The incidence has been estimated to occur in 0.08% of the general population. Id. at 3. "Onset of this disease is more frequent in young adults, between the second and the third decades of life." Id.; accord Exhibit 15 (Ruozhuo Liu & Shengyuan Yu, "Melkersson-Rosenthal syndrome: a review of seven patients," 20 Journal of Clinical Neuroscience 993 (2013)) at 994.

"The etiology of MRS is controversial, and various theories regarding its underlying mechanisms have been proposed. Both genetic and acquired causes, including underlying infection and immunologic insult, have been postulated." Id. at 994. For an article proposing a genetic basis, see Exhibit C (E. Smeets et al., "Melkersson-Rosenthal syndrome and *de novo* autosomal t(9;2l)(p11;p11) translocation," 45 Clin. Genet. 323 (1994)).

II. Facts[2]

In 2017, at the age of 31, Mr. Harlow was serving in the Air Force reserve. In this context, he received a tuberculosis skin test on June 2, 2017 and a flu vaccine on June 3, 2017. Exhibit 2 at 1.

Two days after receiving the flu vaccine, Mr. Harlow developed swelling of his bottom lip and right eyelid. Exhibit 6 at 2 (record created on June 22, 2017). Mr. Harlow initially sought treatment at a Walgreen's urgent clinic. Exhibit 12 at 1-5 (June 17, 2017).

[2] The parties do not dispute the relevant events in Mr. Harlow's medical history. Order for Briefs, issued April 5, 2022, at 4. For this reason and because the outcome does not depend upon Mr. Harlow's disease course, the facts are presented summarily. For a more detailed account, see Pet'r's Br., filed June 21, 2022, at 1-6, and Resp't's Br., filed Aug. 22, 2022, at 2-7.

When the problems persisted, Mr. Harlow sought treatment at an emergency room. The doctor prescribed antibiotics and directed Mr. Harlow to seek care from an ophthalmologist and an ears, nose and throat ("ENT") specialist. Exhibit 6 at 6.

The ENT specialist prescribed a steroid medication and ordered a CT scan. Exhibit 5 at 7. The CT scan showed some soft tissue swelling and a mildly enlarged lymph node. Exhibit 6 at 10.

At the Scott Air Force Base, Paul Hirner, who identified himself as a healthcare professional, submitted information to the Vaccine Adverse Event Reporting Service (VAERS) on July 8, 2017. Mr. Hirner communicated that two days after Mr. Harlow's June 3, 2017 flu vaccine, he developed facial swelling and a stye. Exhibit 1 at 3-7.

Mr. Harlow, eventually, was seen by a doctor who specializes in allergy and immunology, Patrick Win. Based upon information available to Dr. Win, he proposed that Mr. Harlow might suffer from MRS. Exhibit 8 at 7. Although Mr. Harlow told Dr. Win his symptoms started after a flu vaccine, Dr. Win stated: "This is unlikely related to his recent influenza vaccine." Id. at 1, 7.

A punch biopsy of Mr. Harlow's lip was performed on September 6, 2017. The results revealed granulomatosis mucositis. Exhibit 7 at 29-30; Exhibit 3 at 9.

A dermatologist at Washington University, Rebecca Chibnall, saw Mr. Harlow on October 20, 2017. In the history Dr. Chibnall obtained, Mr. Harlow communicated that his symptoms started after a flu vaccine. Dr. Chibnall suspected that Mr. Harlow was suffering from MRS. Exhibit 7 at 37. Dr. Chibnall did not comment, affirmatively or negatively, on Mr. Harlow's statement linking the flu vaccine with his condition. Id. at 35-37.

After Dr. Chibnall's diagnosis of MRS, most of the remaining medical records chart the ups and downs of Mr. Harlow's disease course. As such, these medical records generally do not affect a determination of whether the June 3, 2017 flu vaccination caused Mr. Harlow's MRS. However, a few records do bear on the analysis of causation.

Mr. Harlow informed a physician's assistant in the allergy and immunology clinic, Erica Young, that the flu vaccine preceded his swelling. Thus, Mr. Harlow was "now avoiding" vaccinations. Exhibit 9 at 23. Ms. Young did not concur with or disagree with Mr. Harlow's statement. See id.

Upon referral from Dr. Chibnall, an ophthalmologist, Dr. Couch, saw Mr. Harlow. The consultation report lists flu vaccine as an allergy. Exhibit 7 at 31 (April 26, 2018).

Due to an increase in swelling, representing a possible regression in Mr. Harlow's MRS, he returned to see Dr. Chibnall on October 16, 2018. Dr. Chibnall stated that Mr. Harlow was "unable to receive [the] flu shot since this likely precipitated his condition. Discussed extensively that he needs to try to have everyone else immunized around him for herd immunity." Exhibit 7 at 7.

The medical records submitted in this case do not extend beyond January 2020. See Pet'r's Br. at 6; Resp't's Br. at 7. Via an affidavit, Mr. Harlow testified that he continues to experience paralysis of his facial nerves. Exhibit 17 at 3. The Air Force has deemed that he is "undeployable." Exhibit 55; Exhibit 56.

III. Procedural History

The procedural history is relatively straightforward and non-eventful. Mr. Harlow initiated this case by filing his petition on May 4, 2020. He identified treating doctors supporting his claim via a status report filed on August 27, 2020.

After reviewing this information, the Secretary determined that compensation should be denied. Resp't's Rep., filed Jan. 4, 2021. The Secretary maintained that Mr. Harlow "has not offered an expert report or expert opinion." Id. at 7.

Mr. Harlow submitted a report from the doctor whom he retained, Eric Gershwin, on January 15, 2021. Exhibit 20. The parties discussed this report in a January 22, 2021 status conference and Mr. Harlow was ordered to obtain a supplemental report from Dr. Gershwin because Dr. Gershwin's first report did not discuss timing. Dr. Gershwin filled that gap in another report, Exhibit 34, filed on February 22, 2021.

The Secretary responded to the reports from Dr. Gershwin by filing a report from Jonathan Miner, a rheumatologist. Dr. Miner agreed that Mr. Harlow suffered from MRS. Dr. Miner indicated that while MRS often has a genetic basis, Mr. Harlow was not tested for any genetic abnormalities. Exhibit A.

The Secretary was given an opportunity to seek genetic testing. Order, issued May 14, 2021. The Secretary declined. Resp't's Status Rep., filed June 14, 2021.

The parties exchanged additional reports from their experts. See Exhibit 38 (Dr. Gershwin's report, filed July 27, 2021); Exhibit J (Dr. Miner's report, filed Nov. 29, 2021); Exhibit 44 (Dr. Gershwin's report, filed Dec. 21, 2021); Exhibit L (Dr. Miner's report, filed Feb. 9, 2022).

The parties were directed to support their positions through briefs. Order, issued Apr. 5, 2022. This order alerted the parties that the case might be resolved without a hearing. The parties submitted their briefs.

As to whether a hearing was needed, the parties differed to a degree. Mr. Harlow requested an opportunity to present oral testimony from Dr. Gershwin and to cross-examine Dr. Miner. Pet'r's Br. at 25-26. The Secretary did not specify whether the case should be resolved without a hearing. The Secretary suggested that if a hearing were held, then each party should be allowed to elicit direct testimony from the doctors whom they retained. Resp't's Br. at 21.

Whether an evidentiary hearing should be held is a question within the discretion of special masters. 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). The key question is whether the parties have enjoyed a full and fair opportunity to present their cases.

Here, Mr. Harlow has had a fair and full opportunity to present his case. After Dr. Gershwin presented his initial opinion, Dr. Miner critiqued it. Throughout the pendency of the case, Mr. Harlow was provided multiple opportunities to present expert reports to show that the flu vaccination caused his MRS. Mr. Harlow submitted supplemental expert reports from Dr. Gershwin. The medical theory, proposed by Dr. Gershwin, was not persuasive enough to link Mr. Harlow's MRS to the flu vaccine. Therefore, a hearing is not needed to resolve these issues.

IV. 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 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).

In a case, such as this, in which petitioners are not seeking compensation for an injury listed on the Vaccine Injury Table, petitioners must establish the vaccine was the cause-in-fact of his injury. 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).

V. Analysis

Of the three Althen prongs, the most critical is the first prong, which concerns a theory. Because the lack of proof regarding one Althen prong renders the analysis of other elements moot, the remaining two prongs are discussed only briefly. See Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012); Holmes v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 469, 488 (2014); Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 222 (2012).

A. Althen Prong One

A petitioner must establish a "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278.

1. Mr. Harlow's Evidence and Contentions

Citing Dr. Gershwin's first report (Exhibit 20), Mr. Harlow maintains that the flu vaccine "triggered an innate immune response that, by virtue of a genetic homing defect in chemokine receptors in his facial tissue, caused immune cells to traffic to the affected tissue and trigger a breach in immune homeostasis leading to

a persistent autoinflammatory condition known as Melkersson-Rosenthal syndrome." Pet'r's Br. at 10. This theory necessarily involves a series of steps.

Initially, the person who eventually develops MRS due to a flu vaccine must be an individual "with a genetic defect in chemokine homing in the facial tissues." Pet'r's Br. at 10. Mr. Harlow concedes that in MRS "the specific genetic defect has not been identified." Id.

The second step is that a person receives the flu vaccine. The flu vaccine initiates a response from the immune system.

The immediate response from the immune system includes the release of proinflammatory cytokines and chemokines. Exhibit 22 (Caroline Hervé et al., "The How's and What's of Vaccine Reactogenicity," 4 NPJ Vaccines 39 (2019)) at 2. Chemokines are "chemotactic cytokines that control the migration and positioning of immune cells in tissues and are critical for the function of the innate immune system." Exhibit 29 (Caroline Sokol & Andrew Luster, "The Chemokine System in Innate Immunity," (2015)) at 1, quoted in Pet'r's Br. at 14. Chemokines "recruit innate immune effectors out of the circulation and into the tissue where, in collaboration with other chemoattractants, they guide these cells to the very sites of tissue injury." Id. According to Mr. Harlow and Dr. Gershwin, during this inflammatory stage, "non-antigen specific immune cells in the blood become activated by the vaccination and contribute to innate immune cell activity." Pet'r's Br. at 11-12, citing Exhibit 20 (Dr. Gershwin's first report) at 7.[3]

Next, in Dr. Gershwin's theory, the chemokines home throughout facial tissues. There, the chemokines attract immune cells that cause granulomatosis. Pet'r's Br. at 13-14.[4] Granulomatosis inflammation is often detected in biopsies from people with MRS. Exhibit 27 (Wolfgang Zimmer et al., "Orofacial manifestations of Melkersson-Rosenthal syndrome, A study of 42 patients and

[3] Although Mr. Harlow sometimes describes this process as "bystander activation," this terminology may not be accurate. In an article Mr. Harlow cites (Pet'r's Br. at 12), "bystander activation . . . is characterized by auto-reactive B and T cells." Exhibit 23 (Yovana Pacheco et al., "Bystander activation and autoimmunity," 103 J. Autoimmun. 1 (2019)) at 1. However, Dr. Gershwin's theory does not involve B cells or T cells.

[4] Dr. Gershwin mentioned "trained" innate immunity. Exhibit 20 at 5, 16. In contrast, Dr. Miner disputed Dr. Gershwin's use of this concept. Exhibit J at 2. Resolution of this issue is not required as "the concept of trained immunity is not an essential factor to understand how the flu vaccine is capable of triggering MRS in a susceptible host." Pet'r's Br. at 15; accord Pet'r's Reply at 4.

review of 220 cases from the literature," 74 Oral Surg Oral Med Oral Pathol. 610 (1992)) at 614, 616.

For evidence that this theory could explain how a flu vaccine can cause MRS, Dr. Gershwin largely compared MRS to other autoinflammatory conditions. See Pet'r's Br. at 25-26 (MRS is an "autoinflammatory disorder with a pathogenesis understood by analogy with other more common disorders"); see also id. at 8, 10; Pet'r's Reply at 2. Analogies were required because MRS is such a rare disease such that its etiology "is not well understood." Pet'r's Br. at 8.

Mr. Harlow and Dr. Gershwin acknowledged that no epidemiological study has detected an increased incidence in MRS after flu vaccination. This lack of evidence does not matter because, in Dr. Gershwin's view, the only valid epidemiological study would involve only participants with a known genetic predisposition to developing MRS. Pet'r's Br. at 16, 24; see also Exhibit 38 at 1. Furthermore, Mr. Harlow and Dr. Gershwin concede that they have not presented any case reports presenting a sequence of events in which a flu vaccination preceded the onset of MRS. In their view, the typical delay in diagnosis prevents doctors from identifying any suspected triggers for MRS. Pet'r's Br. at 15-16.

2. The Secretary's Evidence and Contentions

Through Dr. Miner, the Secretary argued that Mr. Harlow's evidence regarding the proposed theory was not adequate. Resp't's Br. at 10-13. The Secretary emphasizes that Mr. Harlow has identified neither epidemiologic studies nor a single case report connecting the flu vaccine to MRS. Resp't's Br. at 12. Dr. Miner focuses on the lack of case reports:

> Even though MRS is rare, the administration of influenza vaccines is common. If there were a strong association between a common event (influenza vaccination) and this rare event (onset of MRS), then we would at least expect to see a series of case reports in the medical literature. Indeed, in families genetically predisposed to MRS, we might expect to observe disease onset after vaccination at least in some people in some of those families, but no such thing has been reported despite hundreds of cases.

Exhibit J at 1-2, quoted in Resp't's Br. at 12.

Otherwise, the Secretary points out that MRS has a genetic component and Dr. Gershwin "admits that petitioner would have likely developed MRS at some

point, regardless of vaccination." Resp't's Br. at 13, citing Exhibit 20 at 5. The Secretary concludes this section of his brief with the statement "Dr. Gershwin has failed to offer any evidence beyond a temporal association." Resp't's Br. at 13.[5]

3. Assessment

To demonstrate the reliability of Dr. Gershwin's opinion, Mr. Harlow faces an uphill climb because, as he admits, the etiology of MRS "is not well understood." Pet'r's Br. at 8. Dr. Gershwin has not identified any medical articles that present any useful information about why anyone develops MRS. Thus, it is not surprising that this case lacks any medical articles on the narrower question as to why a recipient of the flu vaccine could develop MRS. Although literature is not required, Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274 (Fed. Cir. 2005), "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012).

The spectrum of literature about MRS is extremely limited. Mr. Harlow's exhibit list identifies five distinct articles with "Melkersson-Rosenthal" in the title.[6] The Secretary adds three other articles.

Ideas about the causes of MRS are similarly incomplete and undeveloped. The authors of a 2011 article reporting two cases stated that "It is very hard to correlate MRS to a specific etiologic agent and possibly it should be classified as autoinflammatory disorder. Autoinflammatory disorders are characterized by recurrent episodes of inflammation in the absence of pathogens, autoantibodies or antigen specific T cells." Exhibit 25 (Estela Kaminagakura & Jacks Jorge Jr., "Melkersson Rosenthal syndrome: a histopathologic mystery and dermatologic challenge," 38 J Cutan Pathol 241 (2011)) at 243.

The authors of a 2019 case report suggested that their subject's MRS was "probably triggered by a recent viral infection characterized by facial blistering." Exhibit 14 (Mauro Cancian et al., "Melkersson-Rosenthal syndrome: a case report of a rare disease with overlapping features," 15 Allergy Asthma Clin Immunol 1 (2019)) at 5. Authors of another case report identified an instance of a parvovirus infection preceding the onset of MRS. Exhibit D (A. De Maria et al., "Melkersson–Rosenthal syndrome associated with parvovirus b19 viraemia and

[5] This statement overlooks the medical articles Dr. Gershwin cited.

[6] Exhibit 14 is repeated as exhibit 43 and exhibit 15 is repeated as exhibit 26.

haemophagocytic lymphohistiocytosis," 34 Clin and Experimental Dermatology e623 (2009)).

A 2018 medical literature review, identifying more than 200 cases of MRS, concluded that MRS is "an etiological obscure disease." Exhibit 49 (Goetz Wehl & Markus Rauchenzauner, "A Systematic Review of the Literature of the Three Related Disease Entities Cheilitis Granulomatosa, Orofacial Granulomatosis and Melkersson-Rosenthal Syndrome," 14 Current Pediatric Review 196) at 196. They added, "The etiology of MRS is only partly understood with genetic factors, chronic infectious diseases, allergic reactions, and abnormalities of autoimmune mechanisms as possible contributors." Id. at 200. None of the approximately ten articles in the record have identified any vaccine as a potential cause for MRS.

Against this background, Dr. Gershwin's opinion does not carry Mr. Harlow's burden of proof. See Dycke v. Sec'y of Health & Hum. Servs., No. 18-106V, 2023 WL 4310701 at *25 (Fed. Cl. Spec. Mstr. June 7, 2023) (not crediting a theory Dr. Gershwin offered because, in part, "none of the medical literature filed has identified any known cause of [giant cell arteritis]"). In essence, Dr. Gershwin has proposed a theory in which the flu vaccine prompts the production of a specific type of cytokine, chemokines, and the chemokines provoke other aspects of the immune system to cause a disease.

Special masters have generally, although not universally, found theories based upon cytokines unpersuasive. See Giesbrecht v. Sec'y of Health & Hum. Servs., No. 16-1338V, 2023 WL 2721578, at *7 (Fed. Cl. Spec. Mstr. Feb. 8, 2023) (citing cases). As one special master explained, a petitioner's expert starts with one supported step (vaccines induce cytokines) and then leaps to an unsupported step (cytokines are harmful):

> Dr. Gershwin's contentions about cytokine response to vaccination, as bulwarked by reliable literature like Chatziandreou, were medically and scientifically sound. But he has outlined a theory in which the *normal* cytokine upregulation anticipated by vaccination (and even desired, as part of the vaccine's efficacy) becomes aberrant and damaging—without offering the evidence needed to gauge even partly how this would actually occur, and what impact it would have (whether on a healthy person or one susceptible to autoimmune injury, as is posited here). The fact that the initial/innate response to vaccination transiently causes increased

> cytokine levels (a fact that can easily be substantiated by science, as studies often reveal) does not imply an aberrant reaction ensues—and it cannot be assumed this has occurred in a petitioner's case, based solely on the subsequent injury.

Putman v. Sec'y of Health & Hum. Servs., No. 19-1921V, 2022 WL 600417, at *21 (Fed. Cl. Spec. Mstr. Jan. 31, 2022). In a case involving Dr. Gershwin, another special master stated, "given the ubiquitous nature of cytokines in the body, it cannot be enough to simply say 'cytokines did it.'" Rupert v. Sec'y of Health & Hum. Servs., No. 15-841V, 2021 WL 1832909, at *40 (Fed. Cl. Spec. Mstr. May 1, 2021).

Here, Dr. Gershwin's opinion appears even weaker than his opinions that were rejected in Giesbrecht, Putman, and Rupert. Part of this weakness is due to the lack of information about MRS generally. But, Mr. Harlow cannot use the lack of knowledge as a justification for lowering his burden of proof. "The standard of proof does not operate as a sliding scale that varies depending upon the quantity and quality of the scientific evidence that is available." Caves, 100 Fed. Cl. at 143.

Accordingly, Mr. Harlow's evidence regarding Althen prong one falls short. Based upon this finding, he is not entitled to compensation.

B. Althen Prong Two

This element requires "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. The opinions of treating doctors can be quite probative. Cappizano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, the views of the treating doctors are mixed. The most evidentiary valuable statements come from Dr. Win and Dr. Chibnall.[7] The immunologist who

[7] Two other mentions, Mr. Paul Hirner and Dr. Couch, carry less significance. Paul Hirner submitted a VAERS report. Exhibit 1 at 3-7. However, whether Mr. Hirner has any medical training is not clear and the report was submitted before Mr. Harlow was diagnosed with MRS.

The notation of flu vaccine as an allergy in the record of the ophthalmologist, Dr. Couch, could simply reflect information that Mr. Harlow provided to Dr. Couch. See Solak v. Sec'y of Health & Hum. Servs., No. 14-869V, 2020 WL 9173158, at *33 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) (noting that a treating doctor apparently wrote a "letter on the history of prior reaction that Petitioner provided to him. . . I do not find it to be compelling evidence that Petitioner had an adverse reaction to her prior flu vaccines"); Pearson v. Sec'y of Health & Hum. Servs., No. 17-

first raised the possibility of MRS (Dr. Win) stated that "This is unlikely related to his recent influenza vaccine." Exhibit 8 at 7. On the other hand, after Dr. Chibnall treated Mr. Harlow for approximately one year, she stated that the "flu shot . . . likely precipitated his condition." Exhibit 7 at 7.

If Mr. Harlow had met his burden regarding Althen prong one, then deciding Althen prong two would be challenging as the evidence seems nearly balanced. However, as a logical matter, the finding that a petitioner has not established that a vaccine can cause an injury necessarily implies that the vaccine did not cause the injury. See Temes v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 448, 464 (2020) ("the special master appropriately considered the lack of evidentiary support for [petitioner's] theory of causation to analyze whether there was sufficient evidence to establish a logical sequence of a cause and effect showing that the vaccines at issue were the reason for [the petitioner's] injury"); Caves, 100 Fed. Cl. at 145 (2011).

Thus, neither an affirmative nor negative finding is made regarding Althen prong two.

C. Althen Prong Three

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). 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, Mr. Harlow proposes that "the medically accepted timeframe for development of an autoinflammatory condition following a challenge to the innate immune system is between 1-3 days." Pet'r's Br. at 20, citing Exhibit 35 (Lisa Christian et al., "Serum Proinflammatory Cytokine Responses to Influenza Virus Vaccine among Women during Pregnancy Versus Non-Pregnancy," 70(1) Am J Reprod Immunol. (2013)) [hereinafter Christian]. Mr. Harlow further points out

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489V, 2019 WL 1150044, at *1 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (the "substantiation for some of these preexisting allergies comes from records in which [petitioner] provided medical histories to treaters, rather than from independent medical confirmation").

that he developed swelling in his lip and eyelid two days after the vaccination, and, therefore fits the expected timeframe.

The Secretary argues that because Mr. Harlow has not presented a reliable theory, he cannot show an appropriate temporal relationship "as there is not expected timeframe to use as a measuring stick." Resp't's Br. at 16.

The evidence on this point is relatively thin. The one article that Mr. Harlow cited measured the amount of cytokines after flu vaccination produced by pregnant women and non-pregnant women. Exhibit 35 (Christian). While a male, like Mr. Harlow, might be roughly comparable to a non-pregnant woman in terms of the cytokines he produced in response to the flu vaccine, the Christian article shows how quickly some cytokines are produced after a vaccination and how long they persisted. The production of cytokines, however, is not the final step in Dr. Gershwin's theory. After the cytokines (or chemokines) travel to the face, the cytokines recruit other components of the immune system to produce swelling, which can characterize MRS. See Pet'r's Br. at 12-13. Mr. Harlow has not identified any evidence that indicates the harm caused by adverse reaction mediated through the innate immune system happens within three days of the vaccination. This gap in evidence could be construed as a failure on Mr. Harlow's part to satisfy his burden regarding timing.

Whether Mr. Harlow meets his burden is, ultimately, an academic point. Even if his condition arose within a medically appropriate time, proof on this one element would not entitle him to compensation. See Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact."). A successful showing regarding causation-in-fact requires Mr. Harlow establish a theory. As set forth above, the evidence regarding the theory was inadequate.

VI. Conclusion

Mr. Harlow's development of symptoms of what was eventually diagnosed as MRS within three days of his receipt of a flu vaccine has led Mr. Harlow to contend that the flu vaccine caused his MRS. In this litigation, Mr. Harlow retained an expert who supported Mr. Harlow's claim. However, the expert's opinion was not persuasive for the reasons set out above. Therefore, Mr. Harlow is not entitled to compensation.

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