In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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CAROLINE WALKER,	*	
	*	No. 18-299V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: September 27, 2022
	*	
SECRETARY OF HEALTH	*	entitlement; flu vaccine; multiple
AND HUMAN SERVICES,	*	sclerosis; timing; complement
	*	
Respondent.	*	
* *		

Ronald Homer & Meredith Daniels, Conway, Homer, P.C., Boston, MA, for petitioner;
Emily H. Manoso, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Caroline Walker alleged that a dose of the influenza ("flu") vaccination significantly aggravated her previously undiagnosed multiple sclerosis. Ms. Walker retained an expert to support her claim and the Secretary countered with a different expert. The parties advocated for their respective positions in briefs filed before a hearing was held on September 21-22, 2022.

At the end of the hearing, Ms. Walker was found not entitled to compensation. The primary obstacle was that Ms. Walker's neurologic symptoms developed so quickly after she received the flu vaccination (approximately 39 hours later) that the flu vaccine could not have initiated a series of steps that would culminate in neurological symptoms consistent with demyelination in less than two

[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.

days. A second issue was that the theory Ms. Walker proposed to explain—specifically, how a flu vaccination could significantly aggravate multiple sclerosis (a theory involving complement)—was unlikely here. A third issue was that a treating doctor indicated that the flu vaccine was not likely to have contributed to Ms. Walker's multiple sclerosis. Consequently, Ms. Walker failed to meet her burden of proof.

I. Facts[2]

Ms. Walker was relatively healthy until May 2015. By early June 2015, she developed a cough for which she sought treatment from a minute clinic. The doctor prescribed an antibiotic. Exhibit 3 at 14-15.

Two days later, Ms. Walker began a long trip in which she drove her family from their home in North Carolina to visit extended family throughout the Midwest. Exhibit 17 at 5 (affidavit, signed Feb. 26, 2018). During this trip, Ms. Walker experienced tingling in her legs. Id.

According to histories Ms. Walker provided to neurologists approximately four months later, the tingling might have constituted the earliest manifestation of multiple sclerosis. See Exhibit 9 at 4-5 (handwritten history to Dr. Mandell, created on October 19, 2015); Exhibit 8 at 16 (containing Dr. Lidogoster's records stating "[Ms. Walker] had a similar pins/needles sensation in her legs and arms in June, lasting about a month"); Exhibit 6 at 21 (Dr. Conway's letter dated Nov. 5, 2015). However, in Ms. Walker's oral testimony, she suggested that the tingling was because she was driving for many hours.

Months later, Ms. Walker's employer arranged for employees to receive a flu vaccination in its office on September 24, 2015. Exhibit 1. Ms. Walker averred that she received the flu vaccination before noon on that day. Exhibit 17 at 2. Ms. Walker further testified about her daily schedule and why she recalls that the flu vaccine was given to her before noon.

In the evening beginning September 25, 2015, Ms. Walker started to develop numbness and tingling in both hands and both feet. Exhibit 13 at 4 (admission note created on Oct. 1, 2015); id. at 92 (discharge report); Exhibit 7 at 5. Ms.

[2] The parties basically agreed that the medical records accurately describe events taking place contemporaneously when the medical record was created. The parties also basically agree that the chronology of relevant events in Ms. Walker's life is relatively short. Accordingly, the recitation of facts is correspondingly brief.

Walker's oral testimony indicated that the numbness and tingling probably began around 2:00 AM on September 26, 2015. Thus, the interval between the vaccination and the onset of neurologic problems is approximately 39 hours.

The numbness and tingling progressed over the next six days. After Ms. Walker had problems using her hands, she sought medical care from an emergency room at Novant Health Matthews Medical Center. She was admitted and remained in the hospital for two days. Exhibit 13 at 91-93 (containing Ms. Walker's Oct. 3, 2015 discharge report).

A key part of her hospitalization was an MRI Ms. Walker had on October 1, 2015. This MRI showed an enhanced lesion and a non-enhanced lesion. Exhibit 13 at 44. A nonenhanced lesion means that the lesion is old, probably older than 14 days. Exhibit 21 (Dr. Chwalisz's first expert report) at 4; Exhibit A (Dr. Wu's first expert report) at 4; Exhibit 30 (Francois Cotton et al., MRI Contrast Uptake in New Lesions in Relapsing-Remitting MS Followed at Weekly Intervals, 60 NEUROLOGY 640, (2003) (finding that "the average duration of Gd-DTPA enhancement in individual new lesions was 3.07 weeks (median, 2 weeks)")). Because the lesion was nonenhanced, the lesion must have existed before Ms. Walker received the flu vaccine on September 24, 2015.

Because of the findings on the MRI, as well as other clinical manifestations, Ms. Walker was diagnosed as suffering from multiple sclerosis. Exhibit 9 at 3. The parties agreed that multiple sclerosis is the appropriate diagnosis for her. From 2015 through 2020, the neurologist who treated Ms. Walker for multiple sclerosis was Jill Conway.

The course of Ms. Walker's multiple sclerosis since 2015 is relatively typical. Although the parties summarized the medical records in their briefs, see Pet'r's Br. on Entitlement, filed Apr. 16, 2021, at 2-20 and Resp't's Br. on Entitlement, filed July 20, 2021, at 2-9, those events do not contribute to determining whether the flu vaccination significantly aggravated Ms. Walker's multiple sclerosis. Similarly, although Ms. Walker testified quite movingly about the toll that she has endured the last few years, this testimony did not affect the opinions that the experts had already expressed.

II. Procedural History

Ms. Walker began this litigation by filing a petition on February 28, 2018. At various dates, Ms. Walker submitted medical records and affidavits.

The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., Apr. 4, 2019, at 11-13. The Secretary argued that because Ms. Walker had a lesion in her brain before she received the flu vaccination on September 4, 2015, Ms. Walker could not pursue a causation-in-fact claim. Id. at 11. The Secretary further disputed any significant aggravation claim. Id. at 11-12.

To assist in the process of presenting reports from experts, the undersigned issued a set of final instructions on August 14, 2019. Ms. Walker retained Dr. Chwalisz. He is an instructor in neurology at Harvard Medical School. His specific area of interest is in neuro-ophthalmological diseases. Exhibit 22 (Dr. Chwalisz's curriculum vitae). He wrote two reports. Exhibits 21 & 56. In turn, the Secretary retained Dr. Wu, who is an assistant professor in neurology at Washington University Medical School. One of Dr. Wu's research interests is multiple sclerosis. Exhibit B (Dr. Wu's curriculum vitae). Dr. Wu also wrote two reports. Exhibits A and C.

When the parties completed the task of disclosing all the opinions of their experts, the parties argued in legal memorandum. See Order for Briefs, issued Jan. 11, 2011; Pet'r's Br. on Entitlement; Resp't's Br. on Entitlement; Pet'r's Reply, filed Aug. 13, 2021. The case was then marked for a hearing in September 2022. Order, issued Sept. 14, 2021.[3]

The hearing was held on September 21-22, 2022. Dr. Chwalisz, Dr. Wu, and Ms. Walker testified. As mentioned earlier, Ms. Walker was found not entitled to compensation at the conclusion of the hearing and the present document memorializes the reasons for that outcome.[4]

III. Standards for Adjudication

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

[3] Between the time the case was scheduled for a hearing and when the hearing was supposed to be held, the parties were ordered to develop evidence regarding the amount of compensation to which Ms. Walker would be entitled if she were found entitled to compensation. See Order, issued Sept. 14, 2021; Order, issued Sept. 13, 2022. However, because the evidence does not support a finding of entitlement, any evidence about compensation is not relevant.

[4] The present decision is being issued on an expedited basis to facilitate Ms. Walker's submission of a motion for review if Ms. Walker wishes. The decision is being issued before a transcript has been created.

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).

As confirmed in W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013), the elements of an off-Table significant aggravation case were stated in Loving v. Sec'y of Health & Hum. Servs., 86 Fed. Cl. 135 (2009). There, the Court blended the test from Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005), which defines off-Table causation cases, with a test from Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resulting test has six components. These are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

IV. Analysis

In addressing a significant aggravation claim, special masters may focus upon the last three elements in the Loving test, which correspond to the three prongs of the well-established Althen test. Hennessey v. Sec'y of Health & Hum. Servs., No. 01-190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), mot. for rev. denied, 91 Fed. Cl. 126 (2010).

As a preliminary matter, the background of the two experts may be compared. Copenhaver v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 176, 183 (2016) (citing supporting cases); Depena v. Sec'y of Health & Hum. Servs., 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 F. App'x. 938 (Fed. Cir. 2018). Although Dr. Chwalisz and Dr. Wu are both qualified to testify about neurologic issues, the background and experience of Dr. Wu strengthen his opinions vis-à-vis the competing opinions from Dr. Chwalisz. Dr. Wu's current position as an assistant professor place him at a higher rank in academia than Dr. Chwalisz, who is an instructor. More importantly, Dr. Wu conducts experiments in laboratories on animals to help understand the causes and treatment of multiple sclerosis. Dr. Wu has written articles on multiple sclerosis that peer-reviewed journals have published. Exhibit B at 5-8. In contrast, Dr. Chwalisz does not conduct lab experiments and has not written articles about multiple sclerosis. C.f. Exhibit 21. This contrast in experience favors Dr. Wu on the topic of multiple sclerosis.

The opinions of Dr. Chwalisz and Dr. Wu are the foundations for the analysis that follows. As previously explained, this evaluation focuses on the latter three prongs of Loving, which correspond to the prongs of Althen.

A. Loving prong Four / Althen prong one

Pursuant to Althen, a petitioner must present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. Dr. Chwalisz disclosed that the "most likely" theory by which a flu vaccination could aggravate multiple sclerosis within two days involved complement. Exhibit 56 at 3; see also Pet'r's Br. on Entitlement at 37-41 (discussing a theory based in complement). The term "complement" refers "to the entire functionally related system comprising at least 20 distinct serum proteins, their cellular receptors, and related regulatory proteins that is the effector not only of immune cytolysis but also of other biologic functions including anaphylaxis, phagocytosis, opsonization, and hemolysis." Dorland's Illustrated Medical Dictionary at 387 (32d ed. 2013).

Two problems prevent the crediting of this theory. First, multiple epidemiologic studies have failed to detect an increased incidence or worsening of multiple sclerosis after a flu vaccination. Second, there is little basis for finding that complement contributes to the early stages of multiple sclerosis.

1. Epidemiology

While epidemiology is not required, Althen, 418 F.3d at 1279-80, epidemiology remains relevant. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992). For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020).

Here, researchers have explored whether vaccines, including the flu vaccine particularly, either cause or worsen multiple sclerosis. Almost all the studies have failed to detect any increased incidence.

Ms. Walker and Dr. Chwalisz rely upon two studies that suggested flu vaccination might contribute to multiple sclerosis. However, as explained below, both carry relatively little, if any, weight.

The first study is by Dr. Langer-Gould et al. Exhibit 67 (Annette Langer-Gould et al., Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases, 71 JAMA NEUROLOGY 1506 (2014)). Those researchers evaluated health records of people enrolled in Kaiser Permanente Southern California. Using a nested case-control study, the researchers found that "vaccination of any type was associated with increased risk of CNS ADS onset within the first 30 days after the vaccination only in younger (<50 years) individuals." Id. But, this risk appeared to dissipate after more than 30 days. Id. at 1510. Thus, the researchers concluded that "our data do not support a causal link between current vaccines and the risk of MS or other CNS ADS." Id. Because Langer-Gould ultimately did not support a causal link, one judge of the Court of Federal Claims held that a special master erred in relying upon Langer-Gould to support a finding of causation. Doles v. Sec'y of Health & Hum. Servs., 159 Fed. Cl. 241, 247-49 (2022).

The second epidemiologic study on which Dr. Chwalisz and Ms. Walker rely is McNicholas & Chataway. Exhibit 60 (Nuala McNicholas & Jeremy Chataway, Relapse Risk in Patients with Multiple Sclerosis After H1N1 Vaccination, with or without Seasonal Influenza Vaccination, 258 J. NEUROLOGY

1545 (2011)). In this report, the authors found that 33% of 18 participants who received either the seasonal flu vaccine, the H1N1 flu vaccine, or both the seasonal flu vaccine and the H1N1 flu vaccine experienced a multiple sclerosis relapse within three weeks of the vaccination. Id. at 1546. Most of those relapses happened within the first week after the vaccination. The authors stated: "Seasonal influenza immunization does not increase the risk of MS exacerbation; a systematic review found no increased risk of early (3-4 weeks post-vaccination) or late (4-6 months) exacerbations." Id. at 1545.

In contrast, other studies did not detect an increased incidence of multiple sclerosis relapses in people who received a vaccination. Examples include Miller, Confavreux, and Michielsens. Exhibit A35 (David H. Miller et al., Clinically Isolated Syndromes, 11 LANCET NEUROLOGY 157 (2012)); Exhibit A7 (Christian Confavreux et al., Vaccinations and the Risk of Relapse in Multiple Sclerosis, 344 N.E. J. MED. 319 (2001)); Exhibit A33 (B. Michielsens et al., Serial Magnetic Resonance Imaging Studies with Paramagnetic Contrast Medium: Assessment of Disease Activity in Patients with Multiple Sclerosis Before and After Influenza Vaccination, 30 EURO. NEUROLOGY 258 (1990)). These studies were incorporated into larger literature reviews, which also referenced the Langer-Gould and/or McNicholas and Chataway articles. See Exhibit A19 (Dejan Jakimovski et al., Infections, Vaccines and Autoimmunity: A Multiple Sclerosis Perspective, 8 VACCINES 1 (2020)); Exhibit A29 (Mia Topsøe Mailand & Jette Lautrup Frederiksen, Vaccines and Multiple Sclerosis: A Systematic Review, 264 J. NEUROLOGY 1035 (2017)); Exhibit A16 (Christine LeBrun et al., Immunization and Multiple Sclerosis: Recommendations from the French Multiple Sclerosis Society, 31 MULTIPLE SCLEROSIS & RELATED DISORDERS 173 (2019)). These comprehensive reviews also failed to find an increased incidence of relapses. For instance, one of these larger studies examined McNicholas and Chataway and stated that the "study lacks statistical power, since it is based on only 18 patients. To summarize the results of investigated studies, no association seems to exist between seasonal influenza or H1N1 vaccination and MS relapse." Exhibit A29 (Mailand & Frederiksen) at 1047.

For these reasons, the epidemiology weighs against a finding that a flu vaccination can cause an exacerbation of multiple sclerosis. However, epidemiology ultimately cannot establish that a flu vaccination cannot cause a relapse. Thus, the other aspect to Dr. Chwalisz's theory, the mechanism, is discussed next.

2. Mechanism

Dr. Chwalisz advanced the theory that the flu vaccination would lead to the production of complement and complement contributes to the beginnings of multiple sclerosis. While a flu vaccination does lead to the production of complement, Dr. Chwalisz did not establish that complement is a meaningful part of the onset of multiple sclerosis.

To support the connection between complement and multiple sclerosis, Dr. Chwalisz primarily advanced two articles by Ingram. See Exhibit 21 (Dr. Chwalisz's first expert report) at 6; see also Pet'r's Br. on Entitlement at 37-40 (highlighting these two articles in connection with complement). However, one article was irrelevant, and the other article undermined the theory Dr. Chwalisz was putting forward.

A 2009 article by Ingram researched people who had "late-stage" multiple sclerosis. The participants, on average, had suffered for 26 years. Exhibit 35 (G. Ingram et al, Complement in Multiple Sclerosis: Its Role in Disease and Potential as a Biomarker, 155 CLINICAL & EXPERIMENTAL IMMUNOLOGY128 (2009)). Ingram and co-authors proposed that complement might contribute to this lasting problem. They concluded: "Prior understanding of the immunology of MS and knowledge gained from animal studies leads us to conclude that [complement] does not initiate disease, but propagates ongoing disease with increased contribution over the course of the illness." Id. at 135. As such, Dr. Chwalisz conceded during his oral testimony that this study does not inform Ms. Walker's case in which she experienced a clinical manifestation of her multiple sclerosis within two days. [5]

The 2014 article by Ingram attempted to offer theories to explain how multiple sclerosis remains a chronic condition. Exhibit 36 (G. Ingram et al., Complement Activation in Multiple Sclerosis Plaques: An Immunohistochemical Analysis, 2 ACTA NEUROPATHOLOGICA COMMC'NS 1 (2014)). Ingram and co-authors concluded: "In chronic active and inactive plaques, complement markers occurred in the absence of other inflammation markers, including lymphocytes,

[5] After this conclusion was called to Dr. Chwalisz's attention, Ms. Walker's attorney focused a question to Dr. Chwalisz on redirect examination about the phrase "propagates ongoing disease." However, Dr. Chwalisz's response to this query was not credible because, in part, of Dr. Chwalisz's demeanor in answering the question. Moberly, 592 F.3d at 1325-26; Andrew Corp. v. Gabriel Elecs., Inc., 847 F.2d 819, 824 (Fed. Cir. 1988) (indicating a trial judge should indicate when a witness's demeanor contributes to a finding of fact).

plasma cells and foamy macrophages; demonstrating that progression of inflammation in MS CNS does not rely on infiltrating cells; once initiated, inflammation can be driven by innate immune mechanisms such as complement." Id. at 12. Thus, Ingram is inconsistent with the theory that Dr. Chwalisz offered to explain how multiple sclerosis could be aggravated by a flu vaccination received two days earlier.

After considering this evidence, Dr. Wu opined that the idea that complement initiates multiple sclerosis was very improbable. Dr. Wu explained that the medical community is focusing on the role of B cells and T cells as causing multiple sclerosis. Dr. Wu's opinions are persuasive.

Accordingly, Ms. Walker has failed to present a persuasive theory to explain how a flu vaccination can aggravate multiple sclerosis. This lack of proof on Loving prong 4 / Althen prong 1 means that she cannot receive compensation. While her evidence regarding theory was insufficient, Ms. Walker's evidence regarding another element (timing) was even weaker.

B. Loving prong 6 / Althen prong 3

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 anticipated interval largely derives from the offered theory. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013).

Whether a complement-based theory could explain how a flu vaccination can cause the manifestation of neurologic symptoms associated with demyelination in less than two days was a significant point of contention between the experts. Starting with his first report, Dr. Wu explained the steps that must happen for complement to cause damage. See Exhibit A at 5. In his opinion, the steps could not take place in less than two days. Dr. Wu's explanation was very persuasive because it took into account all the steps.

Dr. Wu indicated that a preliminary step is for dendritic cells to capture an antigen (like the flu vaccine) and transport it to a local lymph node. Dr. Wu stated that this step usually takes 24 to 30 hours. Exhibit A at 5-6. Dr. Chwalisz did not contest this point.

Next, the B cells become engaged in the local lymph node. After the B cells are activated, the B cells must move through the circulatory system and penetrate the blood brain barrier to enter the central nervous system. In the central nervous system, B cells become plasma cells, which produce antibodies. The antibodies then initiate an increased production of complement. Through a series of enzymatic reactions depicted in Figure 2 of the 2009 Ingram article, a substance known as the "membrane attack complex" is formed. See Exhibit 35 at 130. The membrane attack complex can destroy the myelin. Dr. Chwalisz and Dr. Wu agreed that the membrane attack complex might damage myelin in minutes.

In his direct testimony, Dr. Chwalisz attempted to illustrate part of this process with reference to Figure 1 in the 2009 Ingram article. See Exhibit 35 at 129. The problem is that that figure begins with activated B cells. B cell activation is a necessary step preceding the formation of the membrane attack complex. See Dorland's Illustrated Medical Dictionary at 388 (32d ed. 2013) (indicating in a caption to a schematic representation of the classical complement pathway that the "pathway is initiated by binding to antibody molecules to a multivalent antigen, followed by a finding of complement protein C1q"). When asked how quickly B cells can become activated, Dr. Chwalisz said the process would take several days. Dr. Wu agreed that B cells activation occurs over the course of multiple days.

Dr. Chwalisz's complement-based theory does not account for the amount of time for B cells activation. In Dr. Chwalisz's oral testimony he suggested that complement "adds fuel to the fire" because complement is how antibodies damage myelin. To build on Dr. Chwalisz's imagery, Dr. Chwalisz has not explained how long it takes to ignite the initial fire to which the fuel is added. The evidence indicates that creating antibodies is a step that takes much longer than two days.

The evidence in Ms. Walker's case includes at least four articles in which researchers attempted to induce animals to suffer from experimental autoimmune encephalitis ("EAE"), which is a model for multiple sclerosis. In these experiments, the researchers increased the likelihood that the animals would develop a disease by using genetically modified rodents. These experiments showed that when the animals did develop an autoimmune disease, the process took multiple days. See Exhibit 25 (Se Blackmore et al., Influenza Infection Triggers Disease in a Genetic Model of Experimental Autoimmune Encephalomyelitis, 114 PROCEEDINGS NAT'L ACAD. SCIS. E6107 (2017)); Exhibit A46 (Soomin Shin et al. Apolipoprotein E Mediation of Neuro-Inflammation in Murine Model of Multiple Sclerosis, 271 J. NEUROIMMUNOLOGY 1 (June 2014)); Exhibit 37 (Francesca Odoardi et al., T Cells Become Licensed in the Lung to

Enter the Central Nervous System, 488 NATURE 675 (2012)); Exhibit A3 (Ingo Bartholomäus et al., Effector T Cell Interactions with Meningeal Vascular Structures in Nascent Autoimmune CNS Lesions, 462 NATURE 94 (2009)). Consistent with these experiments, one reference manual for conducting EAE experiments directs researchers to begin looking for signs of disease in animals after six days. See Exhibit A41 at 9.7.8 (Michael K. Racke, Experimental Autoimmune Encephalomyelitis, 14 CURRENT PROTOCOLS IN NEUROSCIENCE 9.7.1 (2001)).

The two articles on which Ms. Walker and Dr. Chwalisz rely to establish that a flu vaccination can worsen multiple sclerosis, Langer-Gould and McNicholas, provide little assistance with respect to timing. In Langer-Gould, the earliest data point was 14 days. Exhibit 67 (Langer-Gould et al.) at 1511. In McNicholas and Chataway, the information is presented on a weekly basis. Exhibit 60 (McNicholas & Chataway) at 1546. Thus, it is difficult to conclude that a process that might occur within seven or 14 days can also occur within two days.

The finding that a process involving the adaptive immune system cannot be accomplished within two days is consistent with a finding in other cases. Contreras v. Sec'y of Health & Hum. Servs., No. 05-626V, 2012 WL 1441315, at *9-24 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (lengthy discussion of the time for molecular mimicry), mot. for rev. denied in relevant part after intervening proceedings, 121 Fed. Cl. 230, 246-47 (2015), vacated on other grounds and remanded, 844 F.3d 1363 (Fed. Cir. 2017); Forrest v. Sec'y of Health & Hum. Servs., No. 14-1046V, 2019 WL 925495, at *3-8 (Fed. Cl. Spec. Mstr. Jan. 28, 2019).

For these reasons, Ms. Walker has not established another element in her case. This failure constitutes an independent basis for finding that she is not entitled to compensation. However, for the sake of completion, the final Althen element will also be considered.

C. Loving prong 5 / Althen prong two

Pursuant to Althen, a petitioner must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. 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, Dr. Chwalisz acknowledged that none of the doctors who treated Ms. Walker for multiple sclerosis linked the flu vaccination to the disease. The doctor who most directly addressed this question in a medical record was Dr. Conway. Dr. Conway stated that the timing in Ms. Walker's case makes a reaction to the flu vaccine "unlikely." Exhibit 7 at 11. Consequently, the evidence does not preponderate in favor of finding a logical sequence of cause and effect between the September 24, 2015 vaccination and the numbness and tingling Ms. Walker experienced on September 25, 2015.

V. Conclusion

Ms. Walker's case is sympathetic in that she has suffered from a disease that has interfered with her life for approximately seven years. Nevertheless, special masters are called upon to analyze the evidence dispassionately. In this case, the evidence does not show that Ms. Walker is 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 on the web site for the United States Court of Federal Claims.

IT IS SO ORDERED.

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