

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

JAN KELSEY,

*

Petitioner,

*

No. 20-850V

*

Special Master Christian J. Moran

*

v.

*

Filed: February 10, 2026

*

SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

*

*

Respondent.

*

David P. Murphy, Greenfield, IN, for petitioner;
Juliana Kober and Neil Bhargava, United States Dep’t of Justice, Washington, DC,
for respondent.

PUBLISHED DECISION DENYING ENTITLEMENT¹

Jan Kelsey alleges that an influenza (“flu”) vaccination that he received on October 2, 2017, caused him to suffer a neurologic problem, small fiber neuropathy. This neurologic problem was manifest within one day of the flu vaccination. Mr. Kelsey supported his claim through various experts, most recently a neurologist, Norman Latov. He also advocated through briefs.

The Secretary opposes the award of compensation. The Secretary relies upon opinions from a neurologist, Pria Anand, and Herman Staats, who has earned

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.

a Ph.D. in immunology but who is not a medical doctor. Like Mr. Kelsey, the Secretary has advocated through briefs.

Mr. Kelsey has not established that he is entitled to compensation. Mr. Kelsey has not presented a reliable theory for explaining how the flu vaccine can cause small fiber neuropathy within about one day of the vaccination.

I. Facts

Mr. Kelsey was born in 1972. Exhibit 1 (affidavit) ¶ 1. Before the allegedly causal flu vaccination, Mr. Kelsey periodically saw a practitioner of holistic medicine, Kevin Logan. However, the Secretary has not asserted that any medical problems from before the flu vaccine contributed to medical problems after the vaccination. See Resp't's Rep., filed Apr. 30, 2021.

In July and August 2017, Mr. Kelsey received vaccines other than the flu vaccine at issue. More specifically, on July 17, 2017, he received the first dose of the hepatitis B vaccine. Exhibit 9 at 34. He received a dose of the tetanus-diphtheria-acellular pertussis vaccine on July 27, 2017. Exhibit 23 at 22-23. Finally, on August 22, 2017, Mr. Kelsey was given a second dose of the hepatitis B vaccine. Exhibit 24 at 3, 5. Mr. Kelsey alleged that a graduate school that he was attending required these vaccinations. Third Amended Pet., filed June 7, 2024, ¶ 4.

Around this time, Mr. Kelsey was working for Community Health Network. See Exhibits 25 (affidavit) and 26 (employment records); see also Third Am. Pet. ¶ 3. Mr. Kelsey alleged that his employer required him to receive the flu vaccine as a condition of employment. Third Am. Pet. ¶ 5. The date of vaccination is October 2, 2017.

Later, on the date of vaccination, Mr. Kelsey saw a psychiatrist, James Tandy. Exhibit 15 at 2. Mr. Kelsey complained about a sudden onset of panic and “extremely high anxiety” two weeks earlier. Dr. Tandy recommended a change in medication.

Although not immediately documented in a medical record, Mr. Kelsey testified that on the evening of his vaccination, his nerves “lit up like they were on fire.” Exhibit 22 (deposition) at 17; see also Third Am. Pet. ¶ 7 (alleging Mr. Kelsey had a “sensation of having ‘stuck his finger in an electrical outlet’”). For purposes of the present ruling, Mr. Kelsey’s testimony is accepted as accurate.

The day after vaccination, Mr. Kelsey underwent IV hydration and IV chelation at Dr. Logan’s office. Exhibit 14 at 94. However, there are no office

notes. Thus, it follows that Dr. Logan's records do not memorialize any complaint about a problem in Mr. Kelsey's nerves. This lack of notes from Dr. Logan's office continues for three other appointments in October 2017. See Exhibit 14 at 95-98.

Mr. Kelsey returned to his psychiatrist, Dr. Tandy, on October 15, 2017. Dr. Tandy memorialized that Mr. Kelsey "blames pre-grad school vaccinations [for] causing neurological" symptoms. Exhibit 15 at 5. Dr. Tandy recommended increasing the dose of medication.

Mr. Kelsey saw his holistic doctor, Dr. Logan, on November 1, 2017. Exhibit 14 at 4-5. Mr. Kelsey was complaining about anxiety, fatigue, and "vaccine injury." The complaints appear not to originate in Mr. Kelsey's peripheral nervous system. In any event, Dr. Logan planned to treat Mr. Kelsey with injections of amino acids and "vaccine exposure IV." Id. at 5.

The next day, Mr. Kelsey telephoned Dr. Logan and stated that he had "intermittent numbness and tingling of his extremities for several weeks." Exhibit 14 at 7. He stated that the sensation lasted for 10 to 15 seconds. Id. He also had sharp shooting pain in his arms and legs that lasted for several minutes, as well as tingling in his chest. Id. Dr. Logan's assessment was:

Paresthesias - he did have the recent vaccine injury which seems to have caused some neural inflammation and contributed to some symptoms of anxiety which this could be a part of. [W]e will plan to monitor the symptoms and if they progress that he would need to go to the emergency room as it could represent underlying Guillain-Barré syndrome.

Id.

Over the next few months, Mr. Kelsey saw Dr. Logan and Dr. Tandy. However, the details are not particularly relevant. For more information, see Resp't's Rep. at 4.

On February 12, 2018, Mr. Kelsey saw a neurologist, Donald Strobel. Exhibit 12 at 5. Mr. Kelsey complained about headaches and tingling. He stated that he received the hepatitis B vaccine and tetanus-diphtheria-acellular pertussis vaccine "with subsequent post-vaccine dysfunction." This medical record does not memorialize any problem following the flu vaccination. Mr. Kelsey reported that he gained some relief with chelation treatments but plateaued a few months and

has become worse. Dr. Strobel examined Mr. Kelsey and found “good symmetric bulk, tone, and strength” in “both arms and legs.” Id. at 6. For sensory nerves, Dr. Strobel found “Vibratory only 9-10 sec bilat med malleolus.” Id.

Dr. Strobel assessed Mr. Kelsey as having a “Post viral syndrome.” Dr. Strobel ordered a series of tests. One test was an EMG/NCS, which was performed on March 15, 2018. The results were normal. Exhibit 12 at 12.

A follow up with Dr. Strobel occurred on April 16, 2018. Exhibit 12 at 15. According to Mr. Kelsey’s account, his “Neuropathy symptoms and spectrum dysautonomia [are] worsening.” Id. The results of Dr. Strobel’s examination appear to be unchanged. See id. at 17. Dr. Strobel carried forward his assessment of “Post viral syndrome,” adding “sequellae suggestive of non-infectious dysimmune state.” Dr. Strobel also added another condition: “Toxic neuropathy” for which “IVIG [is] in the works. Might need nerve [biopsy] and spinal tap.” Id.

The skin biopsy took place on May 14, 2018. The results are consistent with small fiber neuropathy. Exhibit 12 at 18-19.²

At the ensuing appointment with Dr. Strobel, Dr. Strobel continued to assess Mr. Kelsey with “Post viral syndrome,” “Toxic neuropathy” and “Headache.” Exhibit 12 at 25 (June 5, 2018). As part of the plan, Dr. Strobel ordered IVIG with a note “Start ASAP for severe cidp.” Id.

Around this time, Mr. Kelsey consulted a specialist in pain management. Exhibit 6 at 10. However, the details of these appointments are not particularly relevant to determining whether the flu vaccine caused Mr. Kelsey to suffer small fiber neuropathy. For additional information on more recent medical records, see Resp’t’s Rep’t at 5-10; Pet’r’s Resp. to Tentative Finding at 7.

II. Procedural History

A. Beginning of the Case

Represented by Attorney David Murphy, Mr. Kelsey alleged that the flu vaccine harmed him. Pet., filed July 13, 2020.³ The petition also alleged that Mr.

² Although Dr. Strobel had suggested a nerve biopsy, the biopsy was a skin biopsy. See Exhibit A (Dr. Anand’s report) at 3-4 (differentiating skin biopsies from nerve biopsies).

³ The initial petition alleged that the Tdap vaccine, hepatitis B vaccine, flu vaccine, and tuberculosis vaccine caused Mr. Kelsey to suffer from chronic inflammatory demyelinating polyneuropathy. But, as discussed below, Mr. Kelsey has changed his claim.

Kelsey had filed for worker's compensation benefits but planned to dismiss that claim if he received an award through the Vaccine Program.

An initial status conference was held on November 16, 2020. Mr. Kelsey was directed to obtain additional records. It was also explained that resolution of claims in the Vaccine Program tend to follow (not precede) resolutions of Workers' Compensation claims. The deadline for the Secretary's report was suspended as Mr. Kelsey pursued additional records. Mr. Kelsey obtained the records from his employment.

The Secretary reviewed this material and determined that compensation was not appropriate. Resp't's Rep., filed Apr. 30, 2021. The Secretary questioned whether CIDP was an accurate diagnosis. The Secretary also noted that the evidence did not include a theory by which the flu vaccine can cause CIDP and the timing for the onset of problems appeared unclear. In anticipation of the parties retaining reports from experts, a set of instructions was issued. Orders, issued May 11, 2021 and June 25, 2021.

B. Reports from Dr. Logan and Dr. Strobel

In November 2021, Mr. Kelsey filed reports from Dr. Strobel (Exhibit 30, filed Nov. 1, 2021) and Dr. Logan (Exhibit 32, filed Nov. 12, 2021). There were questions as to whether these doctors had reviewed the Expert Instructions as several points were not covered. Thus, Mr. Kelsey requested an opportunity to obtain supplemental reports.

The next two reports were substantially the same as the previous reports. See Exhibit 33 (Dr. Logan's report, filed Mar. 1, 2022) and Exhibit 34 (Dr. Strobel's report, filed Apr. 1, 2022). As discussed in the May 9, 2022 status conference, which was recorded, one deficiency was that Dr. Strobel failed to explain why CIDP was an appropriate diagnosis. Mr. Kelsey was encouraged to have experts write reports that followed the Expert Instructions because those Expert Instructions contain the elements of a petitioner's case.

Mr. Kelsey submitted another report from Dr. Strobel. Exhibit 35. In a status conference, the Secretary argued that Dr. Strobel had not presented a causal theory.

Mr. Kelsey was directed to clarify his theory of causation. Order, issued Oct. 14, 2022. Mr. Kelsey announced that he was retaining an outside expert to review the case and to prepare a report. Pet'r's Status Rep., filed Oct. 27, 2022.

C. Reports from Dr. Latov, Dr. Anand, and Dr. Staats (First Round)

Mr. Kelsey presented a report from Dr. Latov on December 1, 2022. Exhibit 53. The report is 10 pages, although the bulk of the report is about five pages. On the first page, Dr. Latov describes his qualifications and identifies the material he reviewed. Dr. Latov set out the relevant events in Mr. Kelsey's medical history in about one page. Next, Dr. Latov opines that Mr. Kelsey suffered from small fiber neuropathy, which (according to Dr. Latov) is "a variant of the Guillain-Barre syndrome." Exhibit 53 at 2. On page four of his report, Dr. Latov brings forward two theories to explain how a vaccine can cause injuries such as "GBS and its variants." The two theories are molecular mimicry and bystander activation. On the fifth page of his report, Dr. Latov addresses timing, noting that "Mr. Kelsey reported that his neuropathic symptoms began on the evening following the influenza vaccination." *Id.* at 5. Dr. Latov also asserts that "Mr. Kelsey did not have other identifiable causes for the neuropathy, other than the influenza vaccination." The remaining pages consist of a list of references and material from the Vaccine Adverse Event Report System.

The introduction of Dr. Latov's report led to a reformulation of Mr. Kelsey's position. Mr. Kelsey requested to withdraw the reports from Dr. Logan. Pet'r's Mot., filed Dec. 6, 2022. In the December 7, 2022 status conference, Mr. Kelsey agreed to amend his petition. The Secretary did not object to withdrawing the reports from Dr. Logan, although the Secretary contended that the reliance on Dr. Logan may lack reasonable basis.

Mr. Kelsey did amend his petition on January 11, 2023. He alleged that the Tdap vaccine, the hepatitis B vaccines, and/or the flu vaccine caused him to suffer chronic inflammatory demyelinating polyneuropathy. Second Am. Pet., filed Jan. 11, 2023, at preamble. This amended petition referred to the opinion from Dr. Latov. *Id.* at ¶ 26.

Because Mr. Kelsey appeared to complete the development of his case, the Secretary responded. The Secretary presented reports from two people, Dr. Anand and Dr. Staats.

Dr. Anand's report is essentially six pages with two additional pages for references. Exhibit A. Like Dr. Latov, Dr. Anand starts by identifying the material she reviewed and her qualifications. Dr. Anand's summary of medical records takes about one page. Dr. Anand evaluates whether Mr. Kelsey suffered from chronic inflammatory demyelinating polyneuropathy because the operative petition alleged that the vaccines caused Mr. Kelsey to suffer CIDP. She

maintained that “‘Normal’ EMG/NCS are fundamentally incompatible with a diagnosis of CIDP.” Exhibit A at 3. For small fiber neuropathy, Dr. Anand questioned whether Mr. Kelsey suffered from that condition. Dr. Anand stated “Absent vibratory sensation with preserved pinprick and temperature sensation would not be consistent with a diagnosis of small fiber neuropathy.” Id. at 5. Dr. Anand asserted that Mr. Kelsey “had an incomplete evaluation for potential etiologies of small fiber neuropathy.” Id. Dr. Anand stated that “small fiber neuropathy is associated with a broad range of pathologies, and Mr. Kelsey had several other diagnoses that could have contributed to the development of small fiber neuropathy.” Id. Finally, Dr. Anand maintained that causal theories that Dr. Latov had proposed would take longer than hours. Id. at 6.

Dr. Staats addressed the immunologic aspects of Dr. Latov’s report. Exhibit C. Dr. Staats explained his qualifications, forthrightly stating that he does not provide medical care. Dr. Staats identified the material that he reviewed. Dr. Staats’s recitation of events in Mr. Kelsey’s life is longer than the recitations in other reports, running about four pages. In response to Dr. Latov’s opinion, Dr. Staats opined that the temporal relationship was not appropriate: “This process of a vaccine-induced immune response resulting in the induction of self-reactive immune responses (autoimmune responses) that lead to host tissue damage would require a longer period of time post vaccination than reported by Mr. Kelsey.” Id. at 10.⁴

In response, Mr. Kelsey obtained a second report from Dr. Latov. Exhibit 94. This report is two pages. Without citing any evidence, Dr. Latov stated that “Mr. Kelsey was diagnosed with small fiber neuropathy, which is a type of axonal neuropathy, as confirmed by reduction of the density of nerve fibers.” Id. at 1. Although Dr. Latov quoted the reports from Dr. Anand and Dr. Staats in which each expert asserted that the timing was not appropriate, Dr. Latov did not persuasively refute these points at all. See id. at 1-2.

The Secretary stated that additional reports from experts were not needed. Resp’t’s Status Rep., filed Aug. 31, 2023.

D. Briefing Order and Tentative Finding

The parties were directed to argue their cases through briefs. Order, issued Jan. 25, 2024. On the same day, the undersigned tentatively found that Mr. Kelsey

⁴ Dr. Staats also responded to reports from Dr. Strobel. But, because Mr. Kelsey is not relying upon Dr. Strobel, this aspect is no longer relevant.

was not likely to establish that he was entitled to compensation. Tentative Finding, issued Jan. 25, 2024. The main problem was that Dr. Latov was proposing molecular mimicry as a theory to connect the flu vaccine with Mr. Kelsey's small fiber neuropathy and molecular mimicry requires more than one day.

A status conference was held on February 6, 2024, which was recorded at Mr. Murphy's request. Mr. Murphy, on behalf of Mr. Kelsey, asserted that because small fiber neuropathy is a type of Guillain-Barré syndrome, Mr. Kelsey had presented an on-Table case. This assertion was wrong because Mr. Kelsey's asserted onset (one day) was too rapid to qualify for a presumption of causation. See 42 C.F.R. § 100.3(a)¶ XIV.D. Mr. Murphy also stated that Mr. Kelsey was attempting to obtain another punch biopsy to confirm the diagnosis of small fiber neuropathy.

E. Reports from Dr. Latov, Dr. Anand, Dr. Staats (Second Round)

Mr. Kelsey obtained another set of results from an epidermal nerve fiber test. The results were consistent with small fiber neuropathy. Exhibit 102 (filed Apr. 16, 2024).

In the ensuing status conference, the Secretary requested that petitioner define the cause of action that he is pursuing. Mr. Murphy was uncertain as to whether he should maintain the claim that the flu vaccine caused Mr. Kelsey to suffer CIDP and requested an opportunity to confer with Dr. Latov.

Dr. Latov responded to the January 25, 2024 Tentative Finding. Exhibit 103, filed May 23, 2024. This report is approximately 2.5 pages with another 1.5 pages devoted to references. Dr. Latov maintained that Mr. Kelsey suffered from small fiber neuropathy and the latency between the flu vaccination and the onset of the small fiber neuropathy was one day. Dr. Latov stated that one day is a sufficient amount of time based upon the Schonberger article. *Id.* at 1.⁵ He also invoked the memory response of the immune system.

Mr. Kelsey amended his petition on June 7, 2024. This petition makes clear that Mr. Kelsey is claiming that the flu vaccine caused him to suffer small fiber neuropathy. Third Am. Pet., at Preamble. In other words, Mr. Kelsey is not claiming that the flu vaccine caused him to suffer CIDP. Mr. Kelsey further supported his claim by responding to the order to show cause. Pet'r's Resp., filed

⁵ Lawrence B. Schonberger et al., "Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977," 110 American J. Epidemiology 105 (1979); filed as Exhibit 121.

June 10, 2024. Mr. Kelsey's response included another affidavit from him. Exhibit 129.

The Secretary addressed the latest report from Dr. Latov. In a report, which is essentially one page, Dr. Anand stated that skin biopsies cannot show evidence of demyelinating changes. She also stated that small fiber neuropathy can be caused by conditions other than vaccinations, such as obesity and hypercholesterolemia, that were present in Mr. Kelsey. Exhibit E (filed June 10, 2024).

In another report, Dr. Anand mostly opined that Mr. Kelsey did not meet the diagnostic criteria for small fiber neuropathy. Exhibit G (filed July 15, 2024).⁶ Dr. Anand also again put forward other causes for small fiber neuropathy.

Dr. Staats responded to the portions of Dr. Latov's report that involved immunology. Dr. Staats stated that the proposed temporal relationship was not appropriate. Dr. Staats also pointed out that Dr. Latov had not explained how cytokines cause small fiber neuropathy. Exhibit F (filed July 15, 2024).

Mr. Kelsey filed another report from Dr. Latov. Exhibit 130 (filed Aug. 14, 2024). Dr. Latov stated that Mr. Kelsey's neuropathy was "mixed," involving both small fibers and large fibers. He also repeated points about timing.

Another status conference was held on September 9, 2024. The undersigned explained that Mr. Kelsey's case seemed to lack coherence. One discrepancy was that although Mr. Kelsey seemed to be relying upon a cytokine-driven theory to explain the rapid onset, Mr. Kelsey had not explained how cytokines contribute to the pathogenesis of small fiber neuropathy.

After the Secretary rejected Mr. Murphy's idea that the parties and their experts attend mediation, Mr. Murphy contended that the dispute between the experts was like a situation in which disputes over facts prevented resolution on a motion for summary judgment. However, the undersigned explained that a ruling on the record is not the same as a ruling based upon a motion for summary judgment. Thus, Mr. Kelsey was given an opportunity to decide how to proceed.

⁶ Technically, when this report was filed, the Secretary labeled it as "Exhibit E." Because this designation repeated a letter, the report was struck. The Secretary then re-filed with the correct label.

Mr. Kelsey again attempted to cure the problems noted in the January 25, 2024 Tentative Findings. Pet'r's Resp., filed Nov. 14, 2024. Mr. Kelsey added another report from Dr. Latov. Exhibit 157 (filed Dec. 4, 2024).

The Secretary maintained his position that Mr. Kelsey was not entitled to compensation. Resp't's Status Rep., filed Jan. 22, 2025. Mr. Kelsey has not otherwise replied. Thus, the case is ready for adjudication.

Because both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020).

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 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).

IV. Diagnosis

In Broekelschen v. Sec’y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may “first determine which injury was best supported by the evidence in the record before applying the Althen test.” Here, the appropriate diagnosis is one of the more disputed aspects. Dr. Latov asserted that the appropriate diagnosis is small fiber neuropathy. Exhibit 53 at 2. However, Dr. Anand disagreed. Exhibit A at 5.

Part of the dispute between Dr. Latov and Dr. Anand concerns the diagnostic criteria. Dr. Anand cited diagnostic criteria from Besta and Devigili. Exhibit G at 1. The Devigili criteria have been used in evaluating whether a person suffers from small fiber neuropathy. Brantley v. Sec’y of Health & Hum. Servs., No. 18-1416V, 2023 WL 7924655, at *5-6 (Fed. Cl. Spec. Mstr. Oct. 20, 2023). By way of contrast, Dr. Latov relied upon diagnostic criteria for idiopathic distal sensory polyneuropathy. Exhibit 130 at 1-2, citing Exhibit 140 (Roy Freeman et al., “Idiopathic distal sensory polyneuropathy: ACTION diagnostic criteria,” 95(22) Neurology 1005 (2020)). Pursuant to this standard, Dr. Latov opined that “Mr. Kelsey would fall into the ‘mixed’ category.” Exhibit 130 at 2.

A greater degree of analysis about diagnostic criteria would have been helpful as the experts and the parties failed to engage with this issue. For example, Dr. Anand raised the point about Mr. Kelsey lacking the ability to sense vibrations as a point inconsistent with small fiber neuropathy in her first report. Exhibit A at 5. Dr. Anand reinforced this point in her third report by citing the Besta and Devigili diagnostic criteria. Exhibit G.

In some respect, Dr. Latov appears to agree with at least some portion of Dr. Anand’s opinion in the sense that he says that Mr. Kelsey’s small nerve fibers and large nerve fibers are impaired. See Exhibit 130 (placing Mr. Kelsey into the “‘mixed’ category”). A shift from a diagnosis of small fiber neuropathy to “idiopathic mixed fiber sensory neuropathy” (to borrow a term from Freeman) appears to be more a difference in degree than a difference in kind to Dr. Latov. He maintains that “Influenza vaccine is a recognized trigger of GBS, including all its subtypes.” Exhibit 130 at 2.

Dr. Anand did not refute Dr. Latov’s proposal that Mr. Kelsey suffers from idiopathic mixed fiber sensory neuropathy. Furthermore, the Secretary’s most

recent brief did not discuss diagnosis. See Resp't's Status Rep., filed Jan. 22, 2025. Thus, this diagnosis is accepted as appropriate for Mr. Kelsey.⁷

V. Causation-in-Fact

The Vaccine Injury table does not associate the flu vaccine with mixed fiber sensory neuropathy. See 42 C.F.R. § 100.3(a) ¶ XIV.D. Thus, Mr. Kelsey cannot gain a presumption of causation and must instead show that the vaccine was the cause-in-fact of his illness. In these circumstances, the elements of a causation-in-fact claim are set forth in Althen.

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).

A. Theory

The analysis begins with the theory because the theory influences other aspects of the case. Here, Dr. Latov has changed positions.

Initially, Dr. Latov proposed molecular mimicry and bystander activation. Exhibit 53 at 4. Regardless of the reliability of these theories, Dr. Anand and Dr. Staats questioned whether those processes could occur in about one day. Exhibit A at 6; Exhibit C at 10. The January 25, 2024 Tentative Finding Denying Entitlement stated that Mr. Kelsey had not established that these theories could happen so quickly.

Dr. Latov has moved away from molecular mimicry and bystander activation. See Pet'r's Br., filed Nov. 14, 2024, at 5. Instead, Dr. Latov says that a flu vaccine leads to the production of pro-inflammatory cytokines. Exhibit 103 at 1; Exhibit 158 at 2.

It is well-accepted that vaccinations can lead to the production of pro-inflammatory cytokines. See Ridgway v. Sec’y of Health & Hum. Servs., No. 06-

⁷ The January 25, 2024 Tentative Finding Denying Entitlement noted, without deciding, that Dr. Anand appeared to raise persuasive points against the diagnosis of small fiber neuropathy. Dr. Latov’s shift to mixed fiber neuropathy appears consistent with the Tentative Finding.

834V, 2008 WL 3834146, at *6 (Fed. Cl. Spec. Mstr. July 23, 2008); Jaafar v. Sec’y of Health & Hum. Servs., No. 15-267V, 2018 WL 4519066, at *5 (Fed. Cl. Spec. Mstr. Aug. 10, 2018). The Talaat article is consistent with this understanding.

However, after this point, Dr. Latov’s opinions falter. What do the cytokines do that leads to some type of neuropathy? His report is not clear, and the lack of clarity impairs its persuasiveness. For example, Dr. Latov states that some cytokines can increase the permeability of the blood-brain barrier. Exhibit 158 at 2. Although this point might be accurate, it also seems irrelevant because the blood-brain barrier protects the central nervous system. In contrast, Mr. Kelsey’s mixed fiber sensory neuropathy is a condition affecting the peripheral nervous system.

Dr. Latov says that cytokines can activate CD8+ memory T cells. Exhibit 103 at 2; Exhibit 158 at 3. But, the ensuing questions are how long does activation take? And, once CD8+ memory T cells are activated, what do these T cells do to cause mixed fiber sensory neuropathy? Dr. Latov does not say.

Dr. Latov also refers to people’s ability to respond to a purified-protein derivative test for tuberculosis. Exhibit 158 at 2. However, Dr. Latov does not explain why the purified-protein derivative test, which occurs on the skin, resembles mixed fiber sensory neuropathy. Thus, his attempted analogy is inapt. See Contreras v. Sec’y of Health & Hum. Servs., No. 05-626V, 2012 WL 1441315, at *18-20 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (discussing tuberculosis testing), mot. for rev. granted, 107 Fed. Cl. 280, 305-06 (2012) (discussing the tuberculin test analogy), see also 2014 WL 8098606 (Fed. Cl. Spec. Mstr. Oct. 24, 2014) (decision on remand), mot. for rev. denied, 121 Fed. Cl. 230 (2015), vacated on other grounds and remanded, 844 F.3d 1363 (Fed. Cir. 2017).

Similarly, Dr. Latov raises Stevens-Johnson syndrome, which is a disease of the skin. Exhibit 103 at 2; Exhibit 158 at 4. But, Dr. Latov does not persuasively explain why the pathogenesis of Stevens-Johnson syndrome is comparable to Mr. Kelsey’s disease, mixed fiber sensory neuropathy.

Special masters have generally, but not universally, found that causal theories involving cytokines lack specificity. See Catone v. Sec’y of Health & Hum. Servs., No. 19-690V, 2025 WL 2692275 (Fed. Cl. Spec. Mstr. Aug. 8, 2025); Maxwell v. Sec’y of Health & Hum. Servs., No. 17-1367V, 2025 WL 1291642 (Fed. Cl. Spec. Mstr. Mar. 26, 2025); Giesbrecht v. Sec’y of Health & Hum. Servs., No. 16-1338V, 2023 WL 2721578 (Fed. Cl. Spec. Mstr. Mar. 30,

2023). While those cases are not binding, the reasoning is persuasive. As with the petitioners in those cases, Mr. Kelsey's evidence remains incomplete. Dr. Latov has essentially stated that (a) vaccines can lead to cytokines and (b) cytokines can cause mixed fiber neuropathy. But, Dr. Latov has not supplied a reliable basis for finding the second assertion---cytokines can cause mixed fiber neuropathy---persuasive.

Finally, although Dr. Latov treats small fiber and mixed fiber sensory neuropathy as subtypes of Guillain-Barré syndrome, this characterization does not advance Mr. Kelsey's claim.⁸ First, "Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation." Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (quoting H.R. Rep. No. 908, 99th Cong. 2d Sess., pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356). Second, the Secretary added GBS to the table based upon some epidemiologic studies without providing a mechanism by which a flu vaccine can cause GBS. 80 Fed. Reg. 45132, 45145-46 (July 29, 2015) (notice of proposed rulemaking). Thus, the Secretary's acceptance that a flu vaccine can cause GBS that is manifest within 3-42 days of the vaccination does not fill the gap in Mr. Kelsey's case.

Overall, Mr. Kelsey's attempt to present a reliable and persuasive theory to explain how a flu vaccine can cause mixed fiber sensory neuropathy fell short. On this basis, he is not entitled to compensation.

B. Timing

Via quotations from Dr. Latov's report, Mr. Kelsey argues that: "It would be unreasonable to require that specific mechanisms be identified in every case to prove causation, as that would require conducting laboratory experiments prior to and following the vaccination, which is not practicable or available in the clinical setting." Pet'r's Br., filed Nov. 14, 2024, at 4, quoting Exhibit 158 (Dr. Latov's Fifth report) at 2. The problem with this argument is that Dr. Latov is commenting on the *legal* requirements to receive compensation through a taxpayer-funded program. The Federal Circuit has already spelled out the elements of compensation and one of those elements in a causation-in-fact case is a showing that the interval between the vaccination and the onset of the condition be

⁸ Mr. Kelsey does not assert this argument. See Pet'r's Br., filed Nov. 14, 2024. It is addressed to demonstrate that the entire record has been considered.

medically appropriate. Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347 (Fed. Cir. 2008).

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).

Here, the parties accept Mr. Kelsey’s testimony that within a few hours of the flu vaccination, he started having sensations in his hands. Exhibit 22 at 17; see also Exhibit 14 at 4 (Dr. Logan’s November 2, 2017 report about “intermittent numbness and tingling of his extremities for several weeks”). The ensuing question is whether one day is an interval for which an inference of causation is appropriate. The answer to this question depends, in part, upon the theory being offered. Langland v. Sec’y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013).

Some concepts, such as molecular mimicry, bystander activation, and immune complexes, are generally understood to require more than one day. Thus, as noted above, Mr. Kelsey is no longer relying upon them.⁹

Instead, Mr. Kelsey is putting forward (poorly described) theories involving cytokines. Although cytokines may be produced within a day of a vaccination, the increase in cytokines is not the same as the beginning of a disease. See Samuels v. Sec’y of Health & Hum. Servs., No. 17-071V, 2020 WL 2954953, at *21 (Fed. Cl. Spec. Mstr. May 1, 2020) (“The fact that vaccines can initially (due to adjuvants) cause cytokines to increase [within 24 hours] does not also mean they become pathologic in that same time period”); McGuire v. Sec’y of Health & Hum. & Servs., No. 10-609V, 2015 WL 6150598, at *21 (Fed. Cl. Spec. Mstr. Sep. 18, 2015) (petitioner’s expert “offered a theory involving cytokines, but his testimony revealed that he did not know the time needed to produce [the specific pathologic] cytokines or the duration of [those] cytokines.”). Dr. Latov’s opinion might be more persuasive if Dr. Latov had spelled out the process by which cytokines

⁹ Because Mr. Kelsey is no longer advancing molecular mimicry as a theory to explain how the flu vaccine can cause mixed fiber neuropathy, cases that evaluated the timing for molecular mimicry such as Walker v. Sec’y of Health & Hum. Servs., No. 18-299V, 2022 WL 11141194 (Fed. Cl. Spec. Mstr. Sep. 27, 2022), and Forrest v. Sec’y of Health & Hum. Servs., No. 14-1046V, 2019 WL 925495 (Fed. Cl. Spec. Mstr. Jan. 28, 2019), are not directly germane. See Pet’r’s Br., filed Nov. 14, 2024, at 7-8.

damage peripheral nerves. As noted in the previous section addressing the cytokine theory, Dr. Latov is relatively quiet about how cytokines cause small fiber neuropathy. This lack of detail also hampers assessing the argument that whatever is the process, it can happen within one day.

Without filling a lack of details, Mr. Kelsey analogizes his case to the Schonberger article. Pet'r's Br., filed Nov. 14, 2024, at 4; see also Pet'r's Resp. to Tentative Finding, filed June 10, 2024, at 15. Schonberger is Exhibit 80, 95, and 121. According to Dr. Latov, Schonberger "showed the immune system can be triggered to induce an autoimmune disease within one day of vaccination." But, Schonberger does not support the proposition that incidents of Guillain-Barré syndrome were increased after the swine flu vaccination within two days of the vaccination. See Greenslade v. Sec'y of Health & Hum. Servs., No. 14-1140V, 2024 WL 3527665, at *40 (Fed. Cl. Spec. Mstr. June 28, 2024); Rowan v. Sec'y of Health & Hum. Servs., No. 17-760V, 2020 WL 2954954, at *17 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) ("Schonberger does not otherwise comment on the question of onset, or whether the early cases identified might be vaccine-caused"); Forrest v. Sec'y of Health & Hum. Servs., No. 14-1046V, 2019 WL 925495, at *7 (Fed. Cl. Spec. Mstr. Jan. 28, 2019). Thus, Mr. Kelsey's attempted reliance on Schonberger is unpersuasive.

For the reasons explained above, the evidence regarding timing does not preponderate in Mr. Kelsey's favor.

C. Logical Sequence

Given that Mr. Kelsey has established neither a theory nor appropriate timing, it follows as a matter of logic that he cannot establish a logical sequence of cause and effect, linking the flu vaccination to his mixed fiber neuropathy. See Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012); Temes v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 448, 464 (Fed. Cl. 2020) ("the special master appropriately considered the lack of evidentiary support for [the 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 [the petitioner's] injury"). Nevertheless, this element is briefly reviewed, if only to demonstrate that the entire record has been considered.

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, the parties have not

devoted much attention to the second Althen prong. See Pet'r's Br., filed Nov. 14, 2024, at 2-3. For example, Mr. Kelsey presents a chronology of events that mostly shows how his neurologic condition progressed. See Pet'r's Resp. to Tentative Finding, filed June 10, 2024, at 4-9. But, a chronology of events is not the same as a showing of causation.

Some support from a treating doctor could be found in Dr. Logan's November 1, 2017 report in which Dr. Logan memorialized a complaint about a "vaccine injury." Exhibit 14 at 4. But, the injury does not appear to be similar to mixed fiber neuropathy. In any event, Dr. Logan's documentation that Mr. Kelsey stated that he was suffering from a vaccine injury is not the same as a doctor's opinion about causation. See Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 219-20 (2012); Veryzer v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 344, 354 (2011). This difference between opinions expressed by petitioners and opinions expressed by doctors also is a basis for giving minimal, if any, weight to Dr. Tandy's October 15, 2017 report. Exhibit 15 at 5 (noting that Mr. Kelsey "blames pre-grad school vaccinations [for] causing neurological" problems).

Another potentially helpful statement from a treating doctor is Dr. Strobel's February 12, 2018 record. Exhibit 12 at 5. This record, too, memorializes Mr. Kelsey's statement that the hepatitis B vaccine and the tetanus-diphtheria-acellular pertussis vaccine (not the flu vaccine) harmed him. Although Dr. Strobel later prepared reports for the purposes of litigation (Exhibits 30, 34, and 35) upon which Mr. Kelsey is no longer relying, Dr. Strobel's initial impression was that Mr. Kelsey was suffering from a "Post-viral syndrome." Exhibit 12 at 13. Thus, Dr. Strobel's opinions do not constitute persuasive evidence that the flu vaccine caused Mr. Kelsey's mixed fiber neuropathy.

Although the reports from treating doctors do not meaningfully assist Mr. Kelsey, he could conceivably establish a logical sequence of cause and effect through the expert he retained, Dr. Latov. However, Dr. Latov's basic reasoning is that Mr. Kelsey developed a problem, which is associated with the flu vaccination, after the vaccination. See Exhibit 53 at 5 (discussing the logical sequence prong in two lengthy sentences). The Federal Circuit has rejected such reasoning. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1323 (Fed. Cir. 2010).

For these reasons, Mr. Kelsey has not met his burden of proof regarding Althen prong two.

VI. Conclusion

Throughout the litigation, Mr. Kelsey has demonstrated a belief that a vaccination harmed him. However, special masters cannot award compensation based upon a good-faith belief or upon the sympathy to which a petitioner is entitled for suffering. Instead, petitioners must support their claims with persuasive evidence.

Here, Mr. Kelsey has pursued various ideas but none of them have been supported with persuasive evidence. Without a showing of persuasive evidence, Mr. Kelsey 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