

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

KELLY JUSTICE,	*	No. 22-903V
	*	
Petitioner,	*	
	*	Special Master Christian J. Moran
v.	*	
	*	Filed: January 29, 2026
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Leigh A. Finfer, Muller Brazil, Dresher, PA, for petitioner;
Dorian Hurley, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION¹

Kelly Justice alleges that an influenza (“flu”) vaccine caused her to suffer a neurologic illness known as acute disseminated encephalomyelitis (“ADEM”). To support her claim for compensation through the National Childhood Vaccine Compensation Program, Ms. Justice has submitted her medical records and affidavits. Ms. Justice also relies upon reports prepared by a neurologist whom she

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.

retained, John Hixson. Dr. Hixson generally opines that Ms. Justice suffered from ADEM and the flu vaccine caused the ADEM.

The Secretary opposes an award of compensation. The Secretary relies upon reports from two experts. First, a neurologist, Dara Jamieson, opined that Ms. Justice did not suffer from ADEM. Instead, the appropriate diagnosis for her is a different neurologic problem, multiple sclerosis (“MS”). Second, an immunologist, You-Wen He, challenged the opinion that the flu vaccine caused any harm to Ms. Justice.

As explained below, Ms. Justice has not preponderantly established that she suffered from ADEM. As most of her treating doctors eventually determined, the better diagnosis is multiple sclerosis. Because the question of diagnosis resolves the case, the separate and more complicated question of causation is not reached.

This decision is organized into various parts. Because diagnosis is a fundamental question, Part I introduces the two relevant diseases, ADEM and multiple sclerosis, including the diagnostic criteria for each. Part II summarizes relevant events in Ms. Justice’s medical history and presents the experts’ opinion about the significance of those events in determining diagnosis. Part III reviews the procedural history, and Part IV sets out the standards for adjudication. The finding of fact with respect to diagnosis is found in Part V. Part VI explains why the finding that Ms. Justice suffered from multiple sclerosis resolves her case. Part VII concludes the decision.

I. Medical Conditions

Ms. Justice and her expert, Dr. Hixson, maintain that she suffered from ADEM. Thus, this disease is discussed in the section A. The disease proposed by the Secretary and Dr. Jamieson, multiple sclerosis, is discussed in section B. Both sections introduce some basic ideas with nuances appearing in the context of discussion of Ms. Justice’s medical records.

A. Acute Disseminated Encephalomyelitis (ADEM)

Dr. Jamieson defined ADEM as a “a rare, classically monophasic, immune-mediated, demyelinating CNS disorder generally seen in young children (median age at presentation five to eight years) who are acutely and severely neurologically impaired.” Exhibit A at 13. Dr. Jamieson further relied upon a 2016 article by Daniela Pohl as the diagnostic criteria. *Id.* The diagnostic criteria for ADEM are:

1. A first polyfocal clinical CNS [central nervous system] event with presumed inflammatory demyelinating cause
2. Encephalopathy (alteration in consciousness or behavior unexplained by fever, systemic illness, or postictal symptoms)
3. Brain MRI abnormalities consistent with demyelination during the acute (3 months) phase
4. No new clinical or MRI findings three months or more after the clinical onset

Exhibit A-1 (Daniela Pohl et al., “Acute disseminated encephalomyelitis: Updates on an inflammatory CNS syndrome,” 87 (Suppl 2) *Neurology* S38 (2016)) at S39. Ms. Justice has not challenged the usefulness of the Pohl criteria. See Pet’r’s Br. at 19-20.

B. Multiple Sclerosis

Dr. Jamieson characterized multiple sclerosis as a “a chronic and generally progressive neurological disease with DIT [dissemination in time] and DIS [dissemination in space] of the clinical and imaging manifestations of CNS demyelination.” Exhibit A at 15. Diagnostic criteria for multiple sclerosis are found in the 2017 McDonald criteria.

Number of lesions with objective clinical evidence		Additional data needed for a diagnosis of multiple sclerosis
≥2 clinical attacks	≥2	None*
≥2 clinical attacks	1 (as well as clear-cut historical evidence of a previous attack involving a lesion in a distinct anatomical location†)	None*
≥2 clinical attacks	1	Dissemination in space demonstrated by an additional clinical attack implicating a different CNS site or by MRI‡
1 clinical attack	≥2	Dissemination in time demonstrated by an additional clinical attack or by MRI§ OR demonstration of CSF-specific oligoclonal bands¶
1 clinical attack	1	Dissemination in space demonstrated by an additional clinical attack implicating a different CNS site or by MRI‡ AND Dissemination in time demonstrated by an additional clinical attack or by MRI§ OR demonstration of CSF-specific oligoclonal bands¶

Exhibit A-11 (Alan J. Thompson et al., “Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria,” 17 *Lancet Neurol.* 162 (2018)) at 167 (highlighting added by respondent).

II. Medical Records and Expert Commentary on Their Significance

Due to the complexities of some of the medical reports, the chronological presentation of events in Ms. Justice's medical history is sometimes interrupted to set out the opinions from Dr. Hixson and Dr. Jamieson about the significance of the events being describe. A complete analysis of the persuasiveness of the opinions of Dr. Hixson and Dr. Jamieson regarding the diagnosis of ADEM or multiple sclerosis is deferred until section V.B., below.

A. **Pre-Vaccination and Vaccination**

Ms. Justice was born in 1982. Exhibit 2 at 3. She had a history of scoliosis. Exhibit 2 at 8. However, the Secretary has not argued that she had any symptoms of a demyelinating disease before the vaccination. See Resp't's Br. at 3.

On September 9, 2019, Ms. Justice sought care at a CVS Minute Clinic for a sore throat. Exhibit 1 at 4-8. A rapid strep test was positive for streptococcal infection. She was diagnosed with pharyngitis and prescribed an antibiotic. During this September 9, 2019 visit, Ms. Justice received the flu vaccination, which allegedly harmed her.²

B. **Care from November 1, 2019 through November 18, 2019, Including Hospitalization**

1. November 1, 2019: Chiropractor

Following the vaccination. Ms. Justice's next medical appointment was on November 1, 2019. On that date, she told a chiropractor that she was having back pain. More specifically, she said that she "continue[d] to struggle with pain, discomfort and limitations while at work and performing activities of daily living." Exhibit 6 at 6. The chiropractor obtained imaging and adjusted her back. The chiropractor diagnosed her with thoracogenic scoliosis in the thoracic region, idiopathic scoliosis in the lumbar region, intervertebral disc degeneration in the

² The Secretary contends that the infectious organism that caused Ms. Justice's sore throat is a more likely cause of ADEM. See Resp't's Br. at 51. However, because the evidence does not preponderate in favor of a finding that Ms. Justice suffered from ADEM, the cause of any hypothetical ADEM is not reached.

lumbosacral region, acquired deformity of the pelvis, and muscle spasms in her back. Id.

2. November 2, 2019: Admitted to the Hospital

a) Initial Presentation

The next day, Ms. Justice went to the emergency department at a local hospital. Exhibit 2 at 5. She stated that she developed numbness in her right leg on October 28, 2019. (October 28, 2019 is 49 days after the September 9, 2019 vaccination). She explained that this right leg numbness was “progressively worsening” and she had difficulty walking. When medical personnel reviewed various systems, Ms. Justice reported nausea, tightness in her back, shooting pain down her left leg, decreased sensation when she tried to urinate or move her bowels, and some headaches the week prior.

b) Expert Commentary on Initial Presentation

Based on this history and other histories discussed below, Dr. Jamieson opined that Ms. Justice did not develop features consistent with ADEM. According to Dr. Jamieson, “ADEM in adults generally causes rapid neurologic devastation.” Exhibit A at 13. In contrast, Ms. Justice experienced “relapsing and remitting demyelinating symptoms as disseminated in time (DIT), within multiple weeks to a month, and disseminated in space (DIS) (i.e., location within[] the brain and spinal cord) prior to her eventual diagnosis with RRMS. . . . Ms. Justice also did not have encephalopathy with alteration in consciousness as is generally noted with ADEM.” Exhibit A at 13-14.

Ms. Justice does not persuasively challenge the assertion that her symptoms developed over time. See Pet’r’s Br. Instead, she argues that clinical symptoms in ADEM are variable. Pet’r’s Br. at 18. She relies upon an article by Dimitrios Karussis and Panayiota Petrou. Karussis and Petrou do state that the “clinical presentation of ADEM is widely variable, depending on the distribution of lesions in the CNS.” Exhibit 45 (Dimitrios Karussis and Panayiota Petrou, “The spectrum of post-vaccination inflammatory CNS demyelinating syndromes,” 13 *Autoimmune Reviews* 215 (2014)) at 216. However, Karussis does not further elaborate on whether the symptoms develop abruptly or over time.

c) First Set of MRIs

Based, in part, on Ms. Justice's clinical presentation in the emergency department, the doctor ordered a series of MRIs. Exhibit 2 at 9. MRIs with and without contrast revealed lesions in Ms. Justice's brain. *Id.* at 43-45. These lesions were consistent with demyelination. Another lesion ranging from T1-T2 to T3-T4 was discovered on an MRI of Ms. Justice's thoracic spine. *Id.* at 48. This lesion was also consistent with demyelination. Finally, an MRI of Ms. Justice's lumbar spine showed an unusual curve in her spine but no demyelinating lesions. *Id.* at 46. After the doctor who ordered the MRIs reviewed the results, the doctor transferred Ms. Justice to a facility offering neurologic services, Ohio State University Wexner Medical Center. *Id.* at 9, 19. When Ms. Justice was transferred, her diagnosis was multiple sclerosis. *Id.* at 4.

As part of this litigation, Ms. Justice obtained the MRI images. Exhibits 28-30. Dr. Hixson's reports do not mention whether he reviewed the MRI images. *See* Exhibit 12 at 4 and Exhibit 31. Dr. Jamieson reviewed the images and included snapshots of several of the MRIs throughout her report. *See* Exhibit A. Although Dr. Jamieson's reproduction of the images helps explain what the MRIs are showing, Dr. Jamieson basically concurred with the interpretations offered by the radiologists who reviewed Ms. Justice's images. Thus, this decision will cite to the comments from Ms. Justice's treatment team.

d) Ohio State University Emergency Department

In the emergency department at Ohio State, Ms. Justice provided a history that was mostly similar to the history provided at the first hospital. She complained about numbness and weakness in her right leg. This numbness had developed over the course of one month. She also had right foot drop for one week. Exhibit 3 at 29-30. Ms. Justice also informed the doctors at this hospital that she had gotten MRIs at the other hospital. *Id.*³ The emergency room doctor admitted Ms. Justice to the hospital, where she stayed until November 18, 2019.

In the hospital, various doctors saw Ms. Justice. The histories they obtained were fairly consistent in documenting that she had been experiencing some symptoms for some time. *See, e.g.* Exhibit 3 at 45 (report to internal medicine

³ Ms. Justice also said that she had gotten a flu vaccine one week earlier. Exhibit 3 at 29-30. However, the flu vaccine was actually 54 days earlier.

specialist that Ms. Justice had four weeks of paresthesia); Exhibit 3 at 48 (report to neurologists that she had sensory changes on her left side four weeks earlier and she had intermittent double vision for one week to two weeks).

3. November 3-4, 2019

Ms. Justice got her first dose of intravenous Solumedrol on November 3, 2019. Exhibit 3 at 60-61. Solumedrol suppresses the immune system. See Dorland's Illus. Med. Dict. 1703 (33rd ed.) (defining solumedrol as a trademark for a preparation of methylprednisolone sodium succinate); Id. at 1137 (defining methylprednisolone)

On November 4, 2019, a neurologist (Rawan Tarawneh) and a neurology resident (Rabia Yasin) commented that Ms. Justice might be suffering from multiple sclerosis, but it was unclear whether she had experienced dissemination in time. Another possibility was ADEM. Thus, they recommended additional work up because, in part, they could recommend disease modifying therapies (“DMT”) for multiple sclerosis. See Exhibit 3 at 62-65.

4. November 5, 2019: Second Brain MRI

Ms. Justice underwent another MRI on her brain. The results showed

Multifocal white matter lesions, supratentorial and infratentorial The [two] largest lesions show minimal enhancement, less than on recent outside MRI exam, but this most likely reflects steroid administration. Appearance of lesions is most compatible with demyelinating disease, with ADEM being favored in the differential diagnosis given the clinical history of recent flu vaccination.

Exhibit 3 at 242-43.

5. November 6, 2019: Spinal Tap

Doctors Yasin and Tarawneh reviewed the results of the brain MRI. They again questioned whether there was dissemination in time. ADEM remained within the diagnostic possibilities. Thus, they recommended a spinal tap to look for oligoclonal bands. Exhibit 3 at 87-90.

The spinal tap took place on the same day. The immediate results revealed glucose of 95 mg/dL, protein 32 mg/dL, and mild lymphocytosis with 13 white blood cells (“WBC”) in CSF tube 4, as well as an elevated IgG index of 0.76 in her CSF. Exhibit 3 at 194-97. At this time, the test for oligoclonal bands was pending.

6. November 7, 2019: Potential Change in Treatment

Ms. Justice received the fifth dose of Solumedrol. Exhibit 3 at 91. However, she reported that her right leg weakness was unchanged, and she had numbness over her trunk and legs. Dr. Yasin stated that: “[b]ase[d] on history and imaging[,] diagnosis of ADEM [was] favored over MS,” but that “[r]egardless of diagnosis, [Ms. Justice] ha[d] active demyelinating lesions with no improvement after high dose steroids and so [they] recommend[ed] escalating therapy with PLEX.” *Id.* at 94. Dr. Tarawneh concurred. *Id.* at 91. (“PLEX,” in this context, probably means “plasma exchange.”) *See* Exhibit 3 at 107 (noting that Ms. Justice was being evaluated on November 11, 2019, for “therapeutic plasma exchange”).

7. November 9, 2019: Second Set of Spinal MRIs

Ms. Justice had another set of MRIs on her cervical, thoracic, and lumbar spine. The results showed:

Mildly expansile, non[-]enhancing intramedullary signal abnormality within the thoracic spinal cord extending from the T1-T2 to the T3-T4 levels for a length of approximately 4.1 cm, slightly increased in extent compared to prior examination. Given the findings on recent MRI brain and history, findings are suspicious for evolving transverse myelitis related to demyelinating disease.

Exhibit 3 at 125. Dr. Tarawneh stated that there was “mild progression of spinal demyelination.” *Id.* at 160 (Nov. 10, 2019).

Based upon an article Dr. Hixson cited, Ms. Justice contends that spinal cord lesions are “are common in ADEM, although an isolated spinal cord lesion without supratentorial involvement is rare.” Pet’r’s Br. at 17, citing Exhibit 18 (Amy Waldman, “Acute disseminated encephalomyelitis (ADEM) in adults,” UpToDate (June 1, 2022)) at 7. The Secretary did not address whether a spinal cord lesion is more consistent with ADEM or multiple sclerosis.

8. November 15, 2019: More Test Results

Other results from the tests on Ms. Justice’s cerebrospinal fluid, which was obtained during the November 8, 2019 spinal tap, were returned on November 15, 2019. She tested negative for myelin oligodendrite (“MOG”) antibodies and negative for neuromyelitis optica (“NMO”) / aquaporin-4 antibodies. Exhibit 3 at 204. For oligoclonal bands, the results were more than five “well defined gamma restriction bands that [were] not present in [her] corresponding serum sample.” Id. at 190. These results were “supportive evidence of central nervous system inflammation, multiple sclerosis, or infection.” Id. A progress note stated that the “[o]ligoclonal bands with elevated IgG index [were] concern[ing] for MS.” Id. at 141.

In the litigation, both neurology experts commented upon the significance of the positive oligoclonal bands. Dr. Hixson relies upon an UpToDate article that says “Oligoclonal bands (OCBs) have been reported in 6 to 65 percent of adult patients with ADEM.” Exhibit 18 (Waldman) cited in Exhibit 12 at 5.⁴ Dr. Jamieson appears to agree that oligoclonal bands can be found in ADEM. She wrote: “A minority of patients with ADEM are noted to have positive OCBs in their CSF, but this biomarker is much more characteristic of MS than of ADEM.” Exhibit A at 15-16. Dr. Hixson replied that “the presence of OCBs cannot be used to definitively argue that Ms. Justice’s diagnosis was not consistent with ADEM.” Exhibit 31 at 4. Ms. Justice takes this same position. See Pet’r’s Br. at 19; Pet’r’s Reply at 2.

9. November 18, 2019: Discharge

Ms. Justice’s fifth and final PLEX session was on November 18, 2019. Exhibit 3 at 147, 151. Her lower extremities still had some abnormalities. Her left leg had decreased sensation but normal strength. Her right leg had reduced strength but intact sensation. She also had numbness in her abdomen.

She was discharged. In her discharge report, her diagnoses were “MS [versus] ADEM.” Exhibit 3 at 150-51.

⁴ The Waldman UpToDate article provides different statistical information for children who have oligoclonal bands. In children and adolescents, the presence of oligoclonal bands in the context of ADEM suggests they may develop multiple sclerosis.

C. November 25, 2019: Outpatient with Dr. Fallis

After her discharge, Ms. Justice followed up at the Ohio State University Multiple Sclerosis and Neuroimmunology Center. She first saw neurologist Robert J. Fallis. The history that Dr. Fallis obtained stated that Ms. Justice received a flu vaccine on September 9, 2019 when she also had strep. About three days later, she had paresthesia in her left leg. With this history in mind, Dr. Fallis examined her and detected, among other problems, a “waddling cautious gait.” Exhibit 5 at 146.

Dr. Fallis’s assessment was that Ms. Justice “ha[d] a post-vaccination [NMO spectrum disorder (“NMOSD”)] with ADEM,” and planned for her to receive rituximab infusions and physiotherapy and be pulsed with steroids.” *Id.* at 143, 147. In response to a telephone call, Dr. Fallis instructed his medical assistant to tell Ms. Justice that she had ADEM when she was admitted, but the “underlying issue[.]” appears to be NMOSD. *Id.* at 140.

Ms. Justice received rituximab infusions on December 13 and 27, 2019. Exhibit 4 at 193-222. Rituximab is a monoclonal antibody. *Dorland’s* at 1624.

D. Treatment in 2020 and 2021⁵

After the two steroid infusions, Ms. Justice returned to the OSU MS Center, complaining about, among other problems, a “new daily headache.” Exhibit 5 at 111 (Jan. 30, 2020). Within the last month, Ms. Justice also developed Lhermitte’s syndrome as a new problem. The medical professional who saw Ms. Justice, Kristi Epstein, an APRN-CNP, noted that although Ms. Justice had received two Rituxan infusions, she was developing new or worsened symptoms. Ms. Epstein recommended more steroid therapy, gabapentin for neuropathic pain, diclofenac for headaches, and repeat MRIs.

MRIs on Ms. Justice’s brain and spine showed no new lesions or enhancements. Exhibit 4 at 136-46. Dr. Fallis commented that this set of MRIs were “much better” than the ones from 2019. Exhibit 5 at 96 (May 14, 2020). During this period, Dr. Fallis maintained his opinion that Ms. Justice had ADEM

⁵ Events in 2020 and 2021 (until Ms. Justice saw Dr. Harrington) have relatively little relevance to determining whether Ms. Justice suffered from ADEM or multiple sclerosis. Thus, evidence from this time is summarized without many details. For additional details, *see* Pet’r’s Br. at 9-11 and Resp’t’s Br. at 12-15.

and NMO spectrum disorder. See Exhibit 5 at 47 (June 3, 2021). MRIs from December 2021 also did not detect any new areas of enhancement. Exhibit 9 at 214.

E. December 2021: Beginning Treatment with Dr. Harrington

At the OSU MS Center, Ms. Justice saw Dr. Emily Harrington for the first time on December 17, 2021. Exhibit 9 at 171. As part of the history, Dr. Harrington noted that Ms. Justice “[w]as initially [diagnosed] with MS” and the diagnosis was “changed to NMO given [longitudinally extensive transverse myelitis] T1-4 on spinal MRI.” Id. Dr. Harrington also stated that Ms. Justice had not had her serum tested for AQP4, had negative MOG testing, and had oligoclonal bands greater than 5.

Dr. Harrington personally reviewed the MRI images. In Dr. Harrington’s view, Ms. Justice’s “MRI appear[ed] consistent with NMOSD with longitudinally extensive spinal cord lesion however the several lesions in her brain MRI appear[ed] more MS-like.” Id. at 174. Dr. Harrington planned to “review her MRI with the neuroimmunology group at their next neuroradiology conference in January to get the opinion of the whole group as to her diagnosis.” Id. at 174. Dr. Harrington ordered additional testing and MRIs. In the meantime, Ms. Justice was continued on rituximab as “a good choice to cover both MS and NMO if the diagnosis is slightly unclear.” Id.

Serum assays for NMO/AQP4 were negative. Exhibit 9 at 168 (Dec. 17, 2021). On December 23, 2021, Dr. Harrington informed Ms. Justice that her NMO lab was negative, but that she thought they “should still treat as NMOSD,” and that “[e]ven if [they were] a little unsure[,] [r]ituximab work[ed] well for NMO and MS.” Id. at 165.

Apparently, medical professionals in a neuroimmunology conference reviewed Ms. Justice’s MRIs during January 2022. After this conference, On January 19, 2022, Dr. Harrington informed Ms. Justice that her “[t]he group actually felt [her] MRIs looked more like MS,” and that it was a good plan to continue with rituximab. Id.

F. 2022: Further Treatment

In May 2022, Ms. Justice wanted to cancel an upcoming visit with Dr. Harrington. In part of this message, Ms. Justice expressed her belief that the flu vaccine harmed her. Ms. Justice stated:

We all know this was all a result of a flu shot. I know nobody wants to advertise that, but as the one who is going through this, I'd like to address it. My symptoms started [three] days after receiving it and continued downhill ... I just want honesty from SOMEBODY who can say, ok the flu vaccine did this, so now this is what's happening, and this is what we have to do. It didn't suddenly cause MS, but I may now have MS-like symptoms.

Exhibit 10 at 73-74.

Dr. Harrington responded that she would be happy to discuss petitioner's questions at an upcoming visit and wrote:

I did review your imaging with our group and everyone felt the MRI looks like MS and not NMO. Your antibody test for NMO was also negative. This is important for treatment as there are other treatments for MS if we need to switch. Regarding the influenza vaccination this is something I think we should talk about in person.

Id. at 73.

In the ensuing June 3, 2022 visit, Ms. Justice reported that her chronic conditions had not changed. Dr. Harrington extensively discussed Ms. Justice's diagnosis. Dr. Harrington stated that Ms. Justice met "criteria for MS with her thoracic spinal cord lesion, several brain lesions[,] and OCB." Id. at 57. She further noted that she had reviewed Ms. Justice's 2019 MRIs and discussed them as a group with neuroradiology, and that Ms. Justice had "multifocal presentation [in November] 2019 with multiple enhancing lesions both in the brain and spine," and that "her initial presentation may have been triggered by influenza vaccine but her autoimmune condition based on what we know about [central nervous system ("CNS")] autoimmunity was already primed to occur and the vaccine may have

triggered the flare.” *Id.* at 57. Dr. Harrington also noted that Ms. Justice’s MRIs had been stable since November 2019, her “MRI would be atypical for NMO,” and she was AQP4 seronegative and “did not meet criteria for seronegative NMO with the location of her brain lesions.” *Id.* at 57-58. Dr. Harrington explained that “[i]n neuroradiology review we felt it was more consistent with MS although her spinal lesion is larger than usually seen in MS.” *Id.* at 58. The diagnoses at this visit included multiple sclerosis and demyelinating diseases.

A few days later, Ms. Justice complained about a brain fog. Exhibit 9 at 78 (June 7, 2022). Dr. Harrington referred her to a cognitive specialist. *Id.* at 77; see also Exhibit 10 at 49.

In October 2022, Dr. Harrington changed Ms. Justice’s schedule for treatment to a Ruxience infusion once every six months. Exhibit 9 at 33, 67. After Ms. Justice questioned the basis for the change, Dr. Harrington stated that Ms. Justice’s diagnosis had been changed from NMO to multiple sclerosis. *Id.* at 64-65.

G. 2023-24

Ms. Justice continued her treatment at OSU MS Center. However, these more recent records do not shed much, if any, light on the question of diagnosis.

III. Procedural History⁶

Represented by Attorney Leigh Finfer, Ms. Justice alleged that the flu vaccine caused her to suffer ADEM. Pet., filed Aug. 15, 2022, at preamble. With her petition, Ms. Justice presented medical records and her affidavit. Exhibits 1-8. The case was assigned to a different special master.

The Secretary reviewed the evidence Ms. Justice had filed and recommended against an award of compensation. Resp’t’s Rep., filed pursuant to Vaccine Rule 4 on Mar. 15, 2023. The Secretary contended that “the medical records fail to provide preponderant proof that [Ms. Justice’s] actual diagnosis is

⁶ Because the procedural history lacks any controversy, the events in the litigation are summarized only briefly.

ADEM.” Id. at 19. The Secretary also maintained that Ms. Justice had not established the elements required for a causation-in-fact claim. Id. at 19-21.

The parties supported their respective positions by filing reports from experts. Ms. Justice filed two reports from Dr. Hixson. Exhibits 12 (filed Oct. 12, 2023) and 31 (filed June 21, 2024).⁷ In these reports, Dr. Hixson opined that Ms. Justice suffered from ADEM, not multiple sclerosis. He also opined that the flu vaccine caused Ms. Justice’s ADEM.

In contrast, the Secretary obtained reports from two people. Dr. Jamieson primarily addressed the question of diagnosis, opining that multiple sclerosis and not ADEM was the appropriate diagnosis for Ms. Justice. Exhibit A (filed Apr. 3, 2024); Exhibit E (filed Jul. 30, 2024). Dr. He addressed the question of causation. Exhibit C (filed Apr. 3, 2024).⁸

While the parties were getting reports from experts, the case was transferred to the undersigned. Order, issued Feb. 7, 2024. After Ms. Justice determined that additional reports from experts were not necessary (Pet’r’s Status Rep., filed Aug. 22, 2024), the parties were directed to file briefs. Order, issued Jan. 27, 2025.

The parties advocated through briefs. Ms. Justice submitted her primary brief on March 10, 2025 and her reply on June 9, 2025. The Secretary filed his brief on May 9, 2025. The details of the arguments regarding diagnosis are presented below. With the submission of Ms. Justice’s reply, 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).

⁷ As a point of hopefully constructive criticism, Dr. Hixson might improve his reports by writing more. His first report, which discussed both diagnosis and causation, was approximately six single-spaced pages, not counting pages for references. By way of contrast, Dr. Jamieson’s report, which discussed only diagnosis, was 23 double-spaced pages.

⁸ The details of opinions regarding how a flu vaccine might cause ADEM are not presented in this decision.

IV. 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 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).

V. Analysis

Evidence regarding diagnosis can be categorized as coming from two different sources: the doctors who treated Ms. Justice and the doctors whom the parties retained in the litigation. Although these sources can be differentiated, the various opinions all are based upon common information – Ms. Justice’s signs and symptoms.

A. Treating Doctors

When Ms. Justice was first hospitalized for approximately two weeks in November 2019, the doctors performed many tests on her, including MRIs and spinal taps. As the doctors were trying to determine a diagnosis for her, the doctors considered ADEM and multiple sclerosis as possibilities. See Section II.B, above; see also Pet’r’s Br. at 18-19. Due to developments after the initial hospitalization, the doctors’ opinions about whether she suffered from multiple sclerosis expressed during the first hospitalization carry relatively little weight. In this regard, Ms. Justice’s argument that she was first diagnosed with multiple sclerosis in June 2022 (Pet’r’s Br. at 24) overlooks that multiple sclerosis was consistently considered among diagnostic possibilities.

Beyond the group of doctors who treated Ms. Justice during her initial hospitalization, Ms. Justice appears to rely most heavily upon the assessments by Dr. Fallis. See Pet'r's Br. at 19; Pet'r's Reply at 3. Although Ms. Justice may fairly point out that Dr. Fallis stated that Ms. Justice had ADEM at the time of admission, Dr. Fallis added that her underlying issue appeared to be NMOSD. Exhibit 5 at 140; see also Pet'r's Br. at 8. Two points diminish the value of Dr. Fallis's opinion. First, although Dr. Fallis was aware that testing for the NMO antibody was negative, he did not explain why NMOSD is an appropriate diagnosis. See Exhibit 5 at 141. Second, and more importantly, Ms. Justice is not claiming that the flu vaccine caused her to suffer NMOSD. So, Dr. Fallis's opinion that she suffered from NMOSD (Exhibit 5 at 75) does little to help Ms. Justice establish that she suffered from ADEM.

Contrastingly, the Secretary emphasizes Ms. Justice's most recent neurologist, Dr. Harrington. See Resp't's Br. at 31-34. Dr. Harrington's opinion that Ms. Justice suffered from multiple sclerosis is strengthened because Dr. Harrington consulted colleagues, who also reviewed MRI imaging. The delay between when the MRI images were obtained (November 2019) and when Dr. Harrington's colleagues reviewed them (January 2022) does not diminish the value of these opinions because the MRI images remain the same. Furthermore, although Ms. Justice argues that Dr. Harrington did not explain the basis for the diagnosis of multiple sclerosis (Pet'r's Reply at 4), Dr. Harrington wrote that Ms. Justice "meets criteria for MS with her thoracic spinal cord lesion, several brain lesions[,] and OCB." Exhibit 10 at 57 (June 3, 2022).

In sum, the evidence from the treating doctors weighs in favor of finding that multiple sclerosis is an appropriate diagnosis and ADEM is not.

B. Reports from Experts

In addition to the statements from treating doctors, the parties have put forward opinions from doctors retained in this litigation. These are Dr. Hixson and Dr. Jamieson.

Qualifications of Experts. Both Dr. Hixson and Dr. Jamieson are neurologists. Exhibit 13 (Dr. Hixson's curriculum vitae); Exhibit B (Dr. Jamieson's curriculum vitae). Thus, they have the basic training to diagnose either ADEM or multiple sclerosis. However, neither Dr. Hixson nor Dr. Jamieson appear to focus their work on demyelinating diseases. Rather, Dr. Hixson is more

an expert on epilepsy and Dr. Jamieson is more an expert on headaches and stroke. It appears that the qualifications do not weigh heavily for either doctor.

Initial Onset of Symptoms. The Secretary argues that adults with ADEM typically deteriorate rapidly. Resp't's Br. at 26. Ms. Justice appears not to dispute this statement. Indeed, the "A" in ADEM stands for "acute."

Ms. Justice's symptoms did not develop acutely. She consistently reported symptoms starting and sometimes resolving within the month before her hospitalization. See, e.g., Exhibit 3 at 29-30. Dr. Jamieson's opinion (Exhibit A at 13-14) that Ms. Justice's presentation is inconsistent with how ADEM presents is persuasive.

Encephalopathy. According to Dr. Jamieson, "Encephalopathy (alteration in consciousness or behavior unexplained by fever, systemic illness, or postictal symptoms" is "necessary for the diagnosis of ADEM." Exhibit A at 13, first quotation from Exhibit A-1 (Daniela Pohl et al., "Acute disseminated encephalomyelitis," 87 Neurology S38 (2016)) at S39. Dr. Jamieson further opined that "Ms. Justice also did not have encephalopathy with alteration in consciousness as is generally noted with ADEM." Exhibit A at 14. Dr. Hixson did not discuss either of Dr. Jamieson's points---(1) that encephalopathy is part of the diagnostic criteria for ADEM or (2) that Ms. Justice did not have encephalopathy.

Despite the lack of opinion from Dr. Hixson, Ms. Justice challenges how frequently encephalopathy appears in adult ADEM cases. As she points out, an article Dr. Jamieson cited states: "Contrary to the pediatric population, cases of postinfectious neurologic symptoms in adults are not always associated with encephalopathy but are sometimes termed ADEM nonetheless." Exhibit A-2 (Lahoud Touma and Alexandra Muccilli, "Diagnosis and Management of Central Nervous System Demyelinating Disorders," 40 Neurol Clin 113 (2022)) at 121, cited in Pet'r's Br. at 20. Similarly, another article states: "Encephalopathy, occurring in up to 74% of patients, is considered mandatory for definitive diagnosis." Exhibit 45 (Karussis and Petrou) at 216.

Taken together, this evidence tends to show that encephalopathy more often than not occurs in adult cases of ADEM. However, the lack of encephalopathy does not absolutely preclude a diagnosis of ADEM.

For Ms. Justice, little persuasive evidence shows that she suffered from an encephalopathy. The Secretary cites multiple evaluations from the hospitalization

in which Ms. Justice was not found to be displaying an alteration in consciousness or behavior. See Resp't's Br. at 27. Although Ms. Justice has cited one page (Exhibit 3 at 346) in which she showed sensory and communication deficits, a review of information contained here and on surrounding pages does not appear to support Ms. Justice's argument.

Ms. Justice also points out that after she complained about problems with concentrating, she was referred for cognitive testing. Pet'r's Br. at 21, citing Exhibit 10 at 49, 50. However, this referral occurred more than two years after the initial incident in November 2019. In addition, Ms. Justice has not cited that the results of any cognitive testing showed a decline in her abilities. And, again, it bears repeating that Dr. Hixson did not opine that she suffered an encephalopathy.

Accordingly, the lack of encephalopathy tends to undermine the assertion that Ms. Justice suffered from ADEM.

No New Clinical or MRI Findings. ADEM is a monophasic disease. Exhibit 45 (Karussis and Petrou) at 216. In contrast, multiple sclerosis is marked by dissemination in time. Thus, the appearance of new symptoms or new lesions can help differentiate ADEM from multiple sclerosis.

Here, after November 2019, Ms. Justice was on disease modifying therapies, primarily Rituximab. See Section II.D, above; see also Resp't's Br. at 27-28. The experts do not address how these medications modified her underlying disease.

Ms. Justice accurately notes that after 2019, her MRIs have remained stable. The Secretary and Dr. Jamieson agree. Resp't's Br. at 27; Exhibit A at 8.

CSF Analysis. "Lumbar puncture for CSF analysis in suspected ADEM is performed to obtain evidence of inflammation and differentiate ADEM from other disorders (such as multiple sclerosis)." Exhibit 18 (Waldman) at 7. It appears that doctors are interested in at least two results of studies on a person's cerebrospinal fluid.

First, with respect to the presence of white blood cells and protein, "CSF findings in ADEM are variable; while CSF can be normal, abnormalities are present in 50 to 80 percent of patients." Id. at 8. The white blood cell count can be less than 100 cells/ml. The protein is usually less than 70 mg/dL. Id.

When Ms. Justice's CSF was tested, she had 13 white blood cells and 32 protein mg/dL. Exhibit 3 at 194-97. The experts did not comment extensively on

these two results. Dr. Hixson wrote: “CSF findings in ADEM can be variable, but usually include a lymphocytic pleocytosis, as was found in Ms. Justice’s case.” Exhibit 12 at 5. Dr. Jamieson stated: Ms. Justice’s “CSF was consistent with the diagnosis of MS, showing a normal protein level, a mild elevation in white blood cells.” Exhibit A at 12.

The second aspect of the CSF analysis concerns the presence or absence of oligoclonal bands, which are often abbreviated “OCBs.” In UpToDate, Waldman said: “Oligoclonal bands (OCBs) have been reported in 6 to 65 percent of adult patients with ADEM.” Exhibit 18 at 8.⁹ Waldman, accordingly, questioned the utility of attempting to differentiate ADEM from multiple sclerosis through the presence or absence of oligoclonal bands. Exhibit 18 at 10.

Ms. Justice’s CSF showed more than five OCBs. Exhibit 3 at 190 (results returned on Nov. 15, 2019). According to the laboratory presenting the results, this finding is “supportive evidence of central nervous system inflammation, multiple sclerosis, or infection.” Id.

To a degree, the retained experts differed in their assessments of the presence of oligoclonal bands in Ms. Justice’s CSF. Relying upon the statistics from Waldman, Dr. Hixson opined that “the presence of OCBs cannot be used to definitively argue that Ms. Justice’s diagnosis was not consistent with ADEM.” Exhibit 31 at 4; accord Exhibit 12 at 5. Dr. Jamieson recognized that a “minority of patients with ADEM are noted to have positive OCBs in the CSF,” but maintained that “this biomarker is much more characteristic of MS than of ADEM, as noted by Ms. Justice’s treating neurologists.” Exhibit A at 15-16.

Overall. Dr. Jamieson’s opinion that Ms. Justice suffers from multiple sclerosis is more persuasive than Dr. Hixson’s opinion that Ms. Justice suffered from ADEM. The weight of the evidence, including the presentation at onset, the lack of encephalopathy, the presence of oligoclonal bands, aligns with Dr. Jamieson’s opinion. Although Dr. Hixson may be correct that none of these factors by itself is disqualifying, the collection of evidence says that the diagnosis of multiple sclerosis is more likely.

⁹ Because children suffer from ADEM more frequently than adults, there are more studies about OCBs in ADEM among pediatric patients. But, these studies on children seem to carry less relevance in Ms. Justice’s case because of her age.

C. Summary

Here, taken as a whole, the evidence weighs in favor of a finding that Ms. Justice suffered from multiple sclerosis not ADEM. Although Ms. Justice may legitimately point to statements from some treating doctors as well as the opinion from her expert that favor a diagnosis of ADEM, this evidence is less valuable than the evidence favoring a diagnosis of multiple sclerosis. See Stillwell v. Sec’y of Health & Hum. Servs., 118 Fed. Cl. 47, 60 (2014) (ruling that a special master was not arbitrary in finding that the petitioner did not suffer from ADEM).

VI. Consequence of Finding regarding Diagnosis

Dr. Hixson proposes that a flu vaccine can cause ADEM via molecular mimicry. Exhibit 12 at 5. Likewise, after Dr. Jamieson disagreed about the diagnosis, Dr. Hixson defended his diagnosis. But, Dr. Hixson did not present an alternative theory that the flu vaccine can cause multiple sclerosis. See Exhibit 31. With this evidentiary basis, Ms. Justice argued that “Petitioner has presented a medical theory causally connecting Petitioner’s ADEM to the influenza vaccination.” Pet’r’s Br. at 25.

In this situation, there is no basis to evaluate a hypothetical construct that the flu vaccine caused Ms. Justice’s multiple sclerosis. “In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached.” Lombardi v. Sec’y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

VII. Conclusion

In terms of Ms. Justice’s life, whether her neurologic problems should be categorized as acute disseminated encephalomyelitis or multiple sclerosis may have little effect. Regardless of the name, she suffers the same and for her suffering, she deserves sympathy. But, in terms of her claim in the Vaccine Program, the appropriate diagnosis does matter. Here, the evidence preponderates in favor of finding that she suffers from multiple sclerosis. This finding effectively ends her case because Ms. Justice has not presented any persuasive evidence that a flu vaccine can cause multiple sclerosis. Thus, she 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