

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

ASHRAF MOSTAFA, *

Petitioner, *

v. *

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

Respondent. *

No. 16-1558V
Special Master Christian J. Moran

Filed: March 15, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner;
James V. Lopez, United States Dep’t of Justice, Washington, D.C., for
Respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Ashraf Mostafa, a medical doctor, alleges that an influenza (“flu”) vaccine caused him to suffer a neurologic disorder, acute disseminated encephalomyelitis (“ADEM”). He retained two doctors to assist him, Dr. Souayah and Dr. Chen. The Secretary opposes Dr. Mostafa’s claim. The Secretary retained Dr. Sriram.

The three experts disagree about the diagnosis. Dr. Souayah and Dr. Chen propose that Dr. Mostafa suffered from ADEM. In contrast, Dr. Sriram proposes that Dr. Mostafa suffers from a different neurologic disorder, multiple sclerosis.

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.

Resolving the dispute over diagnosis determines the outcome because Dr. Souayah and Dr. Chen have declined to opine that the flu vaccine causes multiple sclerosis.

With respect to diagnosis, the evidence convincingly favors multiple sclerosis. The parties' briefs make the conclusion that Dr. Mostafa suffers from multiple sclerosis abundantly clear. The Secretary offered several arguments in favor of multiple sclerosis and Dr. Mostafa did not rebut any. The finding that Dr. Mostafa suffers from multiple sclerosis means that he cannot receive compensation.

I. Dr. Mostafa's Medical History²

Dr. Mostafa was born in 1962. At relevant times, Dr. Mostafa worked as an internal medicine physician. Exhibit 2 at 1, Exhibit 6 at 1. He was married to Rasha Morad, who is also a physician. It appears that Dr. Mostafa received his primary medical care from his wife.

Dr. Mostafa received a flu vaccine on November 22, 2013. Exhibit 1 at 1. He alleges this flu vaccine caused him to suffer acute disseminated encephalomyelitis.

Dr. Mostafa sought care from the Johns Hopkins emergency department on December 25, 2013. Exhibit 2 at 1-3. Dr. Mostafa reported that he had experienced "several days of abnormal sensations that started in his feet and spread upward towards his chest." *Id.* A neurologist who saw Dr. Mostafa in the emergency room recommended a follow-up appointment with a neurologist and a trial of gabapentin. *Id.*

The next day, Dr. Mostafa saw Dr. Morad and complained about a worsening numbness, paresthesia, weakness, and urinary retention. Exhibit 7 at 11. Dr. Morad also prescribed gabapentin and she ordered an MRI.

December 28, 2013 MRIs

Dr. Mostafa underwent a series of MRIs on December 28, 2013. Exhibit 18 at 5-6, 14-15. The MRI of Dr. Mostafa's lumbar spine showed "minimal

² More details can be found in the parties' memoranda. *See* Pet'r's Br. at 2-11; Resp't's Br. at 2-11. Given that the diagnosis of multiple sclerosis turns on the results of MRIs, this decision presents those results in more detail. Other medical records have much less influence on determining whether Dr. Mostafa suffers from multiple sclerosis. Therefore, those medical records are not described in detail, if at all.

degenerative changes.” *Id.* at 7. The MRI of Dr. Mostafa’s brain showed “multiple areas of white matter signal bilaterally in the periventricular and supraventricular regions.” *Id.* at 5-6. The radiologist who interpreted the MRI, Nicholas Georges, stated that “the MRI appearance [was] nonspecific, but given the overall appearance and age of the patient [he was] most worried about a demyelinating process such as multiple sclerosis.” *Id.*

The MRI of Dr. Mostafa’s cervical spine revealed a “patchy area of abnormal T2 signal in the upper cervical cord,” which spanned a “craniocaudal dimension of about 2.3 cm beginning at the inferior C2 level and extending to the C3-4 disc space.” *Id.* at 14-15. Dr. Georges stated that “given the MRI brain findings, it is possible that this represents an additional area of white matter signal related to multiple sclerosis.” *Id.*

Due to problems walking, Dr. Mostafa sought care from the emergency room of Good Samaritan Hospital on December 29, 2013. Exhibit 8 at 1-4. A neurologist, Robert Taylor, stated that multiple sclerosis was within the diagnostic differential. Dr. Taylor transferred Dr. Mostafa’s care to the University of Maryland Medical System. *Id.*; see also Exhibit 11 at 3.

Dr. Mostafa remained hospitalized at the University of Maryland Medical System from December 29, 2013 to January 3, 2014. Exhibit 11 at 7. During this time, Dr. Mostafa underwent additional tests.

December 31, 2013 MRIs

Dr. Mostafa underwent MRIs of his brain and cervical spine on December 31, 2013. Exhibit 19 at 1-3. Unlike the previous set, this set of MRIs was conducted with and without contrast. The brain MRI showed, among other things, a lesion in the left periventricular white matter measuring 2 mm in diameter. *Id.* The cervical MRI showed “abnormal contrast enhancement identified along the dorsal aspect of the cord.” The interpreting radiologist wrote that the “changes within the periventricular white matter [were] suggested of demyelinating disease, possibly multiple sclerosis.” *Id.* at 2.

A neurologist, James Russell, evaluated Dr. Mostafa on January 1, 2014. Based in part on the findings from the MRIs, Dr. Russell opined Dr. Mostafa’s diagnosis was “probable MS.” Exhibit 11 at 31.

Dr. Mostafa was discharged on January 3, 2014. *Id.* at 9. Dr. Russell added a clarification to the discharge summary. He wrote: “upon further review of imaging, it is probable that the patient has multiple sclerosis based on the multiple

non-enhancing brain lesions, which appear to indicate lesions of different ages.” Id. at 10.

After discharge from the hospital, Dr. Mostafa saw his primary care doctor (and wife), Dr. Morad. Her impression was “post vaccine encephalomyelitis with significant ADL [activities of daily living] impairment.” Exhibit 7 at 12. She recommended that Dr. Mostafa follow-up with a neurologist.

The neurologist whom Dr. Mostafa saw was Walter Royal, who had seen Dr. Mostafa at the University of Maryland hospital. Dr. Mostafa’s follow up appointment was on January 14, 2014. Dr. Royal detected some sensory deficits as well as other problems. Exhibit 11 at 1-3. Dr. Royal wrote that Dr. Mostafa’s “history of acute disseminated demyelination of the brain and spinal cord [was] consistent with either post-vaccinal encephalomyelitis (the long delay between the time of the flu vaccine and when the patient developed symptoms is not consistent with this diagnosis) or multiple sclerosis.” Id. Dr. Royal recommended repeating the MRIs.

April 5, 2014 MRIs

The next series of MRIs took place on April 5, 2014. Exhibit 18 at 4, 12-13. The brain MRI showed stable white matter lesions with no abnormal enhancement. Id. at 4. The cervical MRI showed that the C2-3 lesion had increased in size and had no abnormal enhancement. Id. at 12-13. But, the interpreting radiologist, Kathleen Standiford, identified an “additional small lesion [on the] left aspect of the cord at C4 and possibly [a] lesion along the right aspect of the cord at C5-6 level.” Id.

Dr. Mostafa appears not to have continued treatment with any neurologist, such as Dr. Russell or Dr. Royal. Instead, he had appointments with Dr. Morad. On May 23, 2014, Dr. Morad stated that Dr. Mostafa was taking gabapentin and Tecfidera. Exhibit 7 at 14. Tecfidera is a drug for treating multiple sclerosis. Exhibit A at 9; O.M.V. v. Sec’y of Health & Hum. Servs., 157 Fed. Cl. 376, 381 n.3 (2021).

In the next appointment with Dr. Morad, she recommended that Dr. Mostafa continued to take gabapentin and Tecfidera. Exhibit 7 at 15 (August 19, 2014). Her impression from this visit was “post vaccine encephalomyelitis/neuropathic symptoms, recurring” and she described the flu vaccine as “contraindicated.” Id.

Charles Haile, an infectious disease doctor, handwrote an “Excuse Slip,” stating that Dr. Mostafa “is by no means to receive the influenza vaccine due to

previous severe neurologic events occurring shortly after previous vaccine.” Exhibit 5 at 1. Other than this “Excuse Slip,” there are no other records from Dr. Haile. See Resp’t’s Br. at 8-9.

Two more appointments took place with Dr. Morad on November 27, 2014 and February 20, 2015. Exhibit 7 at 16-17. Information from these visits does not contribute to determining whether Dr. Mostafa suffered from multiple sclerosis.

April 11, 2015 MRIs

Dr. Mostafa underwent another series of MRIs on April 11, 2015. Exhibit 18 at 2-3, 10-11. When compared to the previous MRI on April 5, 2014, the brain MRI showed no changes. Id. at 2-3. The radiologist, Robert Van Besien, stated: “The distribution and pattern [of lesions] is suggestive of demyelination and in particular multiple sclerosis. Other demyelinating processes or inflammatory processes felt to be less likely.” Id. The cervical MRI also showed no significant changes. Dr. Van Besien stated the cervical lesions “must be considered suspicious for foci of demyelination and in particular multiple sclerosis.” Id. at 10-11.

Dr. Mostafa continued to see Dr. Morad in 2015, 2016, and 2017. Exhibit 7 at 18-23. During this time, Dr. Mostafa underwent another set of MRIs.

May 28, 2016 MRIs

The cervical MRI showed no new lesions in the spinal cord. Exhibit 18 at 8-9. For the brain MRI, interpretations differed. The interpreting radiologist did not appreciate any significant changes. Exhibit 18 at 1. However, Dr. Sriram, who reviewed the MRI images, identified a new lesion in the “right posterior temporal lobe.” Exhibit F at 4.

Dr. Morad continued to treat Dr. Mostafa with appointments on July 5, 2016; November 15, 2016; and February 21, 2017. Exhibit 7 at 22-24.³ These records also tend not to inform whether Dr. Mostafa suffered from multiple sclerosis.

³ For the February 21, 2017 treatment, Dr. Mostafa filed documents that contain different information. Compare Exhibit 7 at 24 with Exhibit 42 at 3. Because of the inconsistencies, the Secretary questioned whether “Dr. Morad’s treatment records for petitioner were generated contemporaneous and based on information obtained during in-person consultations and evaluations.” Resp’t’s Br. at 10 n.3.

As part of this litigation, Dr. Mostafa averred that he continues to “suffer from post vaccine encephalomyelitis, neuropathy (post vaccine), MS and ADEM.” Exhibit 6 at 1-2 (filed April 7, 2017). About one year later, Dr. Mostafa attested that he “sustained [a] demyelinating disorder.” Exhibit 22 (signed March 24, 2018). This March 24, 2018 affidavit does not identify Dr. Mostafa’s injury as multiple sclerosis.

Dr. Morad wrote a letter addressed to the attorney representing Dr. Mostafa on August 30, 2018. She stated that Dr. Mostafa “suffered ADEM as a result of his exposure to the flu vaccine.” Exhibit 25 at 1-2.

To evaluate whether Dr. Mostafa had multiple sclerosis or ADEM, Dr. Morad referred Dr. Mostafa to a neurologist at Hartford Neurology Associates, Syed Shaukat, on January 11, 2019. Exhibit 29. Dr. Shaukat opined that Dr. Mostafa had “a postinfectious/possible flu shot [ADEM] in 2013.” *Id.* Dr. Shaukat also stated that Dr. Mostafa could not be diagnosed with multiple sclerosis because subsequent MRIs did not show new lesions. *Id.*

Additional medical records were not discussed. *See* Pet’r’s Br. at 12, Resp’t’s Br. at 11.

II. Procedural History

Represented by attorneys from Muller Brazil, Dr. Mostafa started this case by alleging that a flu vaccine caused him to suffer multiple sclerosis and ADEM. Pet., filed Nov. 21, 2016, at Preamble. Over the next ten months, Dr. Mostafa submitted various medical records and other evidence.

The Secretary reviewed this material and recommended against compensation. Resp’t’s Rep., filed Sep. 18, 2017. The Secretary argued that most treating doctors did not associate Dr. Mostafa’s neurologic conditions with the flu vaccine. The only exceptions were Dr. Morad, who is his wife, and Dr. Haile, who did not produce any treatment records. *Id.* at 10.

To facilitate the presentation of opinions from experts, the undersigned proposed a set of instructions. When the parties did not object, they became final. Orders, issued Oct. 11, 2017 and Nov. 8, 2017.

After seeking and receiving four enlargements of time, Dr. Mostafa filed the report from Dr. Souayah on March 27, 2018. Exhibit 23. Dr. Souayah opined that Dr. Mostafa suffered from acute disseminated encephalomyelitis. *Id.* at 8-9, 14.

He further opined that the flu vaccine caused the ADEM. Id. at 10-21. This report did not present an opinion regarding timing.

The Secretary responded by submitting a report from Dr. Sriram on July 16, 2018. Exhibit A. Dr. Sriram maintained that Dr. Mostafa did not suffer from ADEM. Dr. Sriram opined that the appropriate diagnosis was multiple sclerosis. Id. at 4-5, 8. Dr. Sriram also opined that the presence of black holes in the December 29, 2013 MRI meant that Dr. Mostafa had lesions before he received the flu vaccine. Id. at 5-7.

To discuss the opinions of Dr. Souayah and Dr. Sriram, a status conference was held on July 27, 2018. The parties discussed the difference regarding diagnosis. The undersigned also noted that Dr. Souayah has not proposed that the flu vaccine can cause multiple sclerosis. Order, issued July 27, 2018. Also, Dr. Sriram did not address whether the flu vaccine can cause acute disseminated encephalomyelitis. The undersigned directed Dr. Mostafa to obtain the original MRI images. Id.

To address diagnosis, Dr. Mostafa submitted a letter from Dr. Morad on September 5, 2018. Exhibit 25. Dr. Morad did not disclose that she was married to Dr. Mostafa. In a November 28, 2018 status conference, Dr. Mostafa's attorney, Ms. Senerth, stated that she believed that Dr. Morad was not Dr. Mostafa's wife. Dr. Mostafa was directed to clarify this relationship. Order, issued Nov. 29, 2018. Dr. Mostafa disclosed that he is legally married to Dr. Morad. However, Dr. Morad and Dr. Mostafa were separated. Pet'r's Status Rep., filed Dec. 28, 2018.

Dr. Souayah addressed some of Dr. Sriram's points in a report filed on November 24, 2018. Exhibit 26. However, the report contained errors in formatting. The report also did not address Dr. Sriram's contention that some of the lesions on the original MRIs from December 2013 probably pre-dated the vaccination. Dr. Souayah also did not opine that the flu vaccine could cause multiple sclerosis. See Exhibit 26. A corrected version of this report was filed on July 23, 2019 as Exhibit 30.

Dr. Sriram maintained his opinion that the correct diagnosis was multiple sclerosis, not acute disseminated encephalomyelitis. Exhibit C, filed Dec. 21, 2018. Dr. Sriram produced images from the MRIs of Dr. Mostafa's brain, showing lesions.

For reasons that are not explained, Dr. Mostafa switched experts. Although he had previously presented reports from Dr. Souayah, Dr. Mostafa submitted a

report from Dr. Chen on January 28, 2019. Exhibit 27. Some parts of Dr. Chen's opinion were either unclear or missing. Thus, Dr. Mostafa was directed to have Dr. Chen clarify her opinions. Order, issued Feb. 1, 2019. Dr. Chen's revised report was filed as Exhibit 28 on May 6, 2019. Dr. Chen stated that: "Dr. Mostafa's symptoms were consistent with acute disseminated encephalomyelitis (ADEM) and not multiple sclerosis (MS)." Id. at 3. She also wrote approximately one paragraph about how a vaccine could trigger ADEM. Id. at 5-6.

Dr. Sriram responded to Dr. Chen's report. Exhibit E, filed July 9, 2019. About half this report was devoted to explaining how lesions develop and why the lesions evident on the December 28, 2013 MRI must have existed before the November 22, 2013 vaccination. Id. at 1-6. The remainder of the report continued the dispute over diagnosis. Id. at 6-8.

It appeared that this report from Dr. Sriram completed the phase in which experts disclosed their opinions and the bases for those opinions. Thus, the parties were directed to advocate for their positions through briefs. Order, issued Jan. 9, 2020.

In a status conference held to discuss the briefing order, the parties discussed the significance of the MRIs. The parties were directed to submit reports from their retained doctors focused on the MRIs. Order, issued Jan. 21, 2020.

Both Dr. Sriram and Dr. Chen submitted charts about the various MRIs. Exhibit F, filed Mar. 23, 2020; Exhibit 35 (Dr. Chen's chart concerning brain MRIs), filed June 22, 2020; Exhibit 38 (Dr. Chen's chart concerning cervical MRIs), also filed June 22, 2020. These charts were helpful in identifying areas of dispute between Dr. Sriram and Dr. Chen.

With the submission of those summary charts, the parties were again instructed to file briefs. Order, issued July 8, 2020. This July 8, 2020 order also memorialized a request from the Secretary that Dr. Mostafa submit statements about benefits from his insurance company.

Dr. Mostafa filed his first brief on September 22, 2020. As discussed in an October 16, 2020 status conference, this brief did not adequately address the fundamental question regarding diagnosis and Dr. Mostafa was given an opportunity to revise his brief. Order, issued Oct. 16, 2020. In addition, Dr. Mostafa was ordered to obtain his insurance benefits statements. Id.

The process of revising the brief did not take much time. Dr. Mostafa submitted a revised brief on January 17, 2021. (All citations to “Pet’r’s Br.” refer to the January 17, 2021 version.)

On the other hand, the process for attempting to gather statements from insurance companies took a significant amount of time. Some of this process was due to miscommunications between Dr. Mostafa and Ms. Senerth, a lack of persistent follow up by Ms. Senerth, and a lack of responsiveness from various insurance companies. After roughly 18 months, Dr. Mostafa filed various documents, which satisfied the Secretary. See Resp’t’s Status Rep., filed Aug. 8, 2022.

After the Secretary determined that additional evidence was not forthcoming, the Secretary advocated for his position, focusing on diagnosis. Resp’t’s Br., filed Dec. 9, 2022. Dr. Mostafa did not file a reply, making the case ready for adjudication.⁴

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.

⁴ The lack of reply left many of the Secretary’s arguments unanswered. Whether any evidence could rebut what the Secretary claimed is not readily apparent. However, it is very clear that the Secretary’s advocacy regarding diagnosis was more thorough and more persuasive than the advocacy by Dr. Mostafa.

Cir. 1993) (disagreeing with dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

In Broekelschen v. Sec’y of Health and Hum. 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.”

IV. Qualifications

Dr. Souayah, Dr. Chen, and Dr. Sriram have interpreted Dr. Mostafa’s medical records. A foundation for their interpretations is the doctor’s qualifications. Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec’y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff’d without op., 730 Fed. App’x 938 (Fed. Cir. 2018); Copenhaver v. Sec’y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

Dr. Mostafa’s expert Dr. Souayah has opined that vaccines have caused various conditions, and, therefore, special masters have summarized his qualifications. See Schussler v. Sec’y of Health & Hum. Servs., No. 16-901V, 2023 WL 4926908, at *12 (Fed. Cl. Spec. Mstr. June 30, 2023); Salmins v. Sec’y of Health & Hum. Servs., No. 11-140V, 2014 WL 1569478, at *10 (Fed. Cl. Spec. Mstr. Mar. 31, 2014).

In brief, Dr. Souayah was appointed a professor in the neurology department of Rutgers University in 2018. Exhibit 31 (curriculum vitae). He received board-certification from three American organizations: neurology and psychiatry in 2003, electrodiagnostic medicine in 2004, and neuromuscular medicine in 2008. Id. at 4. He has written more than 60 articles, which peer-reviewed journals have published. Of this group, one concerned multiple sclerosis. Id. at 22 (item 28). Dr. Souayah has also contributed to two abstracts about multiple sclerosis. Id. at 26 (item 17), 32 (item 92). In the five years before Dr. Souayah wrote his first report, he had treated approximately 60 patients with multiple sclerosis. Exhibit 23 at 1.

Dr. Mostafa’s second expert is Dr. Chen, who has testified in the Vaccine Program less frequently. Since July 2013, Dr. Chen has been an assistant professor of neurology at the University of Pennsylvania. Exhibit 32 (curriculum vitae) at 1. Her relatively short list of publications does not include any about multiple

sclerosis. At the time of her second report (dated April 23, 2019), she had “over 100 outpatients with multiple sclerosis and other demyelinating disorders under [her] care.” Exhibit 28 at 1.

Dr. Sriram has been retained by the Secretary relatively frequently and special masters have set forth his qualifications. See Dunn v. Sec’y of Health & Hum. Servs., No. 16-1506V, 2020 WL 1243237, at *8 (Fed. Cl. Feb. 19, 2020); Morgan v. Sec’y of Health & Hum. Servs., No. 15-1137V, 2019 WL 7498665, at *10 (Fed. Cl. Dec. 4, 2019), mot. for rev. denied, 148 Fed. Cl. 454 (2020), aff’d, 850 F. App’x 775 (Fed. Cir. 2021).

Dr. Sriram was appointed professor of experimental neurology, pathology, microbiology, and immunology at Vanderbilt University in May 1993. Exhibit G (curriculum vitae) at 2. He has directed the multiple sclerosis clinic at Vanderbilt University since 1993. Id. at 5. In the clinic, he sees approximately 1,200 patients yearly in an outpatient setting and about 250 patients in the inpatient setting. Exhibit A at 1. He has authored numerous articles about multiple sclerosis that peer-reviewed journals have published. Exhibit G at 9-22.

On the question of whether a person suffers from multiple sclerosis, Dr. Sriram has superior qualifications.⁵ Dr. Sriram treats people with multiple sclerosis as part of his usual, day-to-day responsibilities. This experience strengthens the reliability of his opinions.

V. Criteria for Diagnosing Multiple Sclerosis

Dr. Sriram rests his opinion that Dr. Mostafa suffers from multiple sclerosis upon the 2017 McDonald criteria. Exhibit A at 4. Dr. Chen also referenced the 2017 McDonald criteria. Exhibit 28 at 3-4. Thus, there is little dispute about the usefulness of the 2017 McDonald criteria. See OMV v. Sec’y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *42 (Fed. Cl. Spec. Mstr. June 16, 2021), mot. for rev. denied, 157 Fed. Cl. 376 (2021).

Nevertheless, Dr. Chen quibbles with some aspects of the 2017 McDonald criteria. She contended that the authors recommended caution when diagnosing people “outside the typical age of presentation (20-50 years of age).” Exhibit 28 at 4. The authors did recommend that doctors use care in diagnosing older people because older people may have alternative diagnoses and comorbidities. But,

⁵ Although the Secretary advanced an argument about the experts’ qualifications (see Resp’t’s Br. at 13-14), Dr. Mostafa did not reply.

ultimately, the authors “agreed that the 2010 McDonald criteria are likely to be applicable in older patients, but recommended further studies to validate the 2017 McDonald criteria in this population.” Thompson⁶ at 165. Dr. Chen’s point of distinction is relatively weak and Dr. Mostafa does not advance it. See Pet’r’s Br. at 13-14. In any event, Dr. Mostafa developed neurologic symptoms when he was 51 years old in December 2013. Thus, the 2017 McDonald criteria remain useful. See Resp’t’s Br. at 18.

The 2017 McDonald criteria require different support, depending upon the number of clinical events and the number of lesions. Thompson at 167. At the relevant time, Dr. Mostafa suffered one clinical event and his MRIs showed more than two lesions. Thus, the additional data to complete the diagnosis of multiple sclerosis is a showing of “Dissemination in time demonstrated by an additional clinical attack or by MRI or demonstration of CSF-specific oligoclonal bands.” Id.⁷ The 2017 McDonald criteria further explain “dissemination in time.” The authors wrote: “Dissemination in time can be demonstrated by the simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up MRI, with reference to a baseline scan, irrespective of the timing of the baseline MRI.” Id. at 168.

Dr. Chen qualifies some aspects of the 2017 McDonald criteria, concerning which lesions are eligible to satisfy the dissemination-in-time requirement. Exhibit 28 at 4. In her view, the qualifying lesions are only those lesions that are at least 3 millimeters and only those lesions found in the brain, not spinal cord. Id., see also Pet’r’s Br. at 14 (advancing these two arguments). The basis for the latter point is a 2016 article by a European group. Filippi.⁸

⁶ Alan J. Thompson et al., Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria, 17 LANCET NEUROL. 162 (2018); filed as Exhibit E-2.

⁷ Dr. Chen does not dispute that Dr. Mostafa’s lesions were disseminated in space. See Exhibit 28; see also Pet’r’s Br. at 13-14; Resp’t’s Br. at 15-16 (citing MRIs showing lesions appeared in different locations).

⁸ Massimo Filippi et al., Magnetic Resonance Techniques for the In Vivo Assessment of Multiple Sclerosis Pathology: Consensus Report of the White Matter Study Group, 21 J. MAGNETIC RESONANCE IMAGING 669 (2005); filed as Exhibit 39.

VI. Analysis

The evidence regarding diagnosis can be divided into two types. First, the parties have offered opinions from experts they have retained. Second, the parties also refer to statements regarding diagnosis from doctors who treated Dr. Mostafa. While in some ways these types of evidence are distinct, they also overlap in the sense that the diagnosis ultimately depends upon Dr. Mostafa's symptoms, signs, and imaging.

A. Opinions from Retained Experts

To start, it is important to repeat that among the group of three neurologists who were retained in this litigation, Dr. Sriram's qualifications on the topic of multiple sclerosis are the strongest. It also happens to be the case, as explained below, that Dr. Sriram's opinions most closely align with the diagnostic criteria and evidence about Dr. Mostafa.

On some topics, Dr. Sriram's opinion matches the opinions from Dr. Souayah and Dr. Chen. For example, the experts agree that Dr. Mostafa clinical presentation in December 2013, when he reported abnormal ascending tingling, were consistent with a demyelinating event. The experts further agree that MRI imaging revealed lesions disseminated in space. The experts, however, part company as to whether the lesions showed dissemination in time.

Based largely on the opinions of Dr. Sriram, the Secretary presented comprehensive and persuasive arguments that Dr. Mostafa's lesions were disseminated in time. Resp't's Br. at 16-20. The Secretary demonstrates dissemination in time in two respects.

First, the December 31, 2013 brain and cervical MRIs arguably show dissemination in time by themselves. These MRIs revealed lesions that enhanced with contrast (meaning that the lesions were relatively new) and lesions that did not enhance with contrast (meaning the lesions were relatively old). Exhibit 19 at 1 (brain MRI) and at 2 (cervical MRI).

Dr. Chen has some legitimate disagreement. One of the potentially relevant enhancing lesions from the brain MRI measured only 2 mm, which is below the cut off in the 2017 McDonald criteria. Exhibit 28 at 4. Dr. Sriram did not address this point in his ensuing report. See Exhibit E. The Secretary argues that Dr. Sriram did not concede that relevant lesions must be 3 mm or greater. Resp't's Br. at 17. But, the lack of concession from Dr. Sriram does not alter the 2017 revised McDonald criteria. If the Secretary and/or Dr. Sriram wants to say that the 2017

revised McDonald criteria should not be followed in some respect, then the Secretary and/or Dr. Sriram should explain this position.

Dr. Chen also states that a lesion from the December 31, 2013 cervical MRI cannot be used to establish dissemination in time. See Exhibit 28 at 4. The basis for this statement is a 2016 report from a European group. Although Dr. Chen criticized a reliance on a cervical lesion in her April 23, 2019 report, she did not repeat this criticism in her summary chart. See Exhibit 38.

This problem presents the inverse of the situation regarding the 3 mm requirement. The 2017 revised McDonald criteria does allow a cervical lesion to fulfill the requirement of dissemination in time. See Exhibit E-2. Dr. Chen has not explained why the 2016 European report is better than the 2017 revised McDonald criteria. In the absence of any justification from Dr. Chen, the more recently promulgated 2017 revised McDonald criteria is appropriate to use. See Resp't's Br. at 18 (advancing the 2017 McDonald criteria as opposed to the older European criteria). Under the 2017 revised McDonald criteria, a cervical lesion can fulfill the dissemination in time requirement.

The second way the Secretary attempts to demonstrate dissemination in time is through the series of MRIs. Again, within this argument, the Secretary focuses on two MRIs---the cervical MRI on April 5, 2014 and the brain MRI on May 28, 2016. Resp't's Br. at 18-19.

For the April 5, 2014 MRI, the interpreting radiologist, Dr. Standiford, identified an "additional" lesion and "possibl[e] lesion." Exhibit 18 at 12-13. Dr. Sriram reviewed the MRI images independently and agrees with this interpretation. Exhibit F at pdf 6. Dr. Souayah also stated that the April 5, 2014 MRI showed an "additional small lesion." Exhibit 23 at 4.

Dr. Chen's disagreement relies upon a comment from Dr. Standiford that the lesions are "stable." Exhibit 38 at 2, quoting Exhibit 18 at 12-13. However, as the Secretary argues, "stable" is not synonymous with "old" or "pre-existing." See Resp't's Br. at 19. Thus, a preponderance of the evidence, consisting of the opinions from Dr. Standiford, Dr. Sriram, and Dr. Souayah, supports a finding that the April 5, 2014 cervical lesion showed a new lesion. This finding is a second and alternate reason for finding that Dr. Mostafa's lesions were disseminated in time.

The analysis of the May 28, 2016 brain MRI is less clear. The foundation is the report from the radiologist who interpreted this MRI and compared it to

previous MRIs, Dr. Standiford. She wrote: “White matter lesions are stable in size and number compared with the prior study.” Exhibit 18 at 1.

Compared with Dr. Standiford, Dr. Sriram interpreted the May 28, 2016 brain MRI differently. In his opinion, a new T2 lesion had developed in the right posterior temporal lobe. Exhibit E at 5-6.

Dr. Chen opined that this allegedly new T2 lesion Dr. Sriram identified was actually old because the lesion was present on the December 31, 2013 brain MRI. Exhibit 35 at 5-8. Dr. Chen further questioned Dr. Sriram’s use of MRI images, stated that Dr. Sriram was not comparing same sections of the brain. Id.

Resolving this dispute is not required. As explained above, a preponderance of the evidence supports a finding that Dr. Mostafa’s lesions were disseminated in time. The December 31, 2013 cervical MRI shows both old and new lesions. In addition, the April 5, 2014 MRI shows an additional lesion. Whether Dr. Sriram accurately identified a new T2 lesion on the May 28, 2016 brain MRI is beside the point. The other explanations justify finding that Dr. Mostafa’s lesions were disseminated in time. Accordingly, Dr. Sriram’s opinion that Dr. Mostafa suffers from multiple sclerosis is persuasive.

B. Opinions from Treating Doctors

The opinions of treating doctors can be quite probative. Cappizano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See McCulloch v. Sec’y of Health & Hum. Servs., No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec’y of Health & Hum. Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26, 2016).

The views of treating physicians should also be weighed against other, contrary evidence present in the record—including conflicting opinions among such individuals. Hibbard v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 742, 749 (2011) (finding that it is not arbitrary or capricious for special masters to weigh competing treating physicians’ conclusions against each other), aff’d, 698 F.3d 1355 (Fed. Cir. 2012); Veryzer v. Sec’y of Health & Hum. Servs., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), mot. for

rev. denied, 100 Fed. Cl. 344, 356-57 (2011), aff'd without op., 475 Fed. App'x 765 (Fed. Cir. 2012).

The Secretary devoted a section of his brief to discussing the diagnoses provided by various doctors who treated Dr. Mostafa. Resp't's Br. at 24-30.⁹ In contrast, Dr. Mostafa refers to the doctors who treated him in a single sentence. Pet'r's Br. at 22. A reply from Dr. Mostafa might have supported his position.

The following doctors offer useful opinions as to whether Dr. Mostafa suffered from multiple sclerosis:

| Date | Name & Specialty | Opinion | Cite (Exhibit and Page) |
|------------|------------------------------------|---|-------------------------|
| 12/13/2013 | Dr. Prashant Raghavan, radiologist | White matter changes were "suggestive of demyelinating disease, possibly multiple sclerosis." | 19 at 3 |
| 12/28/2013 | Dr. Nicholas Georges, radiologist | "it is possible this [referring to lesions on the cervical MRI] represents an additional area . . . related to multiple sclerosis." | 18 at 4 |
| 1/1/2014 | Dr. James Russell, neurologist | "probable MS." | 11 at 31 |
| 1/10/2014 | Dr. Russell | In an addendum to the discharge report: "upon further review of imaging, it is probable that the patient has multiple sclerosis based on the multiple non-enhancing brain lesions, which appear to indicate lesions of different ages." | 11 at 10 |

⁹ Here, the Secretary provided information about the treating doctor's professional background by citing various websites. The better practice would be for the Secretary to print copies of websites and submit them into evidence. See Vaccine Rule 8(b)(2) (stating "The parties may present evidence in the form of documents, affidavits, or oral testimony").

| | | | |
|-----------|---------------------------------------|--|---------|
| 1/14/2014 | Dr. Walter Royal, neurologist | “either post-vaccinal encephalomyelitis . . . or multiple sclerosis” | 11 at 3 |
| 4/11/2015 | Dr. Robert Van Besien, radiologist | “The distribution and pattern [of lesions] is suggestive of demyelination and in particular multiple sclerosis.” | 18 at 3 |
| 4/30/2018 | Rasha Morad, unknown | “Dr. Ashraf Mostaf suffered ADEM as a result of his exposure to the flu vaccine.” | 25 at 2 |
| 1/11/2019 | Dr. Syed Shaukat, neurologist | “I currently feel that the patient had a post infectious/possible post flu shot acute disseminated encephalomyelitis in 2013. I do not feel that he has any progressive multiple sclerosis or any relapsing or remitting form . . . [because] MRIs on his brain have not shown any new MS lesions.” | 29 at 3 |

These statements weigh in favor of multiple sclerosis as the appropriate diagnosis. The opinions of the first two doctors, radiologists Raghavan and Georges, only slightly favor a diagnosis of multiple sclerosis as they have expressed their diagnostic impressions as possibilities. The next two doctors, neurologists Russell and Royal, more definitively state that Dr. Mostafa suffered from multiple sclerosis. The next doctor, radiologist Van Besien, who had the benefit of viewing more MRIs, also proposed multiple sclerosis.

The two treating doctors with different impressions are Dr. Morad and Dr. Shaukat. Dr. Morad’s opinion carries little persuasive value as she did not address the MRI imaging, which is an essential component to diagnosing a person with multiple sclerosis. See Exhibit 25.

Dr. Shaukat, however, refers to reviewing imaging studies. Exhibit 29. Dr. Shaukat wrote: the “subsequent MRIs on the cervical spine and MRIs on the brain

have not shown any new MS lesions.” Exhibit 29 at 3. This statement is inconsistent with the views of Dr. Standiford regarding the April 5, 2014 MRI. Exhibit 18 at 12-13. Without some justification or explanation from Dr. Shaukat, it is difficult to credit his opinion that there are no new lesions.

Furthermore, the Secretary questioned why Dr. Mostafa sought treatment from a neurologist in 2019, which is more than five years after he previously saw a neurologist, Dr. Royal. See Resp’t’s Br. at 28. Again, Dr. Mostafa did not reply to the Secretary’s brief, leaving this question unanswered.

In short, the statements from treating doctors that Dr. Mostafa did not suffer from multiple sclerosis are less persuasive than the statements from treating doctors that Dr. Mostafa did suffer from multiple sclerosis. When added to the opinions of the doctors retained for the litigation, the evidence convincingly establishes that Dr. Mostafa suffered from multiple sclerosis.

The finding that Dr. Mostafa suffered from multiple sclerosis and did not suffer from ADEM is sufficient to resolve the case. Dr. Mostafa and his experts have not presented any argument that a flu vaccine can cause multiple sclerosis. Thus, there is no need to conduct a causation-in-fact analysis.

VII. Conclusion

A premise to Dr. Mostafa’s claim is that he suffered acute disseminated encephalomyelitis. However, the evidence indicates that he did not. The appropriate diagnosis, as found by more than one treating doctor and Dr. Sriram, is that Dr. Mostafa suffers from multiple sclerosis. Dr. Mostafa has not presented any evidence that a flu vaccine can cause multiple sclerosis. Therefore, Dr. Mostafa 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