In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

GREGORY CRESS,	*	
	*	
Petitioner,	*	No. 18-1369V
	*	Special Master Christian J. Moran
v.	*	
	*	Filed: September 23, 2025
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Bridget McCullough, Muller Brazil, Dresher, PA, for petitioner;
Debra A. Filteau Begley, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Gregory Cress alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccination caused him to suffer myelin oligodendrocyte glycoprotein antibody-associated disease ("MOGAD"). The Secretary disputed this allegation, contending that Mr. Cress failed to prove that there is a causal link between the Tdap vaccination and MOGAD. The parties developed their positions by presenting expert reports and by arguing through legal memoranda.

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[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.

The evidence, viewed in its entirety, does not preponderate in favor of Mr. Cress. Mr. Cress has not shown that the Tdap vaccine was the cause-in-fact of his MOGAD. Thus, he is not entitled to compensation.

I. Facts[2]

Mr. Cress was born in June 1979. Exhibit 2 at 1. On September 15, 2015, Mr. Cress received the allegedly causal Tdap vaccine. Exhibit 1 at 1.

By October 6, 2015, Mr. Cress had developed trouble with his vision. Exhibit 2 at 1-18 (treatment in an emergency department). Mr. Cress asserts that this blurry vision marked the onset of his neurologic disorder. See Pet'r's Br. at 21. One of the Secretary's experts placed the onset of a neurologic problem ten days later. Exhibit A (Dr. Sriram's report) at 10. This potential conflict does not affect the outcome of the case. See Resp't's Br. at 1 n.1.

Mr. Cress's illness continued as he received treatment. An October 28, 2015 MRI detected an extensive lesion in his thoracic spine consistent with transverse myelitis. Exhibit 3 at 166-67. While hospitalized, Mr. Cress was given a course of IV steroids. Exhibit 3 (discharge summary) at 72.

As an outpatient, Mr. Cress saw a neurologist, Barry Singer, on February 4, 2016. Dr. Singer diagnosed Mr. Cress as suffering from transverse myelitis and/or neuromyelitis optica (frequently abbreviated "NMO"). Exhibit 10 at 67-68. However, testing for the antibody typically associated with neuromyelitis optica, aquaporin-4 ("AQP4"), was negative. Exhibit 3 at 178 (Feb. 4, 2016). A later test for AQP4 antibodies was also negative. Exhibit 10 at 37 (Mar. 10, 2017).

A neuro-ophthalmologist, Sophia Chung, proposed that Mr. Cress was suffering from sero-negative NMO. Exhibit 9 at 6-7 (June 13, 2017). Testing from later in 2017, possibly ordered by Dr. Chung, revealed that Mr. Cress had

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[2] The discussion of events in Mr. Cress's medical history is relatively short for two reasons. First, the parties basically agree that the medical records accurately summarize events occurring contemporaneously with the creation of the medical records. Thus, there is no dispute over facts to resolve. Second, Mr. Cress's case is being resolved based upon the (lack of) evidence supporting an opinion that the Tdap vaccine can cause MOGAD. Because this information is independent of the evidence about Mr. Cress specifically, a thorough recitation of facts is not necessary. For a more detailed assessment, see Pet'r's Br., filed Oct. 3, 2024, at 2-9 and Resp't's Br., filed Jan. 10, 2025, at 1-10.

myelin oligodendrocyte ("MOG") antibodies. Exhibit 58 at 19 (collected on Oct. 31, 2017).

The detection of MOG antibodies is a basis for the opinions of the experts retained in this case that Mr. Cress suffers from MOGAD. See Exhibit 42 (Dr. Rivzi's report) at 5-6; Exhibit D (Dr. Sriram's report) at 3-4. Although Dr. Rivzi and Dr. Sriram recognize the significance of the October 31, 2017 result, it appears that the results may not have been communicated to some of Mr. Cress's treating doctors, as doctors sometimes recounted that Mr. Cress's test for MOG-IgG was negative.

Lacking awareness of the positive MOG test, Mr. Cress's doctors continued to treat him for NMO. See, e.g., Exhibit 62 at 7; Exhibit 40 at 89. Mr. Cress began seeing a new neurologist, Lokesh Rukmangadachar, on August 5, 2019. Exhibit 35 at 92. Dr. Rukmangadachar ordered repeat testing for MOG antibodies. This test was, again, positive. Id. at 157. In response to this discovery, Dr. Rukmangadachar changed the diagnosis to MOGAD.

Mr. Cress has continued to receive treatment for MOGAD. Unfortunately, however, he has continued to experience relapses and problems, such as difficulty with his vision and weakness. The continuation of problems does not affect an assessment of whether the Tdap vaccine caused his neurologic problem initially.

II. Procedural History

Mr. Cress alleged that the Tdap vaccine harmed him. Pet., filed Sep. 7, 2018. He did not define the illness the vaccine allegedly caused, although the petition mentions transverse myelitis. Over the next year and a half, Mr. Cress periodically submitted medical records.

The Secretary reviewed this material and found that compensation was not appropriate. Resp't's Rep., filed June 24, 2019. In the Secretary's view, a notation by one of Mr. Cress's treating doctors was not sufficient to establish entitlement. Mr. Cress also had not presented the report from an expert. Finally, the Secretary requested various medical records.

Almost a year later, Mr. Cress supported a claim that the Tdap vaccine caused him to suffer NMO with a report from a neurologist, Frederick Nahm. Exhibit 19. The Secretary opposed Dr. Nahm's first opinion with a report from Dr. Sriram. Exhibit A. A review of these opinions as well as the supplemental reports (Exhibits 32 and C) is not required. Dr. Nahm's opinion was premised upon a

diagnosis of NMO, which is no longer Mr. Cress's diagnosis. Further, other than a passing reference to Dr. Nahm in the procedural history, Mr. Cress does not rely upon Dr. Nahm in his arguments regarding entitlement. See Pet'r's Br.

The parties attempted to resolve the case informally. As part of the potential settlement process, Mr. Cress submitted updated medical records. The parties, however, did not resolve the case.

When litigation resumed, Mr. Cress supported his claim with a report from Dr. Rizvi. Exhibit 42, filed June 2, 2023. As mentioned above, Dr. Rizvi stated that Mr. Cress suffered from MOGAD, not NMO. A basis for this opinion is the result of tests from 2017, which Mr. Cress filed as Exhibit 58 on August 1, 2023.

The Secretary addressed Dr. Rizvi's opinion by submitting reports from two experts. The Secretary continued to rely upon Dr. Sriram. Exhibit D, filed Dec. 21, 2023. The Secretary added an immunologist, Dr. You-Wen He. Exhibit E, filed Dec. 21, 2023.

After the expert report phase concluded, the parties were directed to advocate for their positions in written submissions. Order, issued June 12, 2024. After a status conference to discuss the order for briefs, Mr. Cress amended his petition. The June 27, 2024 Amended Petition matches the opinions that Dr. Rizvi disclosed, namely that the Tdap vaccine caused Mr. Cress to suffer MOGAD. In further support, Mr. Cress submitted his 23-page brief on October 3, 2024. The Secretary filed his 38-page brief on January 10, 2025.[3] Mr. Cress did not file a reply. Once the time for submitting a reply lapsed, the case became ready for adjudication.

Adjudication does not require a hearing. Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020).

Mr. Cress has had a fair and full opportunity to present his case. See Demore v. Sec'y of Health & Hum. Servs., 175 Fed. Cl. 756, 764-65 (2025) (ruling special master did not abuse his discretion in declining to hold a hearing). After

[3] The Secretary's brief is particularly thorough.

the Secretary presented reports from Dr. Sriram and Dr. He, Mr. Cress had an opportunity to respond but declined. Pet'r's Status Rep., filed Feb. 21, 2024. Likewise, after the Secretary argued against an award of compensation, Mr. Cress could have replied but did not.

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 a 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 the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

IV. Analysis --- Causation

The Vaccine Act requires that petitioners establish five elements. 42 U.S.C. § 300aa–11(c)(1)(A) through (E). Here, the dispute concerns the third element, causation. For off-Table cases, 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. Althen Prong One – Medical Theory

Here, with respect to the three Althen prongs, the parties primarily dispute the first prong. See Resp't's Br. at 31 (discussing prongs two and three in one

lengthy paragraph). As part of Mr. Cress's burden to establish that the Tdap vaccine was the cause-in-fact of his MOGAD, Mr. Cress must present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. The parties have presented different forms of evidence on this topic, including (1) case reports and case series, and (2) opinions from Dr. Rivzi regarding specific theories. Another category is citation to previous cases, which is not really evidence but still worthy of consideration. These are discussed below.

1. Case Reports

Mr. Cress relies upon case reports about a Tdap vaccine preceding the onset of MOGAD to support the claim that a Tdap vaccine can cause MOGAD. See Pet'r's Br. at 17-18. This position is flawed because case reports provide little, if any, meaningful information about causation. At best, they show temporal data but not necessarily that a Tdap vaccine can cause MOGAD.

Various authorities have commented on the value of case reports. To start, the Federal Judicial Center has published a series of guides designed "to assist judges . . . in reaching an informed and reasoned assessment concerning the basis of expert evidence." Jerome Kassirer and Gladys Kessler, Reference Manual on Scientific Evidence, Preface (3d ed. 2011) ("Reference Manual"). The guidance from the Federal Judicial Center translates to the Vaccine Program because causation for off-Table injuries in the Vaccine Program is the same as traditional causation. See Moberly v. Sec'y of Health and Human Servs., 592 F.3d 1315, 1322-23; Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) ("The absence of elaboration of the law of causation in the legislative history leads us to conclude that the Vaccine Act's requirement of causation in non-Table cases was not viewed as distinct from causation in the tort law."). For examples in which appellate authorities within the Vaccine Program have cited the Reference Manual, see Germaine v. Sec'y of Health & Hum. Servs., 155 Fed. Cl. 226, 228-29 (2021), and Hart v. Sec'y of Health & Hum. Servs., 60 Fed. Cl. 598, 607 n.20 (2004).

A pertinent guide in the Reference Manual states "[a]necdotal evidence usually amounts to reports that events of one kind are followed by events of another kind. Typically, the reports are not even sufficient to show association, because there is no comparison group." David H. Kaye and David A. Freedman, Reference Manual on Scientific Evidence, Reference Guide on Statistics, at 218. These authors also state "some courts have suggested that attempts to infer

causation from anecdotal reports are inadmissible as unsound methodology under Daubert." Id. at 217 n. 14 (citing cases).

Within the Vaccine Program, the Federal Circuit has endorsed, albeit indirectly, a view that case reports merit little weight. In a series of five cases involving autoimmune hepatitis, the (undersigned) special master rejected case reports as evidence of causation. Porter v. Sec'y of Health & Hum. Servs., No. 99–639V, 2008 WL 4483740, at *13 (Fed. Cl. Spec. Mstr. Oct. 2, 2008). Under the caption of a different case, a judge at the Court of Federal Claims disagreed with this weighing of evidence. Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86–87 (2009). When the Federal Circuit reviewed the special master's decision, the Federal Circuit stated that "[t]he special master found that the remaining two articles, both describing single case studies, did not contain any meaningful analysis about causation." Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1253 (Fed. Cir. 2012). The Federal Circuit also stated that the "decision reveals a thorough and careful evaluation of all the evidence including . . . medical literature." Id. at 1254.

Similar indirect support from the Federal Circuit is found in W.C. W.C. v. Sec'y of Health & Hum. Servs., No. 07-456V, 2011 WL 4537877, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011), mot. for rev. denied on this point, 100 Fed. Cl. 440, 456 (2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). At the trial level, the (undersigned) special master declined to rely upon case reports because, among other reasons, "case reports cannot distinguish a temporal association from a causal relationship." Id. at *13. At the Federal Circuit, the appellate court focused primarily upon epidemiologic studies, which undermined the claim that the vaccine significantly aggravated the petitioner's illness. W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1360-61 (Fed. Cir. 2013). However, at the end of its opinion, the Federal Circuit stated that it "cannot say that the special master's . . . weighing of the scientific evidence was arbitrary or capricious." Id. at 1361.

Much of the foregoing analysis regarding case reports was set forth in K.O. v. Sec'y of Health & Human Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016). After K.O., the Federal Circuit has not discussed case reports in a precedential opinion, leaving Porter and W.C. as the leading, although muted, words on the subject.[4] Consequently, judges from the

[4] In a non-precedential opinion, the Federal Circuit held that the special master was not arbitrary in denying compensation. Kalajdzic v. Sec'y of Health & Hum. Servs., No. 2023-1321, 2024 WL 3064398 (Fed. Cir. June 20, 2024). In the underlying decision, the special master gave

Court of Federal Claims have tended to defer to the special master's assessment of case reports. See, e.g., Kelly v. Sec'y of Health & Hum. Servs., 160 Fed. Cl. 316, 321 (2022) (indicating that the special master was not arbitrary in finding that case reports have limited or nonexistent value); Rus v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 672, 682 (2016) (noting the special master could reasonably afford little weight to the medical literature, including case reports). An exception to this trend is Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159 (2021). In Patton, the Court ruled that the special master "erred in his prong one analysis by discounting the evidentiary value of the case reports [petitioner's expert] submitted." Id. at 168. But, Patton does not discuss Porter or W.C. Instead, Patton relies upon Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 475 (2012).[5]

Outside of the Vaccine Program, district courts have examined the value of case reports in the context of claims that drugs or a medical device harmed a person. Examples include: In re: Abilify (Aripiprazole) Products Liability Litigation, 299 F.Supp.3d 1291, 1309 (N.D. Fla. 2018) ("The difficulty with case reports is distinguishing between association and causation"); In re Tylenol (Acetaminophen) Marketing, Sales Practice, and Products Liability Litigation, 198 F.Supp.3d 446, 461 (E.D. Pa. 2016) ("It is true that case reports and anecdotal evidence alone may not be sufficient support for a causation opinion. . . . However, case reports considered in conjunction with other evidence may be an appropriate basis for an expert's causation opinion."); In re Mirena IUD Products Liability Litigation, 169 F.Supp.3d 396, 451 (S.D.N.Y. 2016) ("Case reports are generally

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"little weight" to "case reports filed in support of Petitioner's theory." Kalajdzic v. Sec'y of Health & Hum. Servs., No. 17-792V, 2022 WL 2678877, at *23 (Fed. Cl. Spec. Mstr. June 17, 2022), mot. for rev. denied, 2024 WL 4524777 (originally issued Oct. 27, 2022), aff'd, 2024 WL 3064398 (Fed. Cir. 2024).

[5] Paluck states "case reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value. Nonetheless, the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight.'" Paluck, 104 Fed. Cl. at 475, quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011). The case Paluck quotes, Campbell, cites to Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86-87 (2009). However, the value of the opinion by the Court of Federal Claims seems questionable as the Federal Circuit, as noted above, reversed the outcome in Rotoli, and reinstated the special master's decision, which gave little weight to the case reports. Porter, 663 F.3d at 1253. Paluck, which cited Rotoli, was issued before the Federal Circuit reversed Rotoli.

disfavored by courts as evidence of causation because they merely describe 'reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; [they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.'") (citation omitted).

Mr. Cress discussed case reports and case series showing development of MOGAD after different vaccinations. See Pet'r's Br. at 17-19. As these case reports are part of the record, they must be considered.[6] See 42 U.S.C. § 300aa–13(a)(1) (requiring a special master to evaluate the "record as a whole").

One article, which is perhaps the most supportive article, reports on 50 patients with MOGAD. Exhibit D-6 (Sven Jarius et al., MOG-IgG in NMO and related disorders: a multicenter study of 50 patients. Part 2: Epidemiology, clinical presentation, radiological and laboratory features, treatment responses, and long-term outcome, 13 J. NEUROINFLAMMATION 1 (2016)). Within this group, the authors identified two people who received a polyvalent Tdap (Boostrix for the first patient) or tetanus vaccine (as well as polio and influenza virus for the second patient) and developed MOGAD. The authors considered whether the preceding vaccinations were causal:

> Although a causal link between the two events cannot be proved, the close temporal association is highly suggestive of vaccine-mediated immune activation.… Whether molecular mimicry between vaccine epitopes and neural antigens played a role or whether vaccination only indirectly triggered or promoted the immune reaction against MOG is currently unknown but certainly warrants further investigation.

Exhibit D-6 at 41. Although Jarius and colleagues encouraged this "further investigation" when they wrote this article in 2016, the parties did not identify any articles documenting any further study.

Although not a study, a more recent case report was filed as Exhibit 53 (Neha Kumar et al., "Case Report: Postvaccination Anti-Myelin Oligodendrocyte

[6] Mr. Cress's experts refer to other case reports in their expert reports; however, this decision will focus on the case reports that he advances in his brief.

Glycoprotein Neuromyelitis Optica Spectrum Disorder: A Case Report and Literature Review of Postvaccination Demyelination," 22 Int'l J MS Care 85 (2020)). These authors, too, expressed an interest in more research to determine whether any vaccine contributes to MOGAD. Id. at 87.

Beyond those case reports, other articles are further afield in the sense that they are (a) based upon a vaccine other than the Tdap vaccine, (b) concern a disease other than MOGAD, or (c) are both based upon a vaccine other than the Tdap vaccine and concern a disease other than MOGAD. These differences lessen any value of the cited literature. See Herms v. Sec'y of Health & Hum. Servs., 173 Fed. Cl. 1, 17 (2024), appeal docketed, No. 2025-1007 (Fed. Cir. Oct. 2, 2024).

Whether MOGAD is analogous to other diseases is a challenging topic. As Dr. Rizvi explained, doctors began detecting MOG antibodies in 2007 and this discovery led to the classification of MOGAD as a separate disease. Exhibit 42 at 5. Before the potential for diagnosing MOGAD existed, patients who may have had anti-MOG antibodies were diagnosed as having different conditions such as acute disseminated encephalomyelitis, optic neuritis, transverse myelitis, or seronegative neuromyelitis optica spectrum disease. Id. Thus, from the way that MOGAD originated, these other conditions could be seen as providing a foundation for understanding the causes of MOGAD.

However, Dr. Rizvi recognizes that MOGAD has been "described to be a distinct entity from neuromyelitis optica, multiple sclerosis, and other acute demyelinating conditions like [optic neuritis] or transverse myelitis." Exhibit 42 at 5 (abbreviations omitted). At least in terms of neuromyelitis optica, Dr. Sriram elaborates on why it differs from MOGAD. The "[a]quaporin4 antibody mediated form of NMO is caused by the destruction of the astrocyte in the brain. . . . Loss of astrocytes leads [to] impaired functioning of oligodendrocytes and demyelination. Aquaporin4 antibody positive NMO is therefore considered an astrocytopathy." Exhibit D at 3. In contrast, "MOG is present mainly on oligodendrocytes. MOG antibody mediated disease is caused by the direct loss of oligodendrocytes by the anti MOG antibody." Id.

Thus, the evidence preponderates in favor of finding that the etiology of MOGAD differs from the etiology of NMO, multiple sclerosis, optic neuritis and transverse myelitis. It is important to recognize that medical science is studying these conditions and advancements in knowledge about the causes of these conditions could occur. It is easy to imagine that the evidence about the similarities and differences among these neurologic conditions could differ in

another case. Thus, any finding in that future case might differ from a finding in Mr. Cress's case. See Lampe, 219 F.3d at 1368 (noting special masters may weigh evidence differently).

In the absence of a finding that the pathogenesis of these different neurologic disorders are similar to each other, an extrapolation from what is known about one disorder to MOGAD is unpersuasive. Thus, a detailed analysis of each case report is not required.

In short, the collection of case reports does not meaningfully demonstrate that the Tdap vaccine can cause MOGAD. See Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (indicating that special masters have discretion in how they weigh evidence). However, this literature is not dispositive of the issue. Therefore, the theories Mr. Cress and his expert have put forward are addressed next.

2. Theories

Mr. Cress and his expert, Dr. Rizvi, propose two theories to explain how the Tdap vaccine can cause MOGAD: molecular mimicry and bystander activation. Mr. Cress devotes about one paragraph to each theory. Pet'r's Br. at 15-16.

a) *Molecular Mimicry*

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C., 704 F.3d 1352, and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately five years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and

that the immune system will respond to the relevant amino acid sequence.[7] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68, 478 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild Tdap virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Faulkenberry on behalf of WCF v. Sec'y of Health & Hum. Servs., 176 Fed. Cl. 700, 709 (2025) (finding special master acted within his discretion to reject the theory of molecular mimicry); Stricker v. Sec'y of Health & Hum. Servs., 170 Fed. Cl. 701, 720-21 (2024) (finding the special master did not require scientific certainty in assessing molecular mimicry); Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 660-61 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Doles v. Sec'y of Health & Hum. Servs., No. 2023-2404, 2025 WL 1177875, at *5 (Fed. Cir. Apr. 23, 2025) (noting the Secretary's expert did not challenge molecular mimicry); Patton, 157 Fed. Cl. at 169 (finding that a special

[7] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." Dorland's Medical Dictionary 868 (32nd ed. 2012).

master erred in requiring petitioner submit a study to establish medical theory causally connecting Tdap vaccine to brachial neuritis).

When evaluating a theory of molecular mimicry, one opinion from the Court of Federal Claims is especially illuminating (even if the opinion is not binding). The Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal dismissed, No. 2024-1214, 2024 WL 1255318 (Fed. Cir. Mar. 25, 2024). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop GBS. Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The chief special master denied entitlement. Id. at 656.

The Court of Federal Claims denied a motion for review because the chief special master did not commit any error in evaluating Ms. Dennington's prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." Id. at 653.
- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." Id. at 653-54.
- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.
- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

> In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap,

> molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

Based upon this method of analysis, the evidence Mr. Cress presents falls short of his burden. Dr. Rizvi's discussion of the theory of molecular mimicry is sparse and conclusory. See Exhibit 42 at 7. In response, Dr. He offered several critiques, which Dr. Rizvi did not answer via a supplemental report. See Exhibit E at 14-18. Dr. Rizvi does not present a persuasive reason for linking Mr. Cress's MOGAD to the Tdap vaccine. See Morgan, 850 F. App'x at 784; see also Duncan, 153 Fed. Cl. at 661. Mr. Cress's brief is similarly conclusory on this topic. See Pet'r's Br. at 15.

b) Bystander Activation

In addition to molecular mimicry, Mr. Cress and Dr. Rizvi propose bystander activation. Compared with the numerous cases involving molecular mimicry, there are relatively few cases in which petitioners assert bystander activation.

Dr. Rizvi's discussion of this alternative theory is contained in a single sentence: "stimulation of preexisting anti-myelin-specific 'bystander' T cells already present in the body, but quiescent due to suppression by regulatory immune cells to maintain tolerance to self, could be stimulated by the immune response elicited by vaccination, which would then engage in an autoimmune reaction." Exhibit 42 at 7. Dr. He countered by identifying two deficiencies in Dr. Rizvi's opinion: (1) Dr. Rizvi has not explained how the Tdap vaccine would break tolerance to self, and (2) Dr. Rizvi did not support the proposition that Mr. Cress had anti-myelin T cells before the vaccination. Exhibit E at 15-16.

Under these circumstances, bystander activation has not been established as a reliable theory to explain how a Tdap vaccination can cause MOGAD. See Roby v. Sec'y of Health & Hum. Servs., No. 15-125V, 2020 WL 6240619, at *21 (Fed.

Cl. Spec. Mstr. Sep. 10, 2020) (finding the bystander activation theory too vague to be accepted). Therefore, the evidence does not support a finding that Mr. Cress has carried his burden with respect to Althen prong one.

3. Other Cases

Although not "evidence" as that term is traditionally understood, opinions from other special masters and judges can affect an analysis of whether a certain vaccine can cause a certain condition. In this regard, Mr. Cress advances two cases in which a special master has found a vaccine caused MOGAD: Hock v. Sec'y of Health & Hum. Servs., No. 21-945V, 2024 WL 3826125 (Fed. Cl. Spec. Mstr. July 12, 2024); and L.C. v. Sec'y of Health & Hum. Servs., No. 17-722V, 2021 WL 3630315 (Fed. Cl. Spec. Mstr. July 2, 2021).

Any consideration of other opinions must begin with a recognition that opinions from other special masters are not binding precedent. Boatman v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019). They are not binding because, in part, different finders of fact can reasonably reach different conclusions about similar evidence. See Lampe, 219 F.3d at 1368.

The possibility that different finders of fact may weigh evidence differently contributes to the evaluation of L.C. and Hock. In L.C., the special master concluded that the evidence "is no worse than a 'close' case---and such circumstances counsel for a determination in the Petitioner's favor." 2021 WL 3630315, at *20. About three years later, the special master came to a similar outcome: "as in L.C., I find that Petitioner's showing on prong one was just preponderant enough to make this a 'close' case." Hock, 2024 WL 3826125, at *21. It seems reasonable to suppose that closely balanced evidence that one special master finds barely tips the metaphorical scales of justice in a petitioner's favor could also be found not to weigh in petitioner's favor.

Moreover, the results in L.C. and Hock seem premised, at least in part, upon two assertions about which the undersigned has less confidence. First, Hock was based, again in part, upon "the fact that the flu vaccine has often been found in past Program cases to be associated with comparable central nervous systems inflammatory demyelinating conditions, like ADEM, TM, or optic neuritis." 2024 WL 3826125, at *20. This reasoning also appears in L.C., 2021 WL 3630315, at *18 (noting "numerous reasoned decisions in which special masters determined that a petitioner had successfully established that an acute and monophasic CNS demyelinating injury was vaccine-caused---including due to the Tdap vaccine").

However, the undersigned has tended not to make this finding. See Bowling v. Sec'y of Health & Hum. Servs., No. 18-109V, 2023 WL 6846491 (Fed. Cl. Spec. Mstr. Sep. 20, 2023) (finding that petitioner had failed to establish that the flu vaccine can cause transverse myelitis); Faulkenberry v. Sec'y of Health & Hum. Servs., No. 19-238V, 2024 WL 4892507 (Fed. Cl. Spec. Mstr. Nov. 1, 2024) (finding that petitioner had failed to establish that either the flu vaccine or the hepatitis A vaccine can cause anti-NMDAR encephalitis), mot. for rev. denied, 176 Fed. Cl. 700 (2025); But see Hoffman v. Sec'y of Health & Hum. Servs., No. 19-111V, 2024 WL 4444773 (Fed. Cl. Spec. Mstr. Sep. 13, 2024) (finding, on remand, that petitioner presented a plausible theory causally connecting flu vaccine to chronic inflammatory demyelinating polyneuropathy).

Second, both Hock and L.C. considered the relatively recent discovery of MOGAD, which consequentially meant that the disease had not been studied extensively. L.C., 2021 WL 3630315, at *19 ("Certainly the limited science studying what is a fairly recent diagnostic classification provides some explanation for this paucity [of evidence that the Tdap vaccine can cause MOGAD]"); Hock, 2024 WL 3826125, at *21 ("MOGAD's novelty as a diagnosis, coupled with the extremely limited number of Program decisions addressing the topic, mean that the subject remains open to debate"). However, the paucity of knowledge about the cause of the disease does not mean that the party burdened with presenting preponderant evidence bears a lighter load.

In Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543 (Fed. Cir. 1994), the Federal Circuit commented upon the significance of a lack of evidence. In Knudsen, the special master had found that the petitioners were entitled to a presumption of causation because their child's encephalopathy had developed within one day of the receipt of a diphtheria-tetanus-pertussis vaccine. 35 F.3d at 546. Thus, the Secretary bore the burden of establishing a factor unrelated to the vaccine (here, a viral infection) caused the encephalopathy. Id. at 547, citing Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994) and 42 U.S.C. § 300aa–13(a)(1)(B).

In assessing the burdens associated with proving---or disproving---a viral infection as the cause of an encephalopathy, the Secretary argued that he should not be required to establish the specific type of viral infection because identifying the virus in 1956 would have been "virtually impossible." The Secretary, therefore, argued against a per se rule requiring that the Secretary specify the virus. However, the Federal Circuit held that if "the government cannot prove actual alternative causation, for whatever reason, then the petitioner is entitled to

compensation." Id. at 547. In this context, the phrase "for whatever reason" seems to encompass an underlying lack of knowledge.

A lack of underlying knowledge about an underlying disease was also considered in Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). Ms. Caves alleged that a flu vaccine caused her to develop transverse myelitis. Id. at 121. As part of her motion for review, Ms. Caves argued for a lower standard of proof "because there is a dearth of scientific evidence connecting the influenza vaccine to TM." Id. at 143. The Court of Federal Claims rejected that argument, relying, in part, on Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). The Court of Federal Claims stated: the "standard of proof does not operate as a sliding scale that varies depending upon the quantity and quality of the scientific evidence that is available." 100 Fed. Cl. at 143.

Special masters have recognized Caves's guidance that petitioners' burden to present preponderant evidence explaining how a vaccine can cause a disease is not reduced simply because there is a lack of information available about the disease. See Fiorello v. Sec'y of Health & Hum. Servs., No. 17-1869V, 2024 WL 4133302, at *16 (Fed. Cl. Spec. Mstr. Aug. 12, 2024) ("while the limits of clinical evaluation have some bearing on what evidence petitioners can reasonably be expected to muster relative to Althen prong two, such limitations cannot explain the dearth of evidence or explanation supporting [petitioner's expert's] opinion regarding general causation"), mot. for rev. denied, 175 Fed. Cl. 375 (2025); Gamboa-Avila v. Sec'y of Health & Hum. Servs., No. 18-925V, 2023 WL 6536207, at *30 (Fed. Cl. Spec. Mstr. Sep. 11, 2023) ("the existing scientific and medical evidence relevant to a particular disease and vaccine simply does not support causation, and it is no objection to maintain in response that what a petitioner can offer should be deemed sufficient if it is 'science-y' enough"), mot. for rev. denied, 170 Fed. Cl. 441 (2024), appeal docketed, No. 2024-1765 (Fed. Cir. May 1, 2024); Harlow v. Sec'y of Health & Hum. Servs., No. 22-550V, 2023 WL 8456065, at *7 (Fed. Cl. Spec. Mstr. Nov. 13, 2023) (stating a petitioner "cannot use the lack of knowledge as a justification for lowering his burden of proof" and citing Caves); Trollinger v. Sec'y of Health & Hum. Servs., No. 16-473V, 2023 WL 2521912, at *30 (Fed. Cl. Spec. Mstr. Feb. 17, 2023) ("the absence of sufficient reliable science in support of a theory is not an occasion to accept a non-preponderant showing"), mot. for rev. denied, 167 Fed. Cl. 127 (2023); see also Madala v. Sec'y of Health & Hum. Servs., No. 19-1182V, 2024 WL 3103932 at *23 (Fed. Cl. Spec. Mstr. May 29, 2024) ("[i]nadequate data, even in the face of rare events, however, does not constitute preponderant evidence").

Although neither Caves nor the collection of opinions from special masters cited above constitute binding precedent, the underlying rationale is persuasive. The reasoning in these cases further distinguish L.C. and Hock.

4. Synopsis on Prong One

Hock states that "for present purposes, what matters is the evidence adduced in this case." 2024 WL 3826125, at *21 (emphasis in original). For Mr. Cress's case the evidence consists of a small number of case reports and relatively short opinions from Dr. Rizvi. For the reasons explained above, this evidence does not fulfill Mr. Cress's burden.

To this evidence, Mr. Cress adds arguments based upon L.C. and Hock. But, L.C. and Hock do not shore up the evidentiary shortcomings.[8] Thus, Mr. Cress has not met his burden of proof on Althen prong one.

Because the causation aspect of Mr. Cress's case is resolved based upon the first Althen prong, further evaluation of the remaining prongs is not necessary. When special masters can resolve a case a based upon one issue, they do not necessarily need to address all issues. See, e.g., Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012); Holmes v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 469, 488 (2014); Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 222 (2012). However, if Mr. Cress had presented a persuasive theory causally connecting the Tdap vaccine and MOGAD in Althen prong one, Mr. Cress cannot establish a logical sequence of cause and effect in Althen prong two. A short discussion of Althen prong two follows.

B. Althen Prong Two - Logical Sequence of Cause and Effect

In determining whether petitioners have established that a vaccine did cause a particular injury, the Federal Circuit has directed special masters to consider any statements from treating doctors. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, although Mr. Cress was directed to identify any supportive statements from treating doctors (Order for Briefs, issued

[8] After the parties submitted briefs, a special master found that a petitioner did not establish the Tdap vaccine can cause MOGAD. Ampofo-Addo v. Sec'y of Health & Hum. Servs., No. 21-1231V, 2025 WL 2463643, at *19-21 (Fed. Cl. Spec. Mstr. July 31, 2025).

June 12, 2024, at 7), Mr. Cress did not cite any statements from treating doctors. See Pet'r's Br. at 19-20.

Mr. Cress's argument is essentially that he received the Tdap vaccination, developed an autoimmune process, which resulted in MOGAD, and there is no other explanation. Pet'r's Br. at 20. However, the Federal Circuit has rejected this reasoning. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1323 (Fed. Cir. 2010). Therefore, Mr. Cress has not presented a persuasive argument for Althen prong two.

V. Conclusion

Mr. Cress warrants sympathy for experiencing health problems. However, the requirements of the Vaccine Act must be satisfied before compensation can be awarded. Here, Mr. Cress has not presented sufficient evidence to show that the Tdap vaccine caused him to suffer MOGAD. Accordingly, his claim for compensation is DENIED.

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