In the United States Court of Federal Claims

No. 17-642V
(Filed Under Seal: April 1, 2022)*
(Reissued: April 26, 2022)
FOR PUBLICATION

ELIZABETH DOLES,	*
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Petitioner,	*
	*
v.	*
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SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
	*
Respondent.	*
	*

Jennifer G. Maglio, Maglio Christopher & Toale Law Firm, Sarasota, FL, for Plaintiff.

Catherine E. Stolar, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C. for Defendant, United States. With her on briefs were *Brian M. Boynton*, Acting Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Heather L. Pearlman*, Deputy Director, *Darryl R. Wishard*, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER

Petitioner Elizabeth Doles experienced various neurological symptoms after receiving two vaccinations — first for polio, then for tetanus, diphtheria, and pertussis ("Tdap"). She sought relief under the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 34 ("Vaccine Act"), and the Special Master awarded damages. *See* Special Master's Ruling on Entitlement ("Ruling") at 1 (ECF 73); Special Master's Decision Awarding Damages ("Decision") at 2 (ECF 83). The government moved for review, raising arguments about the nature of Petitioner's medical condition and about whether and how the vaccines relate to her condition.

* This Opinion was issued under seal on April 1, 2022. The parties were directed to propose redactions by April 15, 2022. No proposed redactions were submitted. The Court hereby releases publicly the Opinion and Order of April 1 in full.

Finding errors in the Special Master's Ruling, I **REMAND** for additional proceedings.[1]

BACKGROUND

To obtain compensation under the Vaccine Act, a petitioner must prove that a vaccine caused an injury. *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). There are two ways to show causation: (1) through "a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ('Table injury')," *id.* (citing 42 U.S.C. § 300aa-14(a)), or (2) by proof of causation in fact "where the complained-of injury is not listed in the Vaccine Injury Table ('off-Table injury')," *id.* (citing 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). For off-Table injuries, causation in fact has three elements: "(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." *Id.*

While some Vaccine Act petitioners claim novel injuries resulting from vaccines, others claim that an existing medical condition was "significantly aggravated" by a vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i)–(ii); *see Loving ex rel. Loving v. Sec'y of Dept. of Health & Hum. Servs.*, 86 Fed. Cl. 135, 143 (2009) ("[T]he Vaccine Act specifies that significant-aggravation and new-injury circumstances constitute separate avenues to potential recovery."). Petitioners in the latter category must prove three additional elements: "(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), [and] (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination[.]" *Loving*, 86 Fed. Cl. at 144; *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013).

A petitioner always must prove causation of off-Table injuries by preponderance of the evidence. *See, e.g.*, *Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1366 (Fed. Cir. 2012); *Althen*, 418 F.3d at 1278.[2] Although the petitioner's burden does not "require identification and proof of specific biological mechanisms," *Knudsen*, 35 F.3d at 549, "a 'plausible' or 'possible' causal theory" is

[1] This Court has jurisdiction. *See* 42 U.S.C. §§ 300aa-11(c), 300aa-16(a). The government timely moved for review. *See* 42 U.S.C. § 300aa-12(e)(1).

[2] The government can rebut proof of causation by showing, "also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 547 (Fed. Cir. 1994)); *see* 42 U.S.C § 300aa-13(a)(1)(B).

not enough, *see Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). Proof of causation requires "a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *See Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010); *Moberly*, 592 F.3d at 1322; *see also Knudsen*, 35 F.3d at 549 ("[C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [patient] without detailed medical and scientific exposition on the biological mechanisms.").

This Court may set aside a special master's conclusions as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). "Fact findings are reviewed … under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). When this Court finds error, it may either substitute its own findings and conclusions or remand for additional proceedings. 42 U.S.C. § 300aa-12(e)(2)(B)–(C).

The relevant facts and history of the case are as follows. Petitioner — a 67-year-old woman at the time of her vaccinations — alleged in her Amended Petition that she suffers from central nervous system demyelination "best characterized" as multiple sclerosis ("MS"). Am. Pet. ¶¶ 5–6 (ECF 44). She does not plead exactly when her symptoms began, but she went to the emergency room 44 days after her second vaccination for symptoms that began two nights before. *Id.* at ¶¶ 1–3; Ruling at 6. She claims that her vaccines "actually caused, or, alternatively, significantly aggravated" her injury. Am. Pet. at ¶ 10.

Because Petitioner's alleged injury does not appear on the Table for the relevant vaccines, 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a)(I), (II), (VI), (VII), she must prove causation rather than benefit from the statutory presumption. *Althen*, 418 F.3d at 1278. Central nervous system demyelination is a general term describing a number of medically distinct conditions — including MS, acute disseminated encephalomyelitis ("ADEM"), and focal myelitis or transverse myelitis ("TM"), among others, *see* Steel Rebuttal Report at 2 (ECF 57-2) — so Petitioner presented two experts to explain her theory of injury in more detail.

The first was Dr. Slavenka Kam-Hansen, one of Petitioner's treating physicians, who opined in a letter that Petitioner suffered from ADEM because of the vaccines. Kam-Hansen Letter at 2 (ECF 23-2). Dr. Kam-Hansen opined "that ADEM was more likely to cause [Petitioner's] symptoms" than MS. *Id.* at 1. But then

Petitioner changed course. Her second expert, Dr. John G. Steel, submitted reports arguing that Petitioner did *not* have ADEM, but instead experienced focal myelitis or TM because of the vaccines. Steel Rebuttal Report at 1, 7; *see* Steel Report at 3, 5 (ECF 34-2). Dr. Steel opined that Petitioner has MS, but — although the record of his opinions is not entirely clear — he did not appear to argue that the vaccines caused or aggravated that condition. Rather, he seems to have argued that her MS put her at heightened risk for TM when she received vaccinations. Steel Rebuttal Report at 1–2, 6–7.[3] "Although there is little evidence that vaccinations cause multiple sclerosis in healthy patients," he wrote, "there is convincing evidence that vaccinations occasionally trigger single attacks of TM[] [and other conditions], and there is good reason to think that such an event is more likely in patients with subclinical MS." Steel Report at 5.

Defendant submitted an expert report from Dr. Subramaniam Sriram, who agreed with Dr. Steele that Petitioner has MS, not ADEM, Sriram Report at 7, 13 (ECF 52-1), but concluded that Petitioner's MS was not caused or exacerbated by the vaccines. *Id.* at 16; Sriram Rebuttal Report at 7 (ECF 62-1). He opined that the diagnosis of MS made it inappropriate to diagnose TM as a separate condition. Sriram Rebuttal Report at 1–2.

In response, Dr. Steel emphatically objected not only to Dr. Sriram's characterization of Petitioner's condition, but to Dr. Sriram discussing MS in the first place. Dr. Steel referred to MS as a "red herring" that "has served to confuse the issue," insisting that he "made no assertion of a causal relationship between the vaccines and MS" and that his opinion was "regarding the myelitis only." Steel Rebuttal Report at 1. He criticized Dr. Sriram for addressing MS at all: "Dr. Sriram's rebuttal … focused on MS but did not address the actual causal relationship that I have asserted, between Ms. Doles' April 2016 vaccinations and her subsequent attack of spinal myelitis. By discussing MS only, he failed to address our central point." *Id.* at 1–2.

Petitioner's own argument before the Special Master was in the same vein as Dr. Steel's. Petitioner maintained that "Dr. Steel's theory of general causation" was that her vaccines "can provoke an autoimmune process leading to central nervous system demyelination which manifests as [a form of TM] and this is more likely to occur in patients who are already undergoing another autoimmune process, such as clinically silent MS." Reply Mem. in Supp. of Pet.'s Mot. for Findings of Fact and

[3] Dr. Steel also opined that "[t]he vaccinations likely did not cause the MS but rather unmasked it, i.e. caused it to become clinically significant during her medical evaluation." Steel Report at 3. That language could be read as opining that Petitioner's vaccinations aggravated her MS, but it is difficult to understand in the context of Dr. Steel's other opinions.

Conclusions of Law ("Reply Mem.") at 2 (ECF 72). Petitioner identifies no place in her expert reports or briefing where she plainly argued that her MS itself had been aggravated by the vaccines. Rather, she argued consistently that her MS was an underlying risk factor that put her at risk for other conditions. Pet.'s Mem. in Supp. of Her Mot. for Findings of Fact and Conclusions of Law at 18–20 (ECF 68); Reply Mem. at 2.

The Special Master — who resolved the parties' arguments on the papers, without a hearing — took a tack different from either of the parties. He specifically rejected both Dr. Kam-Hansen's view that Petitioner experienced ADEM and Dr. Steel's view that Petitioner experienced TM, instead agreeing with Dr. Sriram that Petitioner has MS alone. Ruling at 18, 20–22. But unlike Dr. Sriram (or Petitioner and her experts, for that matter), the Special Master determined that Petitioner's MS had been significantly aggravated by her vaccines. *Id.* at 19. The Special Master's main support for that conclusion was a study by Langer-Gould *et al.*, which he interpreted as providing "evidence tending to show that vaccines did contribute to significantly aggravate subclinical autoimmunity into overt MS among the examined population." *See id.* at 24 n.11 (citing Annette Langer-Gould *et al.*, *Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 71 JAMA Neurol. 1506 (2014) ("Langer-Gould") (ECF 57-10)). The Special Master thus issued a Ruling on Entitlement and a Decision based on a theory of injury (MS) and a theory of causation (significant aggravation) that Petitioner never advanced in her expert reports or briefing.[4] The Special Master placed the date of Petitioner's condition "approximately 60 days following her … polio vaccination and 42 days following her … Tdap vaccination." *Id.* at 29.

DISCUSSION

The Special Master's resolution was erroneous for at least two reasons.

First, it was unfair to the parties and frustrates this Court's review. Although the formal requirements of this Court's Rules and the Federal Rules of Civil Procedure and Evidence do not apply to proceedings before the special masters, *see* 42 U.S.C. § 300aa-12(d)(2); RCFC App. B, Rule 8(b)(1), the special masters *are* bound by an obligation to be fair to both parties, and to provide both parties the opportunity to present a case. *See* RCFC App. B, Rule 8(b)(1) ("In receiving evidence, the special master … must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties."); *id.* Rule 3(b)(2) ("The special master is responsible for … affording each party a full and fair opportunity to present its

[4] Petitioner even conceded before the Special Master that "the studies cited by Dr. Steel do not involve vaccines triggering MS[.]" Reply Mem. at 4.

case[.]"); *see also Dickerson v. Sec'y of Dep't of Health & Hum. Servs.*, 35 Fed. Cl. 593, 598 (1996) ("[T]he Court of Federal Claims has promulgated rules of procedure for use by special masters governed by the principles of fundamental fairness to both parties."). The special masters must also conduct their proceedings in a way that "create[es] a record sufficient to allow review of" their decisions. *See* RCFC App. B, Rule 3(b)(2). Given those principles, this Court has required special masters to give parties notice and an opportunity to comment on the evidence and issues the special master considers. *See, e.g.*, *Davis v. Sec'y of Health & Hum. Servs.,* 94 Fed. Cl. 53, 65–66 (2010).

The Special Master failed to do so. As explained, the Special Master adopted a theory of injury and causation that Petitioner never advanced and that does not appear to have been obvious from the evidence submitted. *Compare Sword v. United States*, 44 Fed. Cl. 183, 190 (1999) (finding no surprise where "the Special Master's explanation was hardly out of left field"). As a result, the government never had its opportunity to explain why those theories were mistaken. *Compare Hines ex rel. Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1525–26 (Fed. Cir. 1991) (finding that the special master taking judicial notice of a "[w]ell-known medical fact[]" without "inform[ing] the parties in advance that he intended to do so" did not "violate[] the principles of fundamental fairness" because the objecting party could have raised her concerns on review before the Court of Federal Claims and did not do so) (quotes omitted)*, with Campbell ex rel. Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 781–82 (2006) (finding it "patently unfair" for the special master to rely on extra-record articles of dubious reliability without giving the parties an adequate opportunity to respond to them). To the extent the Special Master relied on evidence in the record, the government addressed that evidence as it related to Petitioner's characterization of her injury, not the Special Master's different characterization. Both parties agree that they were "surprise[d]" — Petitioner's word — by the Special Master's decision to treat this case as one of significant aggravation of an existing condition. Pet.'s Mem. in Resp. to Resp's. Mot. for Rev. ("Pet.'s Resp.") at 1 (ECF 89). And because of the lack of adversarial development of the Special Master's theory, I cannot be sure that the record is adequate for review.

Second — possibly because of the departure from ordinary adversarial processes — the Special Master's Ruling misinterpreted its primary medical authority, the Langer-Gould study. A summary of that study will show why.

The Langer-Gould investigators used the records of a large health system to investigate the association between vaccinations of any type and central nervous system demyelinating conditions, including MS. Langer-Gould at 2. The investigators

bifurcated their findings between patients younger than 50 and those 50 or older. *Id.* at 3.

The investigators expressed the association between vaccination and conditions such as MS in terms of an odds ratio, plus a 95% confidence interval, for developing demyelinating conditions during different time periods (up to three years) after vaccination. *Id.* at 3, 6 (Figure 2). An odds ratio is a way of expressing the relative risk of a condition in a "case" group exposed to a given factor versus a "control" group that was not exposed. Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 568 (3d ed. 2011). "An odds ratio of 1 indicates no association" between the disease and the factors investigated: The risk of the disease is the same whether the group was exposed or not. *Id.* at 291. "A confidence interval is a range of values within which the true value is likely to fall." *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 229 (2021) (quotes and alterations omitted) (quoting *Reference Manual on Scientific Evidence* 621). "By definition, when a statistician uses a 95% confidence interval, that statistician estimates that a sample to be drawn from the population will fail to capture the mean population 1 out of 20 times." *Lax v. APP of N.M. ED, PLLC*, CIV No. 20-264 SCY/JFR, 2022 WL 715735, at *8 n. 9 (D.N.M. Mar. 10, 2022). A confidence interval that straddles an odds ratio of 1.0 is "statistically insignificant," meaning that it is statistically indistinguishable from *no* change in risk. *Germaine*, 155 Fed. Cl. at 228–29 (citation omitted) (quoting *Reference Manual on Scientific Evidence* 621) (discussing the related concept of relative risk).

Looking at all types of vaccines combined, the investigators found no association between vaccinations and MS. For every time period after vaccination, the confidence interval for developing MS straddled an odds ratio of 1.0. Langer-Gould at 6 (Figure 2). There was one statistically significant association between vaccines and the broader universe of demyelinating conditions — an odds ratio of 2.32, with a confidence interval of 1.18 to 4.57 — but only for patients under age 50, and only within 14 days of the vaccine. *Id.* There was no association between vaccines and demyelinating conditions for patients 50 or older for any time period post-vaccination. *Id.* For patients younger than 50, the association between vaccinations and demyelinating conditions disappeared after 14 days. *Id.*

In short, Langer-Gould found no association between MS — the condition the Special Master identified as Petitioner's injury — and vaccinations. The only association found involved demyelinating conditions generally, *i.e.*, conditions *other* than the demyelinating condition Petitioner has. Even if there were an association between Petitioner's personal condition and vaccinations, it did not exist for patients in Petitioner's age group, only younger patients. And even if there were an association for her age group, the effect disappears soon after vaccination, such that there is no

association between vaccinations and demyelinating conditions for *either* age group at the time the Special Master found Petitioner's symptoms in fact developed. In short, there is no way to look at the study's data and find an association between vaccinations and Petitioner's own condition.[5]

Although there can be association without causation, there cannot be causation without association. *See, e.g.*, Olaf M. Dekkers, *The Long and Winding Road to Causality*, 34 European J. of Epidemiology 533 (2019) ("[T]he fundamental prerequisite before judging causality is the presence of an association. …. In short: no causation without association."); *Handbook of Causal Analysis for Social Research* 285 (Stephen L. Morgan ed., 2013) ("Typically, all we can observe in data is whether or not two or more variables are associated, either unconditionally or after conditioning on some other set of other variables. Causality is not observed but must be inferred from these associations. … [I]f two variables are causally related, they must be associated. As the old adage goes, 'no causation without association.'").[6] The fact that the Langer-Gould study shows no association relevant to Plaintiff means that it does not evidence causation: A finding of causation would have to be *despite* the Langer-Gould study, not *because* of it. It was therefore error for the Special Master to treat the Langer-Gould study as supporting Petitioner's proof of causation.

The Special Master's Ruling acknowledged that Langer-Gould "found no long-term association between vaccination and MS," Ruling at 23, but dismissed the point as "only a statistical observation" because a possible mechanism for causation — specifically, "vaccine involvement as an inflammatory cofactor" — might hypothetically take effect later than 30 days after vaccination or in patients older than 50. *Id.* at 24 & n.11, 30. That hypothesis, however, is not *evidence*; it was a *theory* the Langer-Gould study was supposed to test by looking for an association. The Special Master was not permitted to adopt a hypothesis as a theory of causation without evidence to support it. *See Germaine*, 155 Fed. Cl. at 227–28 (citing *Knudsen*, 35 F.3d at 549, and *Boatmon*, 941 F.3d at 1360). And the Langer-Gould study, again, provided no such evidence: It found an association in some circumstances, but not circumstances like Petitioner's.

One might argue that the study supports an inference of causation in the limited circumstance where there was a statistical association. But because association is a prerequisite for conclusions about causation, the Langer-Gould study

[5] Dr. Sriram raised some of these points in a supplemental report. *See* Sriram Rebuttal Report at 5.
[6] *But see* Stephen L. Morgan & Christopher Winship, *Counterfactuals and Causal Inference: Methods and Principles for Social Research* 447 n.9 (2d ed. 2015) (noting "cases for which this may not be true, such as when individual-varying causal effects perfectly cancel out each other or when suppression effects exist").

provides *no* support for a hypothesis of causation in circumstances where an association was lacking. *See Broekelschen*, 618 F.3d at 1345 ("[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case[.]"). To dismiss that finding as a "statistical observation" thus misunderstands what the Langer-Gould study was investigating and the conclusions it reached.

That is not to say that the Langer-Gould study *disproves* causation in Petitioner's case. Scientific studies sometimes yield different results, so perhaps some other study shows an association that Langer-Gould did not. When scientific studies differ, the proper course is to weigh them, in which case a special master's conclusions about inconsistent medical evidence would be upheld unless arbitrary or capricious. *See Broekelschen*, 618 F.3d at 1349; *Greene v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 655, 665, *aff'd*, 841 F. App'x 195 (Fed. Cir. 2020); *Moreno v. Sec'y of Dept. of Health & Hum. Servs.*, No. 95–706V, 2005 WL 6120645, at *6–7, 9–10 (Fed. Cl. 2005). Likewise, the Federal Circuit has made clear that published research is not strictly necessary to show causation in the first place. *See Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009); *Althen* 418 F.3d at 1280. But when the Court or a special master *does* resort to medical literature, a study's findings must be interpreted using correct statistical methods — just as its words must be assigned their correct common or technical meanings.[7]

Because of the importance the Special Master attached to the Langer-Gould study and the government's lack of opportunity to respond to the Special Master's treatment of the rest of the record, I cannot conclude that the Special Master's errors are harmless. *See Davis,* 94 Fed. Cl. at 65–66. But for the same reason, the record is insufficient for me to issue new findings. 42 U.S.C. § 300aa-12(e)(2)(B); RCFC App. B, Rule 3(b)(2). The best course is therefore to remand for further proceedings. 42 U.S.C. § 300aa-12(e)(2)(C). On remand, the Special Master should give the parties the opportunity for briefing — and, if appropriate, new written or live evidence — on

[7] Another possible error in the Special Master's Ruling deserves brief attention. The Special Master wrote that his conclusion about the Langer-Gould study was "consistent with petitioner's burden of proof for a significant aggravation claim" because "Petitioner need only demonstrate that her vaccination affected her condition; she does not have a burden to demonstrate that her ultimate condition is worse than her expected outcome." Ruling at 24–25 (citing *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1081 (Fed. Cir. 2020)). As the parties agree, that is not the law for causation. Resp's. Mem. in Supp. of Mot. for Rev. at 9 (ECF 86-1); Pet.'s Resp. at 5–6. Petitioner argues that in context, the Special Master meant to refer to the standard for aggravation of injuries. Pet.'s Resp. at 6–7. I find the Ruling's language too cryptic to be sure. Be that as it may, the Special Master should use the correct standard on remand.

whether Petitioner's vaccinations aggravated her MS. The Special Master should interpret the medical evidence under the correct legal and scientific standards.

CONCLUSION

For the foregoing reasons, the government's motion for review is **GRANTED** and the Special Master's Decision (ECF 83) is **VACATED**. The case is **REMANDED** for the Special Master to consider the parties' arguments on aggravation of MS and to re-evaluate the medical evidence under the correct legal and scientific standards. The Special Master shall issue a new entitlement decision within **ninety days** of this decision. *See* 42 U.S.C. § 300aa-12(e)(2); RCFC App. B, Rule 28(b).

IT IS SO ORDERED.

s/ Stephen S. Schwartz
STEPHEN S. SCHWARTZ
Judge