

In the United States Court of Federal Claims

No. 17-642V

(Filed: December 16, 2022)*

(Reissued: January 6, 2023)

FOR PUBLICATION

ELIZABETH DOLES, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Benjamin Alexander Christian, Maglio Christopher & Toale Law Firm, Sarasota, FL, for Petitioner. With him on briefs was *Jennifer Anne Gore Maglio*, Maglio Christopher & Toale Law Firm, Sarasota, FL.

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

OPINION AND ORDER

Petitioner Elizabeth Doles experienced various neurological symptoms after receiving two vaccinations. 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 First Decision Awarding Damages (“First

* This Opinion was issued under seal on December 16, 2022. The parties were directed to propose redactions by December 30, 2022. No proposed redactions were submitted. The Court hereby releases publicly the Opinion and Order of December 16 in full.

Decision”) at 2 (ECF 83). The government moved for review, and I remanded to the Special Master for additional proceedings. *See Doles v. Sec’y of Health & Hum. Servs.*, 159 Fed. Cl. 241 (2022). On remand, the Special Master again awarded damages. *See* Special Master’s Decision on Remand (“Second Decision”) at 2 (ECF 102). The government moved for review once more, arguing that the Special Master misconstrued the record, committed legal error, and reached a decision that was arbitrary and capricious. The case has been fully briefed and I have heard oral argument.¹ I **REMAND** for additional proceedings and **ORDER** that the case be reassigned to another Special Master.²

BACKGROUND

I. The Vaccine Act

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

¹ U.S. Mot. for Review of Decision on Remand (“Second Mot. for Review”) (ECF 105); Pet.’s Resp. to Mot. for Review of Decision on Remand (“Second Resp.”) (ECF 109); Tr. (ECF 112).

² 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).

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 1278.³ Although the petitioner’s burden does not “require identification and proof of specific biological mechanisms,” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994), “a ‘plausible’ or ‘possible’ causal theory” is 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.”). A theory of causation must be supported by medical records or an expert’s opinion. *Althen*, 418 F.3d at 1279 (citing 42 U.S.C. § 300aa-13(a)(1)).

II. Procedural and Factual History

The relevant facts and history of the case are fully presented in my previous opinion. *Doles*, 159 Fed. Cl. 241. Briefly, Petitioner 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 claimed that her vaccines “actually caused, or, alternatively, significantly aggravated” her injury. *Id.* 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, and focal myelitis or transverse myelitis (“TM”), among others, *see Steel Rebuttal Report* at 2 (ECF 57-2) — so Petitioner presented experts to explain her theory of injury in more detail.

³ 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).

Her main expert, Dr. John G. Steel, submitted reports arguing that Petitioner 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's vaccines "unmasked" her MS, "i.e. caused it to become clinically significant during her medical evaluation." Steel Report at 3. But while his opinions are at least somewhat ambiguous, he seems to have meant (at least in part) that Petitioner's MS put her at heightened risk for TM when she received vaccinations: "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; *see also id.* at 1–2, 6–7.

Defendant submitted an expert report from Dr. Subramaniam Sriram, who agreed with Dr. Steel that Petitioner has MS, 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 original 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 Conclusions of Law ("First Reply Mem.") at 2 (ECF 72). Petitioner 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); First Reply Mem. at 2.

In his entitlement ruling, the Special Master — who resolved the parties’ arguments on the papers, without a hearing — considered whether Petitioner’s condition “constitutes a manifestation of petitioner’s overall course of MS, as respondent contends, or a separate attack of TM, as petitioner contends[.]” Ruling at 19–20. The Special Master adopted what he considered to be the government’s view and rejected what he considered to be Petitioner’s view: “An examination of petitioner’s clinical history ... show[s] this case to be one of significant aggravation of petitioner’s pre-existing MS rather than including any separate attack of TM as argued by petitioner.” *Id.* at 19. In so doing, the Special Master rejected “Dr. Steel’s assertion of a separate attack of TM,” which the Special Master thought “does not appear on this record to be consistent with the way in which the medical community understands these conditions.” *Id.* at 20.

The Special Master stated that Dr. Steel had “opined a causal relationship between vaccines and myelitis only.” *Id.* at 14. But the Special Master found that Dr. Steel’s understanding of the relevant conditions was “at odds with” one of Dr. Steel’s main authorities. *Id.* at 21 (discussing Elliot M. Frohman & Dean M. Wingerchuk, *Transverse Myelitis*, 363 N. Engl. J. Med. 564 (2010) (“Frohman & Wingerchuk”). The Special Master referred to Dr. Steel when spelling out his conclusions about aggravation of MS, but did not explicitly ground those conclusions in Dr. Steel’s causation opinions. He found it most significant, rather, that Dr. Steel opined that “MS can be conceived as a disorder of immune regulation” with a “multifactorial” etiology. *Id.* at 22–23, 24. The Special Master went on to conclude that Petitioner was entitled to damages for aggravation of her MS.

Because the Special Master surprised the parties in characterizing Petitioner’s injury as aggravation of MS, it violated fundamental fairness and frustrated this Court’s review. *See Doles*, 159 Fed. Cl. at 247. I therefore ordered 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.” *Id.* at 249.

Neither party presented new evidence on remand, and the Special Master did not hear testimony. *See Second Decision* at 6. The Special Master again concluded that Petitioner was entitled to damages for aggravation of MS. But this time, the Special Master expressly rooted his findings in Dr. Steel’s opinions: “Dr. Steel’s medical opinion has been consistent in identifying a significant aggravation of petitioner’s MS, notwithstanding his further references to [TM].” *Id.* at 7. He found that Dr. Sriram had correctly characterized Dr. Steel’s opinions, *id.* at 9 (“Dr. Sriram, fully understood Dr. Steel’s opinion.”); *id.* at 10 (“Dr. Sriram correctly paraphrased Dr. Steel Dr. Sriram understood that Dr. Steel had offered an opinion that petitioner’s vaccines had acted upon her MS disease process.”). He also found that

“Dr. Steel cites to researchers who have included statements in their papers expressing views consistent with the theory offered by Dr. Steel in this case,” including Frohman & Wingerchuk. *Id.* at 33.

The government moved for review once more.

DISCUSSION

The Special Master’s new decision roots his causation finding primarily in Dr. Steel’s opinion. The government argues that the Special Master erred because Dr. Steel, contrary to the Special Master’s finding, did not opine in support of the Special Master’s conclusions about aggravation of MS. Second Mot. for Review at 14–16. The question at this phase of the case is what to do with the Special Master’s interpretation of Dr. Steel’s reports.

The general contours of the standard of review are settled. To obtain relief under the Vaccine Act, a petitioner must support a theory of injury with medical records or expert opinion. *Althen*, 418 F.3d at 1279 (citing 42 U.S.C. § 300aa-13 (a)(1)). This Court may set aside a special master’s factual conclusions as “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 42 U.S.C. § 300aa-12(e)(2)(B). When the special master’s findings of fact are “supported by substantial evidence,” they must be upheld. *Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010).

That standard — which applies to special masters’ interpretations of expert opinion — is “well understood to be the most deferential possible.” *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). Yet it obligates special masters to articulate the reasons for their decisions. Here, whatever interpretations of Dr. Steel’s reports might be conceivably defensible, the Special Master’s interpretation departs from that in his original ruling. But the Special Master did not acknowledge the difference or explain why he adopted a different reading on remand. Because he did not do so, there is no way to review his findings, and they must be set aside.

The Special Master’s duty to explain his changed interpretation flows from several different sources. The Vaccine Act’s “arbitrary and capricious” standard of review is borrowed from the Administrative Procedure Act (“APA”) and is similar in substance. *See Hines on Behalf of Sevier v. Sec’y of Dep’t of Health & Hum. Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991); *see also, e.g., McCarren v. Sec’y of Dep’t of Health & Hum. Servs.*, 40 Fed. Cl. 142, 145 (1997); *Skinner v. Sec’y of Dep’t of Health & Hum. Servs.*, 30 Fed. Cl. 402, 408 (1994). Among other aspects of the APA standard, it is arbitrary and capricious to change positions without explanation: “[A]n ‘unexplained

inconsistency’ ... is ‘a reason for holding an interpretation to be an arbitrary and capricious change[.]’” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (quoting *Nat. Cable & Telecomms. Assn. v. Brand X Internet Servs.*, 545 U.S. 967, 981–982 (2005)) (alteration omitted); see also *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (“[T]he requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it is changing position.”); *Towne v. United States*, 106 Fed. Cl. 704, 710 (2012) (collecting cases). The same is true when agencies change position on remand. See *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1908 (2020) (explaining that new agency action on remand has to comply with applicable procedures). If it is arbitrary and capricious for an agency to change its position without explanation, the same should be true when the standard applies to a special master.

Making a similar point from a different direction, the Federal Circuit has explained that decisions of special masters are *not* arbitrary and capricious if they articulate a rational basis for their conclusions and are supported by substantial evidence. See, e.g., *Hines*, 940 F.2d at 1528. If a special master does not explain why his interpretation of the record contradicts his earlier interpretation, he has not fully articulated a rational basis supported by substantial evidence.

Moreover, a special master is not ordinarily free on remand to contradict prior factual conclusions that have not been disturbed on review in this Court. In *Kottenstette v. Secretary of Health & Human Services* — much like in this case — the Court of Federal Claims remanded a case to a special master “for the limited purpose of reconsideration under the correct legal standard[.]” 861 F. App’x 433, 442 (Fed. Cir. 2021) (internal quotations omitted). On remand, the special master “reweighed the facts to come to contrary findings ... despite declining to reopen the evidentiary record.” *Id.* The Federal Circuit (in an unpublished decision) concluded that was error. *Id.*

The Special Master seems to have changed his interpretation of Dr. Steel’s opinions. In the original ruling that vaccines had aggravated Petitioner’s MS, the Special Master appeared to fault Dr. Steel for opining that Petitioner had experienced an attack of TM distinct from MS. Ruling at 20. The Special Master characterized Dr. Steel’s opinion as extending to “myelitis only,” *id.* at 14, consistent with what the Special Master took to be Petitioner’s overall argument that her condition “constitutes ... a separate attack of TM” rather than “a manifestation of petitioner’s overall course of MS[.]” *Id.* at 19–20.

In the remand decision, the Special Master now interprets Dr. Steel as having opined that Petitioner experienced TM as an aggravation of her MS. Second Decision at 7. That is different from the Special Master's earlier view that Dr. Steel treated the two conditions as separate and opined only on the former. The Special Master even seems to have changed his view of whether Dr. Steel's opinion is supported or contradicted by the same published authority. *Compare, e.g.*, Ruling at 21 (stating Dr. Steel's opinion was "contrary to" study by Frohman & Wingerchuk), *with* Second Decision at 21 (stating Dr. Steel's opinion was supported by Frohman & Wingerchuk). Before, the Special Master seems to have found that vaccines aggravated Petitioner's MS *in spite of* Petitioner's different medical characterization. Now, the Special Master enlists Petitioner's expert to *support* the same causation finding.

Those readings of Dr. Steel's opinions are difficult to square. Petitioner argues that the two opinions are consistent and that the remand opinion simply "offers more detail as to [the Special Master's] thought process in getting from A to B." Tr. at 55. But "[s]quint as [I] may," *see Microsoft Corp. v. IAI Ltd. P'ship*, 564 U.S. 91, 104 (2011), the more natural reading is that the Special Master's findings in fact changed. Petitioner also argues that the Special Master was entitled to adopt a theory of causation supported by medical literature and consistent with her medical records even if no expert opined in support. Tr. at 45–46. Even if that is true, the Special Master chose to rely on his characterization of Dr. Steel's opinions, so his opinion should be reviewed on that ground too.

The Special Master has not explained the shift. Such unexplained changes on remand, as mentioned above, are arbitrary and capricious, frustrate this Court's review, and exceed the scope of the Special Master's authority on remand. When the Special Master's findings are contradicted by his own prior findings on the same record, there is no way to determine whether his substantive conclusions are arbitrary and capricious, or whether they are supported by substantial evidence. The Special Master's opinion should therefore be vacated.

Although I find that the Special Master's change of position is arbitrary and capricious, I "make no determination on the weight of the objective evidence in the record or whether that evidence establishes" preponderant evidence of causation, "for these are factual findings for the Special Master and not this court." *Cottingham on Behalf of K.C. v. Sec'y of Health & Hum. Servs.*, 971 F.3d 1337, 1347 (Fed. Cir. 2020). The question of what Dr. Steel's opinion actually was, and whether Petitioner has established a theory of causation by preponderance of the evidence, remain questions for a special master.

At the same time, it appears to me that the record could benefit from review by fresh eyes. “Albeit with the best of intentions,” *see Regents of Univ. of California v. Credit Suisse First Bos. (USA), Inc.*, 482 F.3d 372, 380 (5th Cir. 2007), the Special Master’s review of the record has yielded apparently contradictory interpretations of essential evidence. On remand, a different special master should consider the record anew. *See* RCFC App. B, Rule 3(d) (authorizing reassignment “[w]hen necessary for the efficient administration of justice”); *cf. Contreras v. Sec’y of Health & Hum. Servs.*, 844 F.3d 1363, 1369 (Fed. Cir. 2017) (suggesting reassignment, under circumstances different from this case, where “fundamental fairness [was] best served by assigning the case to a different special master on remand”).

CONCLUSION

For the foregoing reasons, the government’s motion for review is **GRANTED** and the Special Master’s Decision (ECF 102) is **VACATED**. The case is **REMANDED** to the Office of Special Masters for further proceedings consistent with this opinion. The Office of Special Masters is **DIRECTED** to reassign the case to another special master. *See* RCFC App. B, Rule 3(d). The new special master shall review the record, order any necessary supplemental briefing from the parties, and 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). The evidentiary record shall not be supplemented on remand.

IT IS SO ORDERED.

s/ Stephen S. Schwartz
STEPHEN S. SCHWARTZ
Judge