

(the “Order”). I have thus repeatedly considered whether (under the preponderant legal standard utilized by the test set by the Federal Circuit in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)) the flu vaccine “can cause” narcolepsy, but have determined the theory to be scientifically unreliable (even if some elements of proof offered in favor of the theory are credible)—and the analysis I have employed in reaching that conclusion has been affirmed.

I therefore ordered Petitioners to show cause why this claim should not be dismissed. In so doing, I encouraged them to identify what *new* scientific or medical findings bearing on the subject should reasonably be taken into account in determining whether the present claim was more likely to succeed than prior claims involving what appeared to be the same rejected theory. Order at 2. If Petitioners were able to marshal evidence not previously considered, but which filled in some of the evidentiary “holes” that had prevented me in the past from finding the causation theory preponderantly established, they might provide grounds for another look at the issue. (Although Petitioners were given the opportunity to consult with an expert in their attempt to identify any *new* scientific or medical findings, my Order specifically directed Petitioners to *not* file an expert report at that time. *Id.*)

In response, Petitioners filed a brief on January 4, 2024. Brief, dated Jan. 4, 2024 (ECF No. 20) (“Br.”). In it, they note that they had engaged Michael Lacey, M.D., who reviewed their amended petition, the written “Letter of Plausibility” authored by Dr. Emmanuel Mignot,³ as well as the three Vaccine Program decisions (referenced in my Order to Show Cause) discussing the absence of preponderant evidence that the non-adjuvanted version of the flu vaccine routinely administered to children in the United States can cause type 1 narcolepsy. Br. at 7. Dr. Lacey did not provide his own written statement on the matter, but instead expressed his overall opinions which were then summarized by Petitioners’ counsel in their responsive brief.

Dr. Lacey stated that “[i]t is a fact that [n]eurological autoimmune phenomenon of all sorts have been observed following [a] myriad [of] viral conditions—including acute infections of influenza . . .” Br. at 7. He then appeared to briefly discuss the pitfalls of a study I have discussed in detail in prior decisions, Duffy⁴—noting that the study’s “conclusions are based on a large survey of data, not a survey of all patients” and thus “ignores the fact that isolated cases of rare phenomenon often exist (and are not reported), . . .” *Id.* at 8. Dr. Lacey further opined that Duffy “is actually a retrospective analysis of data collected without regard to controls and therefore is more properly referred to as a ‘Survey’ of a body of data,” meaning that it lacks definitiveness. *Id.*

³ Dr. Mignot, one of B.H.B.’s treating physicians, had earlier in the case offered a brief written statement regarding the medical plausibility for a vaccination-triggering cause of type 1 narcolepsy. *See generally* Ex. 7 (ECF No. 9-7) (“Letter”).

⁴ Dr. Lacey did not provide a citation to the Duffy Study, but a discussion of its relevance to this type of claim can be found in *McCullum v. Sec’y of Health & Hum. Servs.*, No. 14-709V, 2017 WL 5386613, at *17–18 (Fed. Cl. Spec. Mstr. Sept. 15, 2017), *mot. for review den’d*, 135 Fed. Cl. 735 (2017), *aff’d*, 760 Fed. Appx. 1003 (Fed. Cir. 2019).

Petitioners also maintain that the relevant evidentiary standard for establishing the “can cause” *Althen* prong has been met, based on Dr. Lacey’s review of the relevant materials and Dr. Mignot’s opinions. Br. at 8–9. Petitioners argue they can show that B.H.B.’s onset of narcolepsy symptoms occurred less than thirty days post-vaccination, and emphasize the fact that B.H.B. carries a certain genetic component common to the majority of individuals suffering from narcolepsy. *Id.* at 9. Accordingly, Petitioners contend Dr. Lacey’s comments and opinions offer the evidence previously missing from the earlier cases I have decided. *Id.* Petitioners did not otherwise offer any more recent scientific/medical publications, however.

ANALYSIS

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). There is no Table claim involving narcolepsy as the injury, and thus Petitioners may only advance a causation-in-fact claim.

Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “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*, 592 F.3d at 1322 n.2; see also *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in the Federal Circuit’s decision in *Althen*, 418 F.3d at 1278: “(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 proximate temporal relationship

between vaccination and injury.” The failure to meet just one of the three prongs is sufficient basis for a claim’s dismissal. *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff’d*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

As noted above (and as I specifically informed the parties in issuing my show cause order), I have repeatedly determined that the nonadjuvanted form of the flu vaccine administered in the U.S. (and regardless of administration form) has not been preponderantly established to likely

cause narcolepsy. *See generally D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (involving Flumist/nasal spray vaccine), *mot. for review den'd*, 2017 WL 2729570 (Fed. Cl. Mar. 2, 2017), *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018); *McCollum v. Sec'y of Health & Hum. Servs.*, No. 14-790V, 2017 WL 5386613 (Fed. Cl. Spec. Mstr. Sept. 15, 2017) (involving inactivated, intramuscularly-administered form of vaccine), *mot. for review den'd*, 135 Fed. Cl. 735 (2017), *aff'd*, 760 F. App'x 1003 (Fed. Cir. 2019). Other special masters have reached the same conclusion. *Dougherty v. Sec'y of Health & Hum. Servs.*, No. 15-1333V, 2018 WL 3989519 (Fed. Cl. Spec. Mstr. July 5, 2018), *aff'd*, 141 Fed. Cl. 223 (2018). And this summer, the Federal Circuit again concurred with my reasoning, which had resulted in dismissal of a case on the papers rather than after hearing. *Kalajdzic*, 2024 WL 3064398, at *2.

These determinations are of course not binding on the outcome herein. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). But they are persuasive guidance, and they stand as significant obstacles to the claim that the flu vaccine can cause narcolepsy. What is left is the *possibility* that a theory comparable to what is alleged herein could work—but to turn that possibility into a preponderant showing, a claimant would need to marshal arguments and proof *different* from what has been considered so many times before.

Here, and despite due opportunity,⁵ Petitioners have offered no new/different scientific or medical findings that would increase the likelihood that Petitioners can meet their burden of establishing that the flu vaccine “can cause” narcolepsy. Rather, Drs. Lacey and Mignot cite to studies⁶ that have previously been discussed in other decisions where the same/similar theory has been proposed. *See, e.g., McCollum*, 760 F. App'x 1003, 1007; *D'Tiole*, 2016 WL 7664475, at *20–23, *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018); *Kalajdzic*, 2024 WL 3064398, at *3. Nor have Petitioners shown in their briefing that prior determinations that causation was not preponderantly established were in error, or otherwise that independent evidence offered in this case is more supportive of the causal theory. Submission of a “new” expert report from a “new” expert is not enough, especially if that report simply repeats arguments that have been found wanting before.

I do not question Petitioners’ good-faith belief in their claim, and I credit their desire to protect and care for B.H.B. But the context of this case mandates dismissal, since it merely offers

⁵ I initially issued my Show Cause Order in late July 2023, and Petitioners responded to it in January 2024, giving them ample time to locate evidence supportive of the theory. I also permitted them to consult with an expert in so doing, and they offered Dr. Lacey’s opinion. Order at 2.

⁶ Dr. Mignot’s Letter does reference two items not previously offered in my prior cases. *See* F. Han et al., *Decreased Incidence of Childhood Narcolepsy 2 Years after the 2009 H1N1 Winter Flu Pandemic*, 73 *Annals Neurology* 560 (2013); H. Wasling et al., *Quality of Life and Procrastination in Post-H1N1 Narcolepsy, Sporadic Narcolepsy and Idiopathic Hypersomnia, A Swedish Cross-Sectional Study*, 76 *Sleep Med.* 104 (2020). But he provides no explanation for or description of these items that would suggest they advance any new propositions different from what I have so frequently considered in other cases, and they have not been filed herein.

a theory not deemed preponderantly persuasive in prior circumstances—and a theory that I have carefully considered in those prior decisions. The Program operates under a crushing case load, and claims that repeat reasonably-rejected causation theories should not be allowed to go to hearing simply because a claimant *hopes* for a different outcome. Special masters rely on their expertise with prior determinations when faced with new cases—and just as they should seek settlement of claims they expect (based on their experience) are likely to succeed, they should dismiss cases that their hard-earned experience tells them are unlikely to succeed.

Accordingly, the Petition is dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.⁷

IT IS SO ORDERED.

/s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁷ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.