In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-884V

JOYCE E. JEFFRIES, *by and through her Power of Attorney* SHERRY JEFFRIES COMPTON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES Respondent.	Chief Special Master Corcoran Filed: October 31, 2023

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Ryan Pyles, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CLAIM[1]

On February 5, 2021, Joyce E. Jeffries, acting *pro se*,[2] filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program"). Petition (ECF No. 1) ("Pet.") at 1. Ms. Jeffries was originally alleged to have experienced Guillain-Barré syndrome ("GBS") following receipt of an influenza ("flu") vaccine on October 18, 2017, with her GBS further aggravated by a second flu vaccine dose administered in November 2018. Pet. at 1. Petitioner later obtained counsel in the matter, and it was conceded that any claim based on the

[1] Because this Decision contains a reasoned explanation for my actions in this case, it must be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The case was filed on Ms. Jeffries's behalf by Sherry Jeffries Compton, who offered a sworn power of attorney to substantiate her capacity to bring the action for the benefit of Ms. Jeffries. *See* Durable Financial Power of Attorney, dated December 10, 2018 (ECF No. 1-4).

2017 vaccination event would be untimely— leaving only a potential significant aggravation claim based on the 2018 vaccination.

I ordered Petitioner to show cause why that alternative claim should not be dismissed, since it did not appear from a preliminary review of the filed records that she could likely establish that Ms. Jeffries's GBS worsened in the wake of the November 2018 vaccination. *See* Order, dated May 4, 2023 (ECF No. 46) ("Show Cause Order"). The parties have both filed briefs to that end. *See* Petitioner's Memorandum, dated June 23, 2023 (ECF No. 47) ("Mem."); Respondent's Brief, dated August 1, 2023 (ECF No. 49) ("Opp."). Now, for the reasons set forth below, I dismiss the case.

I. Factual Background

Ms. Jeffries was born on September 26, 1953 (and was thus 65 years old when she received the vaccine at issue in 2018). Ex. 1. She had a past medical history of acid reflux, peripheral neuropathy, vertigo, and chronic headaches. Ex. 2 at 3. In 2017, she had seen her primary care physician with complaints of right arm and shoulder pain and stiffness, and "frequent dizzy/imbalance spells that occur 2-3 times per week." Ex. 2 at 3–4.

Medical History After 2017 Vaccine Dose

On October 18, 2017, Ms. Jeffries received the flu vaccine. Ex. 1.[3] Almost two months later, on December 14, 2017, she saw a treater for hypertension medication management, but also reported "[r]ight shoulder is back aching, mainly weather related." Ex. 2 at 5.

Later that same month (from December 25th-27th), Ms. Jeffries was hospitalized after reporting "pain in her lower back that she thought at first felt like a kidney infection," and that "seemed to travel up her back all the way up her back into her left neck and left arm," along with weakness, fatigue, and shortness of breath. Ex. 3 at 80, 234. Although she initially displayed strength in her hands and feet, she also felt paresthesias[4] in her feet, and displayed some face asymmetry (with Ms. Jeffries reporting the latter to have been persisting for some time). *Id.* at 81. Peripheral neuropathy was included in her differential upon discharge (although it was also noted in her history on pre-admission). *Id.* at 80, 98. These records make no mention of any formal diagnosis of GBS, however.

[3] I refer in exhibit cites to the references provided after counsel appeared in the case and began to file records. Some of the initial records filed for Ms. Jeffries while the case was *pro se* are duplicative (and references to any others will be by ECF docket entry information).

[4] Paresthesia is defined as "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." Paresthesia, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=37052&searchterm=paresthesia (last accessed October 12, 2023)

The next-filed medical records are from June 2018, six months later. Ms. Jeffries now returned to the hospital, reporting weakness, fatigue, and some respiratory distress, with onset two days before. Ex. 3 at 403. An exam revealed no neurological deficits other than "muffled" speech. *Id.* at 405. The discharge diagnoses were difficulty swallowing, shortness of breath, throat pain, and "weakness or fatigue." *Id.* at 376–77.

A few days later (June 18, 2018), Ms. Jeffries saw her primary care provider with complaints of difficulty swallowing and breathing, severe headaches, and an inability to stand. She was deemed to possibly be experiencing sepsis,[5] and was instructed to go immediately to the emergency room. Ex. 2 at 7. No records pertaining to the treatment she received at that time were filed, but there are references to what transpired at this time in other records. *See*, *e.g.*, Ex. 5 at 1041 (June 19, 2018 admission history and physical), 1159 (Aug. 27, 2018 record), and 1178 (Sept. 3, 2018 record). It appears (from at least the latter two records) that medical care providers considered the possibility that Ms. Jeffries had been experiencing some form of axonal GBS status in the wake of receipt of immunomodulating infusion treatments like IVIG[6]—although again, nothing filed in the records overall formally confirms that such a diagnosis was ever made in the first place.

Three months later, it appears Ms. Jeffries was admitted to "Midtown Center for Health and Rehabilitation" in Memphis, TN ("Midtown Center") on September 6, 2018. Ex. 5 at 4. A history/diagnostic summary chart from the compilation of 2018 records obtained for this case from Midtown Center report GBS as having been diagnosed that same day (secondary to chronic pulmonary edema) plus other concerns (generalized muscle weakness, anemia, type 2 diabetes, morbid obesity, hyperlipidemia, hypertension, GERD, dysphagia, and difficulty walking). Ex. 5 at 5. That same month (as reported in a record from November 2018), Ms. Jeffries complained of abdominal pain, and had been treated for constipation and a urinary tract infection ("UTI"). *Id* at 1092–93. She was also then evaluated on the Morse Fall Scale, and received a rating of "Moderate Risk for Falling." *Id.* at 424.

There is another gap in filed records for Ms. Jeffries's treatment history through November 1, 2018, at which time a nurse practitioner noted (as memorialized in the history section of a treatment record) that Ms. Jeffries was reporting leg pain and discomfort associated with wheelchair use, with some commentary for the need for her to avoid dependence on the pain

[5] Sepsis, or septicemia, is defined as "systemic disease associated with the presence and persistence of pathogenic microorganisms or their toxins in the blood. Called also blood poisoning and sepsis." *Septicemia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=45415 (last visited October 12, 2023).

[6] "Intravenous Immunoglobulin" is "a therapy treatment for patients with antibody deficiencies. It is prepared from a pool of immunoglobulins (antibodies) from the plasma of thousands of healthy donors." *Intravenous Immunoglobulin (IVIG)*, American College of Rheumatology, https://rheumatology.org/patients/intravenous-immunoglobulin-ivig (last visited October 12, 2023).

medication she was taking. Ex. 5 at 1094. That history also indicated a prior GBS diagnosis. Ms. Jeffries expressed the desire to remain an inpatient at the rehabilitation facility in order to gain strength. *Id.* An exam performed at this time revealed generalized weakness, with specific left lower extremity weakness. *Id.*

Second Receipt of Flu Vaccine in November 2018

On November 5, 2018, Ms. Jeffries received another flu vaccine dose while at Midtown Rehabilitation. Ex. 4 at 1. But records from subsequent periods that month—or even December 2018 for that matter—do not establish any new health concerns or changes in her status. Thus, a November 15, 2018 record memorializes Ms. Jeffries's statement that she believed her existing pain medication regimen was beginning to work. Ex. 5 at 1090. She repeated that view on December 5, 2018, when seen for a routine check-up for a medication refill. *Id.* at 1088. At most, she indicated some ongoing left shoulder pain plus previously-documented bilateral leg pain, and otherwise did not report anything different or heightened from a neurologic perspective. *Id.* However, at this time she was again evaluated on the Morse Fall Scale, and was now rated at "High Risk for Falling." *Id.* at 422.

Two months thereafter, on February 5, 2019, Ms. Jeffries obtained treatment at Midtown Center for a possible UTI, with symptoms occurring over the prior two to three days. Ex. 6 at 1611. She also now reported "pain and feeling a knot on her tailbone," although treatment advice provided in response focused on positional changes to avoid pain associated with being seated or lying down (and thus does not reflect the onset of some truly concerning new neurologic issues). *Id.* A week later, she had another check-in visit for a medicine refill, but with no reports of an increase in or worsening of symptoms. *Id.* at 1609. She also saw the same nurse practitioner on February 13, 2019, to review lab work associated with complaints of dysuria (associated potentially with her UTI). *Id.* at 1635. Records from March 2019 show she was again evaluated on the Morse Fall Scale, but now rated as "Moderate Risk for Falling," one category down from her December 2018 rating. Ex. 6 at 840. Nothing can be discerned from these records that would support the conclusion that Ms. Jeffries's health had taken a turn for the worse—or that the vaccine she had received two months prior had negatively impacted her.

Records from April and May 2019 show that Ms. Jeffries was examined in the context of medication refill requests. Ex. 6 at 1607 (April 2019) and 1603 (May 2019). A history of "chronic pain after developing [GBS]" is referenced—but (once again) no overarching change in her medical status is evident in this record. *Id.* She was later evaluated on the Morse Fall Scale in June 2019, and now received a rating of "Low Risk of Falling," a step down from her previous rating in March 2019. Ex. 6 at 252.

On July 1, 2019, Ms. Jeffries had an initial evaluation with physiatrist Syed R. Ahmed, D.O. Ex. 6 at 1776–78. At this time, she repeated concerns about the kinds of symptoms she complained of before her 2018 (and thus pre-vaccination) rehabilitation hospitalization—leg weakness and tiredness. These are the same symptoms associated with the GBS diagnosis that some records, as discussed above, allude to but do not directly establish. However, the record noted that she had likely experienced "debility" connected to a long in-patient admission. *Id.* at 1776. She also reported "intermittent numbness and weakness in the [bilateral] legs, along with some numbness in the lower back and tingling," plus some arm and shoulder pain. *Id.* Dr. Ahmed assessed her with "ambulatory and ADL dysfunction related to [GBS] with lower>upper limb paresis and neuropathic pain, prolonged hospital course/debility, left trapezius strain." *Id.* at 1777. This record makes no mention of a change in her overall course, or any distinction between her condition pre and post-November 2018 vaccination.

Ms. Jeffries's evaluations in September and October 2019 contained nearly identical observations to those found in the records of earlier visits for medication refills. Ex. 6 at 1594 (August 2019), and 1598 (October 2019). Her August 2019 visit notes that she was hospitalized "due to generalized weakness and difficulty swallowing and was diagnosed with Guillain-Barré Syndrome [sic] to which she has *regained* a large amount of her strength." Ex. 6 at 1594 (emphasis added). Ms. Jeffries was evaluated again on the Morse Fall September of 2019. Ex. 6 at 255 (September 2019). She was again categorized as "Low Risk for Falling." *Id.*

Beyond September 2019, the records contain visit notes from nurse practitioner and physiatrist visits through December 2019. The nurse practitioner's note is nearly identical to previous notes for medication refill visits. Ex. 6 at 1598 (visit on October 9, 2019) The physiatrist's notes are very similar to each other: documenting Ms. Jeffries's medical history, including her GBS diagnosis, and noting continuing issues with back pain. *Id.* at 1724–1773 (physiatrist notes from visits every few days in October 2019 through the end of December 2019.) Recommendations for treating her back pain include the use of ice, creams, changes to her physical therapy regimen, and referrals to specialists. *Id.* Beyond that, Ms. Jeffries had a brief course of foot pain in October 2019. *Id.* at 1728–32.

Besides these records, Petitioner has offered some witness statements[7] to substantiate her claim that Ms. Jeffries experienced worsening after the November 2018 vaccination. *See* Affidavit of Barbara Royals, dated August 22, 2023, filed as Ex. 13 (ECF No. 50-1) ("Royals Aff."); Declaration of Linell Jeffries, dated September 14, 2023, filed as Ex. 14 (ECF No. 51-1) ("Jeffries Decl.").

Ms. Royals reports providing physical therapy ("PT") to Ms. Jeffries in the fall of 2018. Royals Aff. at 1. Ms. Jeffries has trouble with PT "because of her illness," but made a brave attempt

[7] No declaration or sworn witness statement from Ms. Jeffries herself was ever filed in this case.

overall to perform, and began to see improvement (although the specific timeframe in which this was observed is not set forth). *Id.* She eventually completed her exercises, and was even able to take some assisted steps—but then "became too ill and too weak to continue to participate" in PT and was, to Ms. Royal's knowledge, removed from the list of PT patients. *Id.* Thus, Ms. Royals attests to "the sudden marked downturn" in Ms. Jeffries's recovery, but does not mention vaccination or pinpoint a timeframe in which the downturn occurred. *Id.* at 2.

Linell Jeffries is Ms. Jeffries's brother. Jeffries Decl. at 1. He corroborates record evidence establishing that Ms. Jeffries was an in-patient at Midtown Center in September 2018, and received medical treatment and PT in association with unspecified "life-threatening illnesses" she had experienced prior to that time. *Id.* By November/December 2018, however, "it was obvious" that she could no longer complete PT, and proved too weak to leave her bed. *Id.* Mr. Jeffries adds that he learned from a Midtown Center nurse that Ms. Jeffries had "accidentally" received the flu vaccine (although he does not specify when), and that it had been determined that she should not again receive it. *Id.* at 2. Since then, Ms. Jeffries has remained at the Midtown Center—weak, suffering from limb pain, and still confined to bedrest. *Id.* (No additional records were filed in this case, however, that would corroborate that contention).

II. Procedural History

This case was originally assigned to another special master, and at that time it was noted that Petitioner (who began the matter as a *pro se* litigant) needed to file medical records to support her claim. ECF No. 11. Once the case was transferred to me, I pointed out the continued lack of evidentiary support, but also (and as addressed in Respondent's Rule 4(c) Report) that any claim based on an October 2017 vaccination was likely time-barred under the Vaccine Act's three-year limitations period. ECF No. 27. To be a viable Table claim, onset must have occurred no later than December 2017, based on the Petitioner's allegations—and hence the claim in question needed to have been filed before December 2020 (whereas *this case* was begun in February 2021). Pet. at 1–2. However, it seemed possible that a significant aggravation claim based on the alleged subsequent November 2018 vaccination would be viable (given that the case was filed in February 2021, and hence within the limitations period)—*if* proof of that vaccination could be offered. Pet. at 3.

Petitioner thereafter spent an inordinate amount of time attempting to find the missing proof, risking dismissal of the case in the process, but by the end of April 2023 had filed records that did seem to establish *both* the November 2018 vaccination and some evidence of an earlier GBS diagnosis (although as my review of the record above should indicate, it is hardly crystal clear from this record *when* that diagnosis occurred). *See, e.g.*, Ex. 4 at 1; Ex. 5 at 970. But because the alleged aggravation was not similarly evident from the record, I issued a show cause order, and the parties have now responded.

III. Parties' Arguments

Petitioner has offered a two-page brief arguing for the claim's viability. *See generally* Mem. In so doing, she endeavors to identify a cognizable difference in Ms. Jeffries's pre and post-vaccination health. She specifically points to Ms. Jeffries's "fall scale rating," observing that this rating (which presumably is an assessment of the risk of falling) as provided at the time of her Midtown center rehabilitation admission in early September 2018 was lower than in December 2018 (at which time her hospital discharge was also deemed inappropriate). Mem. at 1; Ex. 5 at 424 (December 2018 fall risk rating of 55) and 422 (September 2018 fall risk rating of 35)**.** Thus, the intervening November 2018 vaccination likely worsened her course overall. And she notes her own personal observations of Ms. Jeffries's worsening, although her sworn declaration does not set them forth in any detail.[8] Petitioner's Declaration at 1.

Respondent asks for the dismissal of the Petition. He maintains that the record lacks support (either in the form of a treater view or other record) that Ms. Jeffries experienced a GBS worsening, or secondary relapse or flare, associated with the early November 2018 vaccination. Opp. at 8. In responding to the Show Cause Order, Respondent notes, the Petitioner has identified no new symptomatology that represents a relapse of GBS, nor has she alleged *with particularity* even general symptomatology that reflects post-vaccination. Instead, the record uniformly establishes that Ms. Jeffries remained at her baseline state of health in the months after November 2018. The fact that overall her health remained sub-par is not evidence of worsening sufficient to establish a causation claim of significant aggravation. And Respondent denies that the witness vouching for Ms. Jeffries's worsening can fill the evidentiary holes. *Id.*

IV. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

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.

[8] Rather, Petitioner's declaration only addresses the difficulty she has faced in obtaining Ms. Jeffries's medical records from Midtown Rehabilitation with power of attorney, but does not discuss her health issues as related to the vaccine claim. Petitioner's Declaration at 1–2.

Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9] Although the Vaccine Table only sets forth the claim of GBS occurring after administration of the flu vaccine, the Act would appear also to permit a claim of significant aggravation as well (assuming preexisting GBS could be demonstrated, plus onset in the timeframe set for the Table claim). Section 11(c)(1)(C)(i).

For both Table and Non-Table claims, 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 *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(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."

Each *Althen* prong requires a different showing. 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.

[9] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

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 Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *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"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). 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).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Elements of Significant Aggravation Claim*

Where a petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (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), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

In *Sharpe v. Sec'y of Health & Hum. Servs.,* 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, A Petitioner need not demonstrate an *expected* outcome, but merely that her current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. And a claimant may make out a prima facie case of significant aggravation overall without eliminating a preexisting condition as the potential cause of her significantly aggravated injury (although the Circuit's recasting of the significant aggravation standard still permits Respondent to attempt to establish alternative cause, after the burden of proof has shifted to Respondent). *Id.* at 1083.

C. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical

records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the

accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

D. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

Despite a more-than-fair opportunity, Petitioner has not demonstrated that Ms. Jeffries's GBS was worsened by her November 2018 vaccination. This is a fact determination—the medical records, viewed in their totality, do not establish worsening. The claim thus fails on the second and third *Loving* prongs (or, if viewed solely as a Table claim, relying on the flu vaccine-GBS construction, on Petitioner's fundamental inability to prove significant aggravation).

A threshold issue is whether Ms. Jeffries ever *did* experience GBS—and if so, when. Earlier in the case's life, Petitioner had hoped to establish that the October 2017 flu vaccine Ms. Jeffries had received had caused GBS, with onset occurring "[w]ithin a few weeks" after—

meaning later that same fall. Pet. at 1 ¶3.[10] Such a claim would be untimely, of course, since the case (filed in February 2021) was initiated more than three years after onset. Section 16(a)(2). In fact, the record (at least as filed in the case) suggests little evidence of neuropathic symptoms that could support a GBS diagnosis before late December 2017 (*see,* e.g., Ex. 3 at 80–81, 98, 234). Thus, not only was a claim based on the 2017 vaccination untimely, but the claim itself would likely have failed for other reasons, since it appears onset likely fell outside the Table's three to 42-day timeframe, measured from date of vaccination.

Petitioner therefore limited her claim to the contention that a second flu vaccine dose received the following year worsened Ms. Jeffries's GBS. Certainly a claim based on a November 2018 vaccination and filed in the winter of 2021, as here, would be timely. But the question of the status of Ms. Jeffries's health when she received the second vaccine dose is still pertinent to the claim. GBS is not generally deemed a relapsing or chronic condition, even if it leaves some neurologic sequela in its wake.[11] *See, for example, Blackburn v. Sec'y of Health & Hum. Servs.*, No. 10-410V, 2015 WL 425935 at *21 (Fed. Cl. Spec. Mstr. Jan. 9, 2015) (distinguishing the symptoms of GBS/AIDP from chronic inflammatory demyelinating polyneuropathy, and noting that GBS is typically acute and monophasic). Indeed, if Ms. Jeffries's GBS had occurred in December 2017, she would not *still* be suffering from it almost a year later. And even if the record preponderantly supported the conclusion that Ms. Jeffries experienced GBS a second time, in June or September 2018 (hence eight-plus weeks before vaccination), this would more likely than not be too temporally attenuated to when her worsening manifested to constitute significant aggravation. All these questions weaken the contention that the first *Loving* prong can be met—or, if the claim is considered solely as a Table claim, that Ms. Jeffries was suffering from GBS *at the time* of her November 2018 vaccination.

But even if I assume that Ms. Jeffries only experienced GBS closer in time to her November 2018 vaccination—or that she merely seeks to establish that the vaccine generally "worsened" her health in some nonspecific manner[12] - the record filed in this case does not establish that her condition worsened thereafter. Rather, the evidence clearly preponderates in favor of the conclusion that Ms. Jeffries's health "baseline" was generally poor in the fall of 2018—as much due to her lengthy convalescence as to any lingering neuropathic symptoms – and remained so thereafter, with some occasional "ups and downs," but no general worsening trend.

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[10] This is completely consistent with GBS's understood acute and monophasic character—as well as the fact that a Table GBS claim after receipt of the flu vaccine requires proof of onset no later than 42 days post-vaccination. 42 C.F.R. § 100.3(a)(XIV)(D)

[11] Although there does exist a chronic peripheral neuropathy, chronic inflammatory demyelinating polyneuropathy ("CIDP"), Petitioner does not allege this as Ms. Jeffries's injury—and the record does not support it as a credible explanation for Ms. Jeffries's health issues.

[12] Such a contention would, however, run into the problem of alleging *symptoms* without identification of an actual injury.

That record establishes a history of chronic pain pre-vaccination, with some treater concerns for over-medication as well. Ex. 5 at 1100, 1109, 1094 (November 1, 2018 notes stating "[d]id explain to pt I room that she needs to attempt to step down from her pain meds in an attempt to wean off of them") and 1092 (November 8, 2018 discussion of weaning from 20, to 15, to 10 mg pf Oxycodone every 6 hours, and sister's agreement that Ms. Jeffries "needs to attempt to wean down from meds before discharge home.") Nevertheless, there is also post-vaccination evidence that treatments were providing her some relief. *Id.* at 1088.

Thereafter, records from throughout 2019 emphasize Ms. Jeffries's continuing history of chronic pain, the need for orthopedic interventions for some limb-specific pain, and her medication regimen. *See* Ex. 6 at 1609 (February 2019), 1607 (April 2019), 1603 (May 2019), 1601 (June 2019), 1594 (August 2019), and 1598 (October 2019). The amount of oxycodone Ms. Jeffries took stayed consistent during this time: two 5 mg pills every six hours. *Id.* Notably, this a lower dose than she was taking in the month *before* receiving the vaccine. *See* Ex. 5 at 1100 and 1109 (notes from October 2018 appointments). The August 2019 notes even state that she was hospitalized "due to generalized weakness and difficulty swallowing and was diagnosed with Guillain-Barré Syndrome [sic] to which she has regained a large amount of her strength." Ex. 6 at 1594. Thus, it can be ascertained from the record that Ms. Jeffries's health was overall *not worse* post than pre-vaccination (even if throughout she faced consistent medical issues).

The record also does not establish any notable post-vaccination incident in November or December 2018 that demarcates a decline in Ms. Jeffries's condition. Nor does it establish a second (or third) "flare" of GBS any time after the second vaccination. Of course, GBS *is not characterized* by a remitting/relapsing course in any event. *See, for example, Blackburn*, 2015 WL 425935 at *25 (finding that Petitioner's injury was likely not GBS when the treatment record showed a relapsing course of symptoms). It is therefore not evident how *any* Petitioner would ever demonstrate a vaccine worsened GBS, absent evidence that the vaccination occurred extremely close-in-time to the claimant's onset and/or initial treatment.

Petitioner was provided the opportunity to show—by citation to diagnostic comments in the record or other evidence—that there is reason to proceed with this case. But all she has done is cherry-pick an isolated item or two of evidence—proof relating to a predicted "fall rate" from a pre-vaccination period, or a recommendation to delay discharge – and then propose that proof of worsening is found in this record. But not only are these not contextualized in comparison to the greater medical record I have summarized, they are themselves undermined by evidence from that record that Ms. Jeffries's fall risk actually *improved* post-vaccination and over time. *See,* e.g., Ex. 5 at 422 ("High" fall risk rating in December 2018), and 840 ("Moderate" fall risk rating in March 2019), and 252 ("Low" fall risk rating in June 2019). Such evidence does not preponderantly suggest worsening, given the totality of the evidence as reviewed above.

The witness statements filed in this case are similarly unhelpful in establishing worsening. The Petitioner (Ms. Jeffries's sister) makes a statement describing the difficulty she has faced in obtaining Ms. Jeffries's records from Midtown Rehabilitation Center. The statement does not discuss specifics of any changes in the course of Ms. Jeffries's health in the relevant timeframe. *See* Sherry Compton's Sworn Declaration at 1–2 (ECF No. 41-1). The statements from Ms. Jeffries's physical therapist and brother make only general references to pain and weakness that eventually prevented Ms. Jeffries from getting out of bed. *See* Pet. Ex. 13 and Ex. 14. They are not specific enough, in a temporal sense or by reference to details, to demonstrate any worsening attributable specifically to GBS.

Thus, Petitioner cannot establish under *Loving* prong three that Ms. Jeffries's condition post-vaccination was worse than before (again—applying the exceedingly-generous assumption that as of November 2018 she was *still* suffering from GBS, as opposed at most to its sequelae), and therefore the claim is highly unlikely to succeed—justifying dismissal.

In so holding, I emphasize the more than fair opportunity Petitioner was given to marshal evidence in favor of her claim. This case was filed almost three years ago. Although counsel only appeared for Petitioner in the summer of 2022, she was still provided ample time to obtain relevant records—and then to lay out some evidentiary roadmap to demonstrate why the claim is viable. Instead, she has filed a thin, unpersuasive brief that relies on limited evidence from an overall record that mainly underscores Ms. Jeffries's consistently poor health. It is not improper to dismiss such a claim – where the record establishes only that a covered vaccine was received *in the midst* of treatment of ongoing and persistent concerns about the injured party's health, but not that the party's course spiraled downward post-vaccination.

CONCLUSION

Based on the entire record in this case, I find that Petitioner cannot carry her burden of proof on a claim of significant aggravation based on the November 2018 vaccination at issue, and therefore dismissal of the claim is required. 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.[13]

[13] 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.

IT IS SO ORDERED.

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