In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-285V

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KIMBERLY F. FLOWERS,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: May 8, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

Jeremy McKenzie, McKenzie & Hart, LLC, Savannah, GA, for Petitioner.

Alec Saxe, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

Petitioner Kimberly Flowers filed this Petition on March 13, 2020, alleging that she suffered from Guillain-Barré syndrome ("GBS") as a result of an influenza ("flu") vaccine she received on October 26, 2018. Petition (ECF No. 1) at 1. The case was originally assigned to the "Special Processing Unit" ("SPU"), based on the expectation that a Table claim might be easily established. But a number of disputed fact issues prevented its easy resolution, and the claim was eventually transferred to my regular docket. *See* Order, dated Sept. 6, 2023 (ECF No. 35).

I thereafter issued an Order to Show Cause why the claim should not be dismissed, given my preliminary assessment that onset of Petitioner's GBS appeared to have occurred too close in time to the vaccination date to meet the Table requirement—and that a non-Table claim was also unlikely to succeed, for largely the same reasons. Order, dated Sept. 18, 2023 (ECF No. 37). The parties have now filed responses.

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) 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 in its present form. *Id."*

For the reasons set forth in more detail below, I hereby deny entitlement. The record preponderates in favor of the conclusion that Petitioner's GBS onset occurred too soon post-vaccination to meet the Table timeframe—and given that record, such a short onset would also not be medically-acceptable even under a non-Table, causation-in-fact analysis.

I. Fact History

Prior to the vaccination at issue, Petitioner had experienced a number of health issues. Generally, her history includes obesity, irritable bowel syndrome, hypertension, type 2 diabetes, bipolar disorder, and immune thrombocytopenic purpura—an autoimmune blood platelet deficiency disease for which she received specific treatment. In January 2016 she was diagnosed with a lung neuroendocrine tumor and had a resection, although the tumor proved to be nonaggressive. *See generally* Ex. 8.

In addition, a month before the October 2018 vaccination, Petitioner obtained neurologic treatment for chronic daily headaches she had been experiencing since 2014 but which responded to certain medications specific to neurologic pain. Ex. 8 at 674–75. She also then reported left anterolateral thigh numbness and tingling. *Id.* The neurologist who saw her, Dr. Yi Tsai, deemed the headaches to be likely caused by cervical spondylosis, however, rather than migraine-related (although EMG[2] testing was ordered to more definitively rule out a neuropathic cause). *Id*. at 680–81. Dr. Tsai also proposed that the thigh numbness was attributable to a condition involving sensory nerve compression. *Id*. at 681.

Vaccination and Subsequent Neurologic Symptoms

On October 26, 2018, Ms. Flowers went to the TownPark Advanced Care Center ("TP-ACC") in Kennesaw, Georgia for a "wound check"—a blister on her right breast that she reported had been present for a week, but which had enlarged despite her own home treatment. Ex. 1 at 4–5. Her physical exam was normal and no other symptoms were reported at the visit, with the blister deemed to be the product of a "mild secondary infection." *Id*. at 5–6. Petitioner received the flu vaccine at this time. *Id*. at 9, 13.

There is no immediate contemporary record evidence of any vaccine reaction. However, eleven days later, on November 6, 2018, Ms. Flowers returned to TP-ACC with several complaints, including cough, shortness of breath, and paresthesias she characterized as "tingling all over her

[2] "Electromyography" is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited May 8, 2024).

body." Ex. 2 at 11, 12. She specifically reported not only that these symptoms had begun "shortly after" receiving the flu vaccine, but that (in her view) they had been caused by it. *Id*. at 11, 12. Examination resulted in no specific findings, and Petitioner was discharged with the assessment "adverse affect of flu Vaccine," and directed to visit her primary care physician. *Id.* at 11.

Petitioner went back to TP-ACC on November 8, 2018, now complaining of weakness. Ex. 3 at 4. She specifically stated at this time that "since [her] flu vaccine on 27th (sic) [she] ha[d] been ill with cough, fatigue, severe joint pain and [nausea/vomiting]." *Id*. And although her visit two days prior had not resulted in any adverse findings, she could now barely walk and was experiencing severe pain. *Id*. The physical exam performed at this time confirmed her complaints, revealing both global weakness and a need for assistance in ambulation, although lab work was negative, and Petitioner was discharged with an assessment of "musculoskeletal pain, pruritus." *Id.* at 7, 11.

Suspicion of GBS and Hospitalization

The very next day (November 9, 2018), Ms. Flowers was transported by ambulance to Emory St. Joseph's Hospital's Emergency Room. Ex. 7 at 1. She informed emergency treaters than she had received the vaccine in October, but then (after some symptoms that seemed reflective of an upper respiratory infection) began to experience body pain and generalized numbness/weakness, progressing to the point where she had been unable to walk at all over the prior two to three days. *Id*. at 5; *see also* Ex. 4 at 50 (Petitioner informing treaters of symptoms since vaccination) and 53, 90, 91. She also noted that initial numbness and tingling around her teeth and hands had progressed to her entire body but mostly affecting her lower extremities. *Id*. at 50. The physical exam performed by ER treaters demonstrated only trace deep tendon reflexes ("DTRs") in her lower extremities, but symmetric reflexes in her upper extremities, and her lower extremity motor strength was 3 out of 5. Ex. 4 at 51. Petitioner was admitted to the hospital, with initial treaters expressing concern for the need to "[r]ule out Guillain-Barre syndrome or other neurologic disorder." *Id*. at 52.

During her early hospitalization, Petitioner continued to inform treaters that her symptoms had begun not long after the October vaccination, although they had only become acute shortly before her ER visit. *See, e.g.*, Ex. 4 at 173 (November 10, 2018, neurology note stating that Petitioner "presents due to acute onset of bilateral parethesias/weakness in ascending manner after flu vaccination on 10/27"), 132 (November 13, 2018, nursing note stating petitioner "presented with progressive neurologic decline over 2 weeks post flu shot and acute URI/diarrhea symptoms"). The overall impression was deemed to be attributable to "some kind of demyelinating/inflammatory process." *Id.* at 93.

Petitioner had her first neurology consult with Dr. Ramesh Kumar early on during her in-patient experience, again providing a comparable history (including onset of symptoms right after vaccination) to what she had offered other treaters. Ex. 4 at 103. A neurology-oriented exam

performed at this time revealed normal upper-extremity strength compared to absent lower-limb strength, but only slightly-abnormal reflexes (1+) with no clonus. *Id*. at 105. And a lumbar puncture performed on November 9, 2018, revealed elevated nucleated cells and protein levels. *Id.* at 88. Dr. Kumar assessed Petitioner with "[p]ain/sensory symptoms/leg weakness/gait disorder [status post] flu vaccine in Oct 2018 of unclear etiology," adding that Petitioner's overall presentation was "[n]ot typical for GBS or [Miller Fisher Syndrome] variant," with the reflex condition specifically attributed to possibly chronic diabetes, but that out of an abundance of caution IVIG[3] treatment would be utilized. *Id.*

Petitioner received her first course of IVIG the next day. Ex. 4 at 87. However, the IVIG did not ameliorate her bilateral lower extremity weakness, and on November 12, 2018, it was ceased, and she was instead placed on PLEX[4] (plasma exchange). *Id.* Around this initial treatment period, Petitioner also experienced a seizure on November 10, 2018, and "had a prolonged post ictal period with suspected airway edema." *Id*. Petitioner was intubated, and treaters proposed she had acute posterior reversible encephalopathy syndrome ("PRES").[5] *Id*. at 138.

On November 13, 2018, Ms. Flowers was transferred to Emory University Hospital Midtown for further EEG monitoring and intensive care management, remaining there until the first week of December, when she was discharged to the Shepherd Center, an in-patient rehabilitation center in Atlanta, Georgia. Ex. 4 at 89; Ex. 10 at 534, 554, 1333. Petitioner's initial neurologic work-up from this time memorializes her report that *the same day as vaccination,* she had experienced "gradual weakening to [bilateral lower extremities] that worsened to the point that her husband had to carry her to the restroom," later progressing the point where she sought emergency care earlier that month. Ex. 10 at 554; Ex. 14 at 80.

[3] "Intravenous immunoglobulin," or "IVIG," is a blood product used to treat patients with antibody deficiencies, including neurological disorders. *Clinical Use of Intravenous Immunoglobulin*, NCBI (2005) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (last visited on May 8, 2024).

[4] "Plasma exchange" is defined as "the removal of plasma from withdrawn blood, usually to a greater extent than in plasmapheresis, with retransfusion of the formed elements into the donor; done for removal of circulating antibodies or abnormal plasma constituents. The plasma removed is replaced by type-specific fresh frozen plasma or albumin." *Plasma Exchange*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=73970&searchterm=plasma+exchange (last visited May 8, 2024).

[5] "Reversible Posterior Leukoencephalopathy Syndrome" is defined as "a syndrome resulting from leukoencephalopathy with edema in posterior parts of the occipital and parietal lobes, characterized by headaches, confusion, seizures, and visual disturbances; the brain lesions are most often related to hypertension, and sometimes to use of certain immunosuppressive drugs or to some other cause. Called also posterior leukoencephalopathy s., posteriors reversible encephalopathy s., and posterior reversible leukoencephalopathy s." *Reversible Poster Leukoencephalopathy Syndrome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111286 (last visited May 8, 2024).

Treatment in 2019 and Beyond

Petitioner received ongoing rehabilitation therapy and treatments at the Shepherd Center from December 6, 2018, until February 16, 2019. *See generally* Ex. 5. During her stay, she experienced posterior laryngeal stenosis and required the placement of tracheal stents which were removed before her discharge. *Id*. at 1888. By the time of her release, Petitioner was able to perform all activities of daily living with supervision, and could ambulate with assistance (although she mostly utilized a motorized wheelchair). *Id*. at 1899. Her discharge diagnosis was lengthy, but does seem to accept GBS as explanatory of her presenting symptoms, while including diabetes plus the concurrent, unrelated conditions she experienced during hospitalization, like PRES. *Id.* at 1886.

The next medical record bearing on the claim is from May 2019, when Ms. Flowers saw neurologist Dr. Cui Yang at Kaiser Permanente/Townpark Medical Center. Ex. 14 at 79. The "history of present illness" section from the record of this visit identified "the second day" from vaccination as when Petitioner first began to experience weakness and paresthesias in her extremities." *Id.* It also noted that Petitioner reported since her Shepherd Center discharge that she was still experiencing severe pain. *Id.* at 80. At the same time, however, Petitioner now displayed greater strength in upper and lower extremities, as well as normal reflexes. *Id.* at 83–84. And a sensory exam revealed normal/symmetric response to light touch in all extremities. *Id*. at 84.

In her assessment, Dr. Yang allowed for the *possibility* of GBS attributable to the flu vaccine, but also noted that "normally [GBS] happened days or weeks after getting a vaccination, but her symptoms started one day after her flu shot," which "doesn't fit the typical GBS." Ex. 14 at 87. Also inconsistent with a GBS diagnosis was the fact that Ms. Flowers had displayed in this exam normal reflexes; even though Dr. Yang allowed that Petitioner's reflexes might not have been the same at the time of her hospitalization, GBS was more commonly characterized by persistent DTR deficits, which sometimes never recovered (and usually were a final improvement after treatment). *Id.* And while Petitioner did display elevated protein levels after her lumbar puncture, other imaging performed in the course of Petitioner's treatment had not revealed the presence of inflammation or other corroborative factors. *Id.*

Dr. Yang subsequently recommended an NCS/EMG study to look for "evidence of GBS (demyelinating features), [l]arge fiber [d]iabetic neuropathy or cervical/lumbar radiculopathy." Ex. 14 at 87. That study was performed in mid-June 2019, and revealed abnormal results, with "electrophysiological evidence of a generalized length-dependent sensorimotor polyneuropathy, affecting the lower extremity, which is predominately axonal loss in type, and severe in degree electrically." *Id.* at 121–29. But these findings were interpreted by Dr. Yang to be consistent with polyneuropathy seen in diabetes mellitus, rather than to reveal "typical demyelinating features" of a condition like GBS. *Id*. at 123–24. As treatment, Dr. Yang proposed "diabetes control/rule out other treatable causes/symptomatic treatment, plus pain management and PT, with a neurologic follow-up

later. *Id.* at 124.

Records for treatment obtained in 2020 largely reflect concerns about diabetes-associated symptoms. *See, e.g.*, Ex. 15 at 54, 57–58 (February 2020 visit with primary care physician), 117–18 (April 2020 telehealth call), 153–54 (July 2020 visit to primary care physician). But no mention was made in this time period of Petitioner's GBS, or of any ongoing neurologic-associated symptoms. Petitioner did, however, go to a follow-up neurologic treatment appointment in August 2020. *Id.* at 202. At this time, she reported ongoing neuropathic pain, and difficulty ambulating, with those difficulties confirmed on exam. *Id*. at 203, 209. At the same time, however, the physical exam also revealed only slightly decreased strength in lower extremities (4/5), along with normal reflexes and normal response to sensory touch. *Id*. at 208–09.

II. Expert Report

Petitioner has offered a single expert report in this case, from David M. Simpson, M.D., a neurologist. Report, dated Dec. 11, 2023, filed as Ex. 1 (ECF No. 39-1) ("Simpson Rep.").

Dr. Simpson is a Professor of Neurology and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai, where he has worked as an Attending Neurologist since 1984. Simpson Rep. at 1.[6] He received his medical degree from SUNY at Buffalo School of Medicine, and underwent residency and fellowship training at Cornell University Medical Center and Massachusetts General Hospital. *Id*. He is certified by the National Board of Medical Examiners, the American Board of Psychiatry and Neurology with subspecialties in Clinical Neurophysiology and Neuromuscular Medicine, and the American Board of Neuromuscular and Electrodiagnostic Medicine. *Id.* He has been published extensively, and has given numerous presentations and lectures on the subject of neurological disorders, including peripheral neuropathy. *Id.*

The first section of Dr. Simpson's report summarizes the materials he reviewed for his opinion, along with a brief review of Petitioner's medical history. Simpson Rep. at 2–5. That history includes the instances discussed above where Petitioner informed treaters that her neurologic, GBS-related symptoms began shortly after vaccination. *Id.* at 2, 4. He then provided an overview of GBS—and acute inflammatory demyelinating polyneuropathy, or "AIDP"—the GBS sub-variant he seemed to embrace as applicable to Petitioner. *Id.* at 5. He also discussed biologic mechanisms by which GBS might occur, as well as the basis for an association between it and the flu vaccine (although this case does not turn on whether the flu vaccine "can cause" GBS—and hence I do not include herein a detailed explication of this aspect of his opinion). *Id.* at 5–6. And Dr. Simpson contended that nothing else in the record could explain Petitioner's GBS, despite some nonspecific

[6] Petitioner did not file a CV for Dr. Simpson, but his report contains a summary of his professional background, and I am otherwise familiar with his career history from opinions he has offered in other cases.

mention of URI-like symptoms before Petitioner's hospitalization. *Id.* at 7.

Dr. Simpson's report goes on to address the central issue in resolving this case: Petitioner's onset and its medical acceptability. Simpson Rep. at 6–7. He noted that Respondent seemed to accept there was some ambiguity in the record regarding the actual onset for Petitioner's GBS. *Id.* at 6. In Dr. Simpson's review of the record from "the early weeks" of Petitioner's illness, there were only references like "since" or "shortly after," which he deemed temporally nonspecific. *Id.* Moreover, to the extent Petitioner was later more precise in reporting a one to two-day post-vaccination onset, those recollections had been obtained "many months following disease onset," and should not be considered accurate—especially since patients often had difficulty recalling "the precise timing of onset of symptoms." *Id.*

Because of such ambiguity, Dr. Simpson maintained that record evidence from her November 2018 treatment was the better way to assess "the timing and progression of symptoms and signs." Simpson Rep. at 6. That evidence revealed Petitioner began experiencing neurologic symptoms, like paresthesias or ambulation difficulties, between November 6-8, 2018—thus no sooner than *eleven* days post-vaccination. *Id.* As a result, Dr. Simpson concluded that "the occurrence and evolution of objective neurologic signs did not occur until the second week following vaccination." *Id.* at 7.

However, Dr. Simpson argued, even if onset had occurred within 72 hours of vaccination, such a timeframe would still be medically acceptable. In support, he referenced a single item of literature. Simpson Rep. at 7; Y. Park et al., *Clinical Features of Post-Vaccination Guillain-Barré Syndrome (GBS) in Korea*, J. Korean Med. Sci. 2017 Jul;32(7):1154–1159, ("Park").[7] Dr. Simpson deemed a two-day onset to be acceptable, noting that Park's authors observed an onset of neurological symptoms occurring within three weeks in 47 of 48 of the analyzed GBS cases, and occurred within two days in a bit more than half. Simpson Rep. at 7.

III. Procedural History

This case was filed a little over four years ago. After its activation from "pre-assignment review," it was initially assigned to the SPU. But despite the parties' efforts, settlement proved impossible, largely if not wholly because of the onset issues discussed above. Accordingly, in September 2023, the matter was reassigned to my personal docket (*see* ECF No. 35), and I ordered the parties to formally brief the longstanding onset issue. *See* Petitioner's Brief, dated Dec. 14, 2023 (ECF No. 39) ("Br."); Respondent's Response, dated Jan. 19, 2024 (ECF No. 40) ("Opp."). That process has been completed, and the matter is now ripe for resolution.

[7] Petitioner has not filed Park, but as noted below in my analysis, I am familiar with the article and have discussed it in other cases in which the flu vaccine is alleged to have caused GBS.

IV. Parties' Arguments

A. *Petitioner*

Petitioner defends her GBS onset as consistent with the Table's timeframe as well as the third prong set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). First, she argues her onset was not likely as close to vaccination as many records suggest, pointing to her witness statements plus those of her husband and daughter.[8] She explains that the medical records do not provide any clarification as to the precise timing of Petitioner's onset of GBS-related symptoms, and that the only medical record that provides a specific time frame for onset was documented at an appointment with Dr. Yang on May 3, 2019. Br. at 3; Ex. 14. However, Petitioner maintains that Dr. Yang mistakenly believed that Petitioner received the flu vaccine on October 28, 2018 (as opposed to October 27, 2018), and that the note that Petitioner began experiencing problems "since the second day" post-vaccination technically "falls in line with [her] contention that she did not have any problems until at least three days after her vaccination." Br. at 4. Moreover, Petitioner contends that Dr. Yang also documented, contradictorily, Petitioner's symptoms as beginning one day following her flu vaccine. *Id.*; Ex. 14 at 87. Therefore, Petitioner argues that a "self-contradictory medical record entered months after Petitioner received her flu vaccine" should not be given greater weight than direct testimony of Petitioner and her family, coupled with other, more contemporaneous medical records. Br. at 4.

Additionally, Petitioner maintains that she has submitted an expert report from Dr. Simpson who opined that Petitioner "did not exhibit any symptoms specifically consistent with GBS until more than three days after her vaccination." *Id.*; Simpson Rep. at 7. Dr. Simpson relies on multiple studies supporting a connection between vaccination and the development of demyelinating neuropathy, thus satisfying the first *Althen* prong. Similarly, Dr. Simpson noted no logical alternative causes, and stated that symptoms onset beginning within several days to two weeks post-vaccination and followed by progressive neurological sensory and motor deficits is consistent with an AIDP/GBS diagnosis. *Id.* Finally, to support a proximate temporal relationship, Petitioner argues that "the earliest that any record suggests that Petitioner could have experienced any complications . . . was two days after her flu vaccination" and that such a time frame is consistent with the Park Study which Dr. Simpson relies on. *Id.* Thus, Petitioner maintains that she has sufficiently shown that her symptoms meet the Table requirements, or in the alternative, that she has provided record proof to satisfy an off-Table claim. Br. at 10.

[8] *See* Affidavit of Kim Flowers, dated Jan. 15, 2021, filed as Ex. A (ECF No. 26-1); Affidavit of Paul Flowers, dated Jan. 15, 2021, filed as Ex. B (ECF No. 26-2); Affidavit of Miranda Flowers, dated Jan. 15, 2021, filed as Ex. C (ECF No. 26-3).

B. *Respondent*

Respondent maintains that Petitioner has not established a viable Table claim. Opp. at 8. Respondent notes that in the first two weeks immediately following Petitioner's receipt of the flu vaccine, she consistently reported experiencing symptoms "since" vaccination. *Id.*; Ex. 2 at 11, 12; Ex. 3 at 4, 5; Ex. 4 at 50, 53, 103, 132, 173, 175. He further argues that Petitioner's use of the terms "since" and "shortly after" are clear indications that her GBS-related symptoms likely began less than three days post-vaccination. Opp. at 10. Indeed, Respondent points to several other medical records that suggest Petitioner began experience neurologic symptoms as early as "upon returning home" from receiving the vaccine at issue. *Id.*; Ex. 10 at 534, 554. Respondent maintains that such records bulwark the notion that Petitioner's symptoms began outside of the Table timeframe. Opp. at 11.

Respondent also argues that Petitioner has not established a viable off-Table, causation-in-fact claim. Opp. at 11. He criticizes Petitioner's expert report from Dr. Simpson, noting that the single item of literature he references to support a temporal association—the Park study—has been found unreliable in its attempt to establish an off-Table Flu/GBS claim, where onset occurred less than 72 hours post-vaccination. *Id.* at 13; *Block v. Sec'y of Health & Hum. Servs.*, No. 19-969V, 2021 WL 5709764, at *4 (Fed. Cl. Spec. Msrt. Oct. 29, 2021). Moreover, because Dr. Simpson lacks immunological expertise, his report is not compelling on foundational matters of "can cause" causation relating to what onset is medically acceptable. Opp. at 14 (*citing Block*, 2021 WL 5709764, at *5 (finding that Dr. Simpson did not possess adequate immunological expertise to credibly support a shorter onset timeframe)). Similarly, Respondent maintains that Petitioner failed to offer a treating physician willing to opine a shorter-than-usual vaccine caused onset—noting that nothing about Petitioner's case suggests otherwise. Opp. at 17.

V. 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. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9] In this case, Petitioner asserts a Table claim, along with a causation claim in the alternative. Br. at 2, 5.

[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*

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*, 418 F.3d 1274 , 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."

Each of the *Althen* prongs 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.

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.

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104 F. Appx. 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).

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); *see also 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)); *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). Otherwise, petitioners *always* have the ultimate burden of establishing their 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 denied*, 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. denied 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. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *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.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health*

& Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *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

Petitioner cannot establish entitlement under *any* possible version of the claim—Table or not.

The Table elements for a flu-GBS claim cannot be met (and to the extent there was any ambiguity as to this question in my prior Order to Show Cause, I hereby dispel it). The medical records preponderantly establish that Petitioner's onset most likely occurred *less than* three days after vaccination—thus sooner than the 3-42 day timeframe provided for by the Vaccine Injury Table. 42 C.F.R. § 100.3; Ex. 4 at 103; Ex. 10 at 534, 554; Ex. 14 at 11, 87. And this is not a case where a claimant confuses some initial vaccine reaction-associated malaise with what later proved to be onset of GBS, such that I could distinguish the two and focus on the "real" onset of neurologic symptoms. Rather, Petitioner *consistently* claimed to have begun experiencing neurologic symptoms within a day or two of vaccination—even as soon as the very same day. Ex. 10 at 534, 554. It makes no difference that those symptoms progressed over time, with Petitioner experiencing worsening that later encouraged her to seek emergency care less than two weeks post-vaccination—for (as noted in the Table) GBS nadir from onset typically progresses *up to* 28 days after symptoms first manifest. 42 C.F.R. § 100.3(c)(15)(i).

Dr. Simpson's onset arguments are unpersuasive. First, although it is true that certain timing references in the contemporaneous records are nonspecific and vague, that does not mean a one to two-day onset lacks overall preponderant support, based on *all* of the evidence. And vagueness in identifying an onset date does not preclude my finding. Program claimants often use imprecise terminology in describing to treaters when symptoms began. But more often than not, terms like "since" or "shortly after" are reasonably understood by the special masters to mean *very* close in time—immediately, or at most within a day or two. (Indeed, in the context of claims that a vaccine caused a "shoulder related to vaccine administration, or "SIRVA," a patient's reports of pain conveyed with similarly nonspecific language are *consistently* interpreted to mean within 48 hours of vaccination). *See, e.g.*, *O'Leary v. Sec'y of Health & Hum. Servs.*, No. 18-584V, 2021 WL 3046617, at *10 (Fed. Cl. Spec. Mstr. June 24, 2021); *accord Williams v. Sec'y of Health & Hum. Servs.*, No. 17-1046V, 2020 WL 3579763, at *5 (Fed. Cl. Spec. Mstr. Apr. 1, 2020) (holding that "based on the record as a whole, I find the notations characterizing onset as 'since,' 'after receiving,' 'following', and 'very soon after' injection are best understood as indicating onset was effectively immediate, or within 48 hours of vaccination"). Since the Program does not reject vague onset references outright, they deserve evidentiary weight—and here, coupled with other record evidence more precise on onset timing, they support the conclusion that Petitioner's onset began less than three days of vaccination, and perhaps as early as the same day.

Second, Dr. Simpson's onset arguments confuse when Petitioner's GBS could be *diagnosed*, or when it worsened to the point of nadir, with when onset actually began. It is a foundational matter of Vaccine Program law that onset occurs at first manifestation of a symptom, *regardless* of whether the disease it foretells could be diagnosed at that time—and thus whether the onset symptoms would be clearly understood to reflect the start of the illness. § 300aa-16(a)(2); *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013). In addition, there is a distinction between the start of an acute and monophasic illness like GBS, and when it reaches nadir (as the Table reflects). Here, the evidence preponderantly establishes that not only was Petitioner experiencing sufficiently-alarming neurologic symptoms to seek treatment for them eleven days post-vaccination, but that *at that time and consistently thereafter* she reported they had begun no later than a day after vaccination. Ex. 4 at 87. This record thus plainly preponderates in favor of a one to two-day post-vaccination onset—meaning the Table timeframe cannot be evidentiarily be satisfied.

Other fact arguments about onset timing are not well-supported by the record. Petitioner may be correct, for example, that Dr. Yang's records from May 2019 may well be internally inconsistent on onset, or presume a wrong vaccination date. Yet, as discussed above, not only are there ample records much closer in time to vaccination suggestive of an early onset, but some that even pinpoint it as the same day. *See, e.g.*, Ex. 10 at 534, 554. It remains the case that overall, preponderant evidence is not favorable to Petitioner's onset contention.

This leaves a potential non-Table, causation-in-fact claim that would have to meet the three prongs set by the Federal Circuit in *Althen*. But the claim (again) fails on the third, timeframe prong, because a one to two-day onset (or even sooner) has not been shown to be medically acceptable.

Petitioners asserting a non-Table flu vaccine-GBS claim are not formally limited by the Table's timeframe element, and thus can attempt to demonstrate that an onset sooner than three days post-vaccination is medically acceptable. Nevertheless, that timeframe *best captures* the most likely period in which vaccine-caused GBS would begin, based on the most persuasive and reliable science currently available. *See Rowan v. Sec'y of Health & Hum. Servs.*, No. 17-760V, 2020 WL 2954954, at *14–16 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (discussing the relationship between Table requirements and non-Table claims in context of flu-GBS claims). Special masters should not simply extend the Table's defined timeframe period (which reflects careful and reasoned analysis of medical and scientific evidence) on the say-so of an expert—since to do so would eliminate the distinction between Table and non-Table claims entirely. *Velasquez v. Sec'y of Health & Hum. Servs.*, No. 19-1703V, 2024 WL 829599, at n.13 (Fed. Cl. Spec. Mstr. Jan. 31, 2024).[10]

[10] The same reasoning applies in the opposite direction for this kind of claim. I would not likely find (under *Althen* prong one) the flu vaccine *cannot* cause GBS in a non-Table context, even if Respondent sought mightily to so establish—and even if he offered persuasive evidence in support—since to do so would be to wholly contradict the Table version of such a claim.

Instead, petitioners seeking to prove a shorter timeframe is medically acceptable need to explain what about *the specific facts of their case* suggests a faster onset would occur. This has been done, and Petitioner references some instances of it. Br. at 10 (citations omitted). But this occurs only where other factors establish that some synergistic combination of causes involving the vaccine and the claimant's own preexisting health likely caused a faster immune stimulation process. *See, e.g.*, *Orton v. Sec'y of Health & Hum. Servs.*, No. 13-631V, 2015 WL 1275459 (Fed. Spec. Mstr. Cl. Feb. 23, 2015) (dismissing claim where inadequate evidence established the medical acceptability of a one-day onset of GBS); *Rowan*, 2020 WL 2954954, at *19 (dismissing claim because it did not demonstrate 30-36 hour onset in elderly petitioner). And here, as Respondent establishes, the kind of special factors evidenced from the medical record that would render a short onset more acceptable are absent. Opp. at 15–16.

Dr. Simpson's opinion does not establish unusual circumstances relevant to the Petitioner that would explain how vaccination could have so quickly caused her to begin experiencing neurologic symptoms. He references Park in support—but I have in other cases (also involving Dr. Simpson) noted that this article only reveals that a different country's vaccine compensation program *paid* damages in a few cases involving short onset, with no discussion of whether such an onset actually had scientific or medical support. *See, e.g.*, *Block*, 2021 WL 2182730, at *5, 8–9 (dismissing flu-GBS Table claim due to onset occurring outside the defined 3-42 day timeframe, and discussing Korean vaccine injury program referenced in Park).[11] This is hardly robust proof that a short onset is medically acceptable—at all, let alone in this case.

In addition (and although the claim is properly dismissed on the basis of the third *Althen* prong), the second, "did cause" prong is also unsatisfied. There is no evidence of any suspicious vaccine reaction that could suggest an aberrant immune response had begun. No testing or clinical

[11] I specifically noted in *Block* the following:

> In support of his opinion, Dr. Simpson cited to Y. Park et al., *Clinical Features of Post-Vaccination Guillain-Barré Syndrome (GBS) in Korea*, J. Korean Med. Sci. 2017 Jul;32(7):1154-1159, filed as Exhibit 22 (ECF No. 21-9) ("Park"). Simpson Rep. at 7. Park reviews post-vaccination GBS cases submitted for compensation to the Korean Advisory Committee on Vaccination Injury Compensation between 2002 and 2014 as part of the National Immunization Program in South Korea. Park at 1154-55. Park's authors note that of the 48 flu-GBS cases approved for compensation in South Korea during that period, more than half of the cases (25) involved onset of neurological symptoms within two days of vaccination. Id. at 1155-56 and Fig. 1.
>
> * * *
>
> Park does not, however, discuss whether that timeframe was deemed medically acceptable, or what set of criteria was applied in awarding injury compensation in these Korean cases, although it does assert that the GBS diagnoses were mostly confirmed with commonly-applied diagnostic criteria deemed acceptable by the world-wide medical/scientific community. Park at 1155.

Block, 2021 WL 2182730, at *5. Thus, I rejected Park as reliably supporting the contention that a less than three-day, post-vaccination onset was medically acceptable. *Id.* at *8.

observations are evident that would be consistent with vaccine causation, other than the temporal relationship. At most, there is some record evidence that treaters took note of the pre-onset vaccination (perhaps based on Petitioner's prompting), but without opining to a causal relationship. And I am not obligated to accept their opinions at face value merely because they treated Petitioner contemporaneously, but may weigh them against not only contrary evidence, but their own internal reliability. *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 2569773 at n.67 (Fed. Cl. Spec. Mstr. Aug. 11, 2009) ("[h]owever, 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"). Ultimately, Petitioner's treaters did not coalesce around vaccination as the reason for her GBS.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

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.[12]

IT IS SO ORDERD.

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

[12] 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.