In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1660V

DEBORAH BECKWITH,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: August 29, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

David J. Carney, Law Offices of Green & Schafle, LLC, Philadelphia, PA, for Petitioner.

Parisa Tabassian, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 4, 2021, Deborah Beckwith filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleged initially that she experienced Guillain-Barré syndrome ("GBS") due to *three* separate doses of the influenza ("flu") vaccine received within two consecutive days (September 23 and 24, 2019). Petition (ECF No. 1) at 2.

Earlier in the case's life, a fact dispute arose regarding whether Petitioner could prove she had received *any* of the alleged vaccine doses. Petitioner was, however, able to substantiate the receipt of one dose of flu vaccine—in the early morning hours of September 24, 2019. *See* Order Granting Second Motion for Reconsideration, dated July 26, 2023 (ECF No. 37) ("Fact Order").

[1] 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 in its present form. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

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But this prevented Petitioner from arguing that the unique circumstances of receiving multiple doses of the same vaccine in a short timeframe contributed to her injury. Fact Order at 2. And it prevented her from succeeding on a Table flu vaccine-GBS claim as well, since her GBS onset appeared to have occurred *prior* to the 3–42 day timeframe for such a claim. *Id.* at 2–3. This left only a causation-in-fact claim to resolve.

After the parties filed some expert reports, I ordered Petitioner to show cause why I should not dismiss the claim for failure to meet the third prong of the test for entitlement set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Both sides have now briefed the issue. Petitioner's Response to Show Cause Order, dated Dec. 2, 2024 (ECF No. 56) ("Br."); Respondent's Show Cause Response, dated Jan. 29, 2025 (ECF No. 60) ("Opp."); Petitioner's Reply, dated Mar. 13, 2025 (ECF No. 62) ("Reply"). Now, for the reasons set forth in greater detail below, I deny entitlement. Petitioner has not demonstrated that her GBS onset occurred in a medically-acceptable timeframe.

I. Brief Factual History

Petitioner's pre-vaccination history includes gastroesophageal reflux disease, cholecystectomy, alcohol dependence, chronic obstructive pulmonary disease, biliary duct dilation, B12 deficiency, post-traumatic stress disorder, anxiety, and depression. Ex. 3 at 316, Ex. 5 at 14.

On September 23, 2019, Ms. Beckwith went to the Emergency Department at Robley Rex Department of Veterans' Affairs Medical Center in Louisville, KY, reporting abdominal pain that had persisted *for 11 days* (and thus beginning well before the vaccination at issue). Ex. 3 at 319. She reported vomiting after eating, with pain usually receding after vomiting, but added that the vomiting was impacting her ability to eat. *Id*. Petitioner also noted that she was "recovering from an [upper respiratory infection ["URI"]] that resolved a week ago before presentation w/ + coughing, N/V/D, malaise, [and] chills." *Id.* at 6. Shirley J. Cardona, M.D., diagnosed her with "[s]epsis secondary to infection of the common bile duct," and admitted Petitioner that same day for further examination. *Id*. at 314, 322.

Records filed in this case establish that in the early morning of September 24, 2019, Petitioner received a flu vaccine. Ex. 15 at 6. Admittedly, another, one-page record suggested either that Petitioner received a dose the day before; later in the day on September 24th; or even *three* doses in that two-day period. *See* Ex. 1 at 3 (Immunizations summary record). But I have found only that the dose administered in the morning of September 24th has preponderant evidentiary support. *See* Fact Order at 2.

There is no evidence of any immediate vaccine reaction. After vaccination and then during the morning of September 24, 2019, Dr. Cardona examined Petitioner again. Ex. 3 at 314. Dr. Cardona expressed the concern that Petitioner might be experiencing cholangitis due to her prior

gallbladder removal, as well as in light of her cholestatic pattern liver function tests, and therefore referred her to gastroenterology. *Id*. She was subsequently examined by gastroenterologist Cristian Riosperez, M.D. *Id*. at 316. Dr. Riosperez noted that Petitioner's abdomen "showed [i]ntrinsic and extrinsic biliary duct dilation similar to [her medical history] in 2018." *Id*. Petitioner had a 1.2 centimeter filling defect with central gas seen in her distal common bile duct, and was reporting nausea, diarrhea, and abdominal pain. *Id*. Dr. Riosperez recommended an endoscopic retrograde cholangiopancreatography ("ERCP")[3] under anesthesia to evaluate further the nature of Petitioner's symptoms. *Id*. The next morning (September 25, 2019), Petitioner awoke reporting transient double vision, but no other neurologic symptoms. Ex. 3 at 297. She subsequently underwent the proposed ERCP in the afternoon. *Id*. at 256.

It was after the performance of the ERCP that Ms. Beckwith first reported neurologic symptoms that better reflected GBS onset. Thus, in a progress note from September 30, 2019, neurologist Alexi Hernandez, M.D., stated as follows:

> A few or several hours following the procedure, while the admitting team was evaluating her, she noticed horizontal diplopia and, *over the following hours* developed numbness in both hands as well as numbness in both feet, which progressed and, at this point both her arms are entirely numb up to the level of her shoulders and her legs are numb up to the level of the lower i/3 of them .

Ex. 3 at 256 (emphasis added). Later (and now approximately 72 to 80 hours after the ERCP), Petitioner stated she had difficulty swallowing, felt "wobbly" on her feet, had a numbness in her jaw and neck, and had slurring speech. *Id*. at 256. Thus, Petitioner was experiencing clinically-evident neurologic symptoms the evening of the ECRP procedure—which itself occurred less than *two days after vaccination.*

Several days later, on September 30, 2019, and based on Petitioner's presentation since the diagnostic procedure, Dr. Hernandez's assessment was GBS, Miller-Fisher variant ("MFS"),[4] noting "[a]cute progressive cerebellar syndrome, complete external ophthalmoplegia, areflexia and distal sensory polyneuritic symptoms in an ascending fashion, after several days of abdominal pain and several hours after undergoing ERCP [on September 25, 2019]." *Id*. at 264. Dr. Hernandez recommended Petitioner be transferred to the intensive care unit with strict neurological monitoring and a lumbar puncture evaluation. *Id*.

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[3] "Endoscopic Retrograde Cholangiopancreatography" is "a combination of retrograde and transhepatic cholangiography, done to demonstrate all portion of the biliary tree; it is performed by cannulation of the bile duct and pancreatic duct through the papilla of Vater using a flexible fiberoptic endoscope with retrograde injection of a radiopaque medium." *Endoscopic Retrograde Cholangiopancreatography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=65009 (last visited Aug. 29, 2025).

[4] "Fisher Syndrome" is defined as a "variant of Guillain-Barré syndrome characterized by areflexia, ataxia, and ophthalmoplegia" and is also known as Miller-Fisher syndrome. *Fisher Syndrome*, Dorlands, Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110608 (last visited Aug. 29, 2025).

On October 1, 2019, Petitioner underwent a lumbar puncture with cerebrospinal fluid ("CSF") analysis. Ex. 3 at 244, Ex. 4 at 299. Dr. Hernandez noted that her CSF displayed an elevated protein level of 65, supportive of a GBS diagnosis, although she was not also reporting weakness. Ex. 3 at 244. Based on these findings, Dr. Hernandez recommended five rounds of plasmapheresis treatments, which concluded on October 9, 2019. *Id*. at 121.

On October 16, 2019, Ms. Beckwith was discharged to inpatient rehabilitation. Ex. 3 at 36. Petitioner still had transaminitis[5] due to acute choledocholithiasis and cholangitis. *Id*. at 121. She remained an inpatient at Frazier Rehabilitation Institute through mid-November. Ex. 5 at 5. Records from this time memorialize an onset of neurologic symptoms following the September 25, 2019, ERCP procedure, which included "ataxia, weakness, pain, areflexia, dysphagia, dysarthria, hypophonia, tremors and sensory deficits in extremities." *Id*. at 14.

Petitioner has filed additional medical records setting forth her treatment into 2020 and beyond. But they do not shed light on the causation issues relevant to the disposition of this claim, and I therefore do not include further evaluation of them.

II. Expert Opinions

The parties filed fairly extensive expert reports in support of their positions, and multiple iterations of them as well. But because my analysis turns on only one *Althen* prong, in the interests of brevity I discuss in detail herein only those portions of the reports bearing on the medical acceptability of the timing of Petitioner's onset.

A. *Petitioner's Experts*

1. Dr. Joseph Jeret – Dr. Jeret is a neurologist. Although he filed other reports,[6] only one is relevant to the prong three issue in dispute. *See* report, dated Sept. 5, 2023, filed as Ex. 16 (ECF No. 42-1) ("Jeret Rep.").

[5] "Transaminitis" is defined as "high levels of a particular type of enzyme in your blood, called a transaminase. The most common ones are alanine transaminase (ALT) and aspartate transaminase (AST) (also called alanine transferase and aspartate transferase). These enzymes are released into [the] blood by [the] liver. If a blood test show [one's] transaminases are elevated, it suggests that [the] live is under stress." *Transaminitis,* Transaminitis, Cleveland Clinic, https://my.clevelandclinic.org/health/symptoms/transaminitis (last visited Aug. 29, 2025).

[6] Earlier in the case (and before the question of vaccination proof was resolved), Dr. Jeret offered a report presuming that Petitioner had received three doses of flu vaccine, as originally alleged. *See* Report, dated October 19, 2022, filed as Ex. 11 (ECF No. 24). But that factual premise has been undermined, and I disregard this earlier report in reaching my conclusion in this case (and in any event Dr. Jeret recapitulated his arguments relevant to onset in his subsequent reports). Dr. Jeret also prepared a second report after my vaccination administration ruling. Report, dated April 19, 2024, filed as Ex. 76 (ECF No. 53-1) ("Second Jeret Rep."). This supplemental report only briefly addresses the timing/onset issue. *See* Second Jeret Rep. at 3–4. And it repeats the same arguments, and references the same items of literature, as contained in the first report pertaining to *Althen* prong three. It therefore merits no additional review or comment.

Dr. Jeret received his undergraduate degree from CUNY Brooklyn College in Brooklyn, New York in 1984, and his medical degree from SUNY Health Science Center at Brooklyn in 1988. *See* Curriculum Vitae, filed as Ex. 12 (ECF No. 24-2) ("Jeret CV") at 1. Thereafter, he completed a one-year general internal medicine preliminary year at Maimonides Medical Center, followed by a three-year residency in Neurology and a one-year fellowship in Clinical Neurophysiology at SUNY Downstate. *Id.* He is board certified in Neurology by the American Board of Psychiatry and Neurology and is currently employed by Optum Health Care as an active neurologist and is on staff at two community hospitals—South Nassau Community Hospital and Mercy Medical Center. *Id.*; Jeret Rep. at 1. Dr. Jeret has published numerous articles in areas related to neurology, reflecting his broad general practice. *Id.* at 2–7; Jeret Rep. at 1.

In his report, Dr. Jeret noted that some records filed in this case suggested Petitioner had received three flu vaccine doses within 24 hours, but he seems to have accepted my fact finding that only the dose recorded as having been administered the morning of September 24, 2019, was likely received. Jeret Rep. at 4. He nevertheless opined that an onset of neurologic symptoms the following day (which he concluded had occurred "approximately 36 hours later") was medically acceptable for flu vaccine-caused GBS. *Id.* at 10.

In support, Dr. Jeret offered several items of literature. One was a study relying on data from South Korea. Y. Park et al., *Clinical Features of Post-Vaccination Guillain-Barré Syndrome (GBS) in Korea*, J. Korean Med. Sci. 2017 Jul. 32(7):1154–59, filed as Ex. 45 (ECF No. 44-8) ("Park"). Park's authors relied on data derived from South Korea's vaccine adverse event compensation program, identifying 48 cases (over a 12-year period) in which individuals were compensated for GBS post-vaccination injuries. Park at 1154–55. Park observed an onset of neurological symptoms occurring within three weeks in 47 of 48 of the analyzed GBS cases, and occurring within two days in a bit more than half. Park at 1156.

In another item referenced by Dr. Jeret (a retrospective study of passive surveillance data derived from the Vaccine Safety Datalink), researchers observed evidence of "[o]nset as early as 1 day after flu vaccination." Jeret Rep. at 10; S. Perez-Vilar et al., *Guillain-Barré Syndrome After High-Dose Influenza Vaccine Administration in the United States, 2018-2019 Season,* 223 J. Infec. Dis. 1:416 (2021), filed as Ex. 43 (ECF No. 44-6) ("Perez-Vilar"). Perez-Vilar's authors employed two post-vaccination risk periods, including a broader one of 1–42 days, and did observe cases with onset in the one to seven-day range. Perez-Vilar at 421 (Figure 2) and 423 (Figure 3). But the article makes no determination about the relative risk temporally from vaccination (beyond noting a significant drop-off well past 42 days), and in fact determined that the risk was statistically *insignificant* for a 1–42 day timeframe (and based on the season analyzed only), deeming their findings "reassuring" as to the flu vaccine's safety. *Id.* at 423.

A third article was similar, both in terms of its literal observations from data as well as their meaningfulness when applied to this case. L. Polakowski et al., *Chart-Confirmed Guillain-Barré Syndrome After 2009 H1N1 Influenza Vaccination Among the Medicare Population, 2009-2010,*

178 Am. J. Epidemiol. 6:962 (2013), filed as Ex. 42 (ECF No. 44-5) ("Polakowski"). Polakowski relied on data from a pool of Medicare recipients (hence an elderly population), focusing on instances of GBS arising temporally after receipt of the H1N1 flu vaccine—ultimately identifying 31 vaccinated individuals in a particular vaccination season (out of a total of approximately 3.4 million in the initial pool) who met the study's diagnostic criteria for GBS, and who experienced symptoms onset within 119 days of vaccination. Polakowski at 962–66. As with Perez-Vilar, some of the final pool subjects had reported onset within a few days of vaccination. *Id.* at 967. However, the relative risk for a more confined temporal period (8–42 days) was higher than for the broader, 1–42 period. *Id.* at 965–67, 969. Polakowski did not reach conclusions about more specific questions of temporal risk, and noted further that although the risk associated with this particular vaccination period was higher than when compared to controls, it was lower than with respect to prior vaccination seasons. *Id.* at 971.

Dr. Jeret also offered some literature specific to the GBS variant Petitioner likely experienced, Miller-Fisher. Jeret Rep. at 10. M. Kazi et al., *Miller-Fisher Syndrome After Vaccination in the United States: A Centers for Disease Control and Prevention/Food and Drug Administration Vaccine Adverse Event Reporting System Study 1999-2017,* 60 Musc. & Nerve S1:534 (2019), filed as Ex. 13(f) (ECF No. 24-8) ("Kazi"). Kazi is a one-page abstract referencing an observational study that relied on passive surveillance data derived from the Vaccine Adverse Event Reporting System ("VAERS").[7] Kazi at 534. Based on an 18-year period (and an unspecified number of vaccines administered), its authors identified only 87 instances in which Miller-Fisher syndrome was reported after receipt of several different vaccines (including flu vaccine), finding no "increase in incidence of [Miller-Fisher syndrome] after vaccination as compared to the general population. *Id.* But Dr. Jeret emphasized that of the instances of GBS observed, "76% were reported within 6 weeks and 24% within 2 weeks," along with an "increased risk within the first 6 weeks," and therefore (in Dr. Jeret's estimation "onset after 2 days is consistent with this review—arguably the largest study of post-vaccine MFS on record!" First Jeret Rep. at 10.

2. Dr. Omid Akbari – Dr. Akbari is an academic immunologist, and he prepared two lengthy written reports[8] on behalf of Petitioner. Report, dated Oct. 24, 2024, filed as Ex. 18 (ECF No. 43-1) ("First Akbari Rep."); Report, Apr. 23, 2024, filed as Ex. 77 (ECF No. 53-2) ("Second Akbari Rep.").

[7] VAERS a database maintained by the Centers for Disease Control. VAERS collects information about adverse events reported to have occurred after the administration of licensed vaccines in the U.S. *See About VAERS*, Vaccine Adverse Event Reporting System (VAERS), https://vaers.hhs.gov/about.html (last visited Aug. 29, 2025).

[8] Dr. Akbari's two reports collectively total *67 pages*—in a flu-GBS case that presents non-controversial issues about general causation, and where it has been fairly self-evident for some time that only the third causation prong was in dispute. This reflects a failure by counsel to avoid incurring unnecessary expert costs, and I will take into account that failure when any fees award is issued in this case.

Dr. Akbari is a professor of allergy and immunology of Keck School of Medicine at the University of Southern California. *See* Curriculum Vitae, filed as Ex. 19 (ECF No. 43-2) ("Akbari CV") at 2. He received his bachelor's and master's degrees from University College London in 1993 and 1995, respectively. *Id.* at 1. Thereafter, he received his Ph.D. in Cellular and Molecular Immunology from the National Institute for Medical Research in London before completing a post-doctoral fellowship at Stanford University. *Id.* Dr. Akbari has and continues to serve on the editorial board of several journals, and he has numerous publications focused on the area of immunology and allergy research. *Id.*; First Akbari Rep. at 2. He also has particular experience on the subjects of "immune tolerance and how immune cells induce autoimmune and allergic diseases." First Akbari Rep. at 2. Dr. Akbari is not a medical doctor, however, and therefore he does not diagnose or treat patients with neurological diseases in a clinical setting.

First Report

Dr. Akbari's first report makes contentions relating to GBS onset parallel with what Dr. Jeret offered, although he invokes more microbiologic and immunologic concepts in doing so. *See generally* First Akbari Rep. at 10–12, 27.

Although prong one causation is not at issue in this case, a brief summary of Dr. Akbari's theory is still necessary, since it bears on whether Petitioner's GBS began in a medically acceptable timeframe. *See generally* First Akbari Rep. at 7–17. Dr. Akbari offered a sweeping, all-encompassing theory, in which a vaccine (a) causes a local reaction, stimulating an immune complex called the "inflammasome," (b) encourages the production of cytokines as well as T "helper cells" that are integral to the process of production of antibodies by B cells, (c) impacts the function of immune regulatory cells that suppress aberrant immune responses, and (d) eventually prompts the creation of antibodies in response. *Id.* at 7–8. Although these processes bridge the initial, innate response (which is rapid) with the slower, secondary/adaptive response, there is also a class of "innate like lymphocytes ("ILLs") that act quickly, and are likely involved "in the induction of demyelinating diseases such as GBS." *Id.* at 10.

Dr. Akbari stated that molecular mimicry (between a vaccine or infectious antigens and a self-tissue component) is accepted as a likely mechanism for GBS. First Akbari Rep. at 5. But he applied an expansive definition of it, to mean not just cross-reactivity due to autoantibody attacks driven by similarity between foreign antigens and self, but to include T cell reaction as well. *Id.* at 6. He also claimed that molecular mimicry was accepted despite the difficulty in ever showing an actual mimic (a convenient assertion that largely excuses individuals who wish to invoke the concept from having to substantiate it). *Id.* at 7. In addition, Dr. Akbari noted that GBS is likely encouraged along by a particular type of T helper cell that causes production of proinflammatory cytokines. *Id.* at 9.

Based on the foregoing, Dr. Akbari contended that "an early onset of GBS after flu immunization" was medically acceptable. First Akbari Rep. at 10. (In support, he referenced the

same articles cited by Dr. Jeret, such as Park or Perez-Vilar). He observed studies where onset was seen within three days of vaccination, like Park in particular. *Id.* at 11–12. He noted that the flu vaccine's initial stimulation of the inflammasome was also likely to encourage a faster immune response, particularly by encouraging the production of proinflammatory cytokines. *Id.* at 13–17; S. Crooke et al., *Inflammasome Activity in Response to Influenza Vaccination is Maintained in Monocyte-Derived Peripheral Blood Macrophages in Older Adults,* 2 Frontiers in Aging, Art. 719103, filed as Ex. 46 (ECF No. 44-9) ("Crooke"), at 7–8 (inflammasome response to vaccination in older population was consistent with younger groups, even though vaccination generally was less immunogenic).

In addition, at least one study established that T cells could quickly impact the nervous system "within the first few hours after being in the periphery," and thereby cause (along with ILLs) "injury and demyelination." First Akbari Rep. at 27; R. Ransohoff et al., *Three or More Routes for Leukocyte Migration into the Central Nervous System,* 3 Nat. Revs. Immunol. 569 (2003), filed as Ex. 72 (ECF No. 45-15) ("Ransohoff"). Ransohoff, however, focuses on the central nervous system (the "CNS"), and movement of immune cells (including leukocytes) to and from the periphery, and its authors emphasized how little remains known about this topic. Ransohoff at 578–79. More significantly, GBS is *not* a CNS disease, and so the speed with which a leukocyte might be thought capable in some instances of moving into, or out of, the CNS does not suggest GBS will occur as quickly as Dr. Akbari posits.

Second Report

Dr. Akbari's second report mostly covered ground not directly pertinent to the timeframe/onset dispute, but he did attempt to bulwark some of his points on this subject. *See generally* Second Akbari Rep. at 27–30. For example, Dr. Akbari took issue with the argument of Respondent's immunologic expert (Dr. William Hawse) that not enough was known about ILLs and their relationship with vaccination and GBS to deem them an explanation for a fast onset, maintaining that ILLs were known to be fast-acting, could promote production of cytokines and T helper cells, and likely played some role in encouraging "the development of demyelinating and autoimmune disease," including acute forms of GBS. *Id.* at 28. He also emphasized that "there are no clear boundaries between innate and adaptive immunity" in any event (suggesting implicitly that assumptions about the time it takes for adaptive responses to occur was unfounded). *Id.* at 27. Dr. Akbari allowed, however, that there remains a "need for greater understanding of ILL function in the hyper-acute phase of inflammation such as vaccination and adverse effects that may occur within hours or few days"—and acknowledgement that the science on this subject is far less firm than he implied. *Id.* at 28.[9] Dr. Akbari nevertheless concluded that "the prompt response of [ILLs]

[9] This section of Dr. Akbari's report referenced (by my informal count) *more than 15* individual items of literature. *See generally* Second Akbari Rep. at 27–29, 35–36 (references 28 to 42). I have reviewed these articles—but none are specific to the context of GBS onset occurring more rapidly than usual, due to suspected involvement of ILLs. Rather, these items largely (like Dr. Akbari's report overall—as well as the opinions he often provides in Vaccine Program cases) make reliable scientific observations about immune system functioning in disparate contexts, but without

to flu immunization play a pivotal role in triggering an early-onset demyelination cascade." Second Akbari Rep. at 29. He deemed it likely the Petitioner "possessed a higher number of ILLs," assuming "genetic or environmental factors" relevant to her (although not substantiated in this case) explained this. *Id.*[10]

At bottom, Dr. Akbari maintained that a GBS onset within less than two days of vaccination had been shown to be "plausible." Second Akbari Rep. at 30. He emphasized that the 3–42 day timeframe embraced by the Table version of the claim was "arbitrarily defined" by the "Vaccine Court"—a wholly-erroneous contention, since Table claims are not established by OSM, but instead reflect *Respondent's* determinations, supported by applicable medical science. *Id.* Dr. Akbari further contended that "we know" GBS can begin earlier or later after vaccination, given personal genetics and individual immune variance. *Id.* And he added that "[i]f the Court never accepted time frames outside of those on the Vaccine Injury Table, then there would not exist a causation-in-fact case, which, to my understanding, is not the purpose, scope or intent of the Vaccine Court." *Id.*

B. *Respondent's Experts*

1. Dr. Peter Kang – Dr. Kang, a neurologist, prepared one expert report on Respondent's behalf. Report, dated March 28, 2024, filed as Ex. C (ECF No. 50-1) ("Kang Rep.").

Dr. Kang attended State University of New York ("SUNY"), for his undergraduate degree, the University of Pittsburg School of Medicine for his medical degree, and Washington University School of Medicine for his Master of Science in Clinical Investigation. *See* Curriculum Vitae, filed Mar. 29, 2024 (ECF No. 50-14) ("Kang CV") at 1. He then completed an internship in Preliminary Internal Medicine, a residency in Neurology, and a fellowship in Neurocritical Care at Washington University School of Medicine. *Id.* Dr. Kang is currently the Program Director for the Neurology Residency Program at Washington University School of Medicine, as well as Teaching Faculty and Attending Physician in the Neurointensive Care Unit, General Neurology Ward Service, and Resident Continuity Clinic at Barnes-Jewish Hospital. *Id.* at 2. His clinical practice primarily focuses on the care of individuals suffering neurologic conditions such as cognitive impairment, disorders of consciousness, motor and sensory deficits, gait and balance disorder. Kang Rep. at 1. Dr. Kang is board certified by the American Board of Psychiatry and Neurology in both Neurology and Neurocritical Care. Kang CV at 3.

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appreciably advancing the notion that *the flu vaccine is likely to spur more quickly a pathogenic response* leading to GBS.

[10] As additional support for his opinion, Dr. Akbari referenced a Program decision. Second Akbari Rep. at 29, *citing Harris v. Sec'y of Health & Hum. Servs.,* No. 18-944V, 2023 WL 2583393 (Fed. Cl. Spec. Mstr. Feb. 21, 2023) (finding Tdap vaccine causal of GBS, with onset within one day). Putting aside the questionable value of a medical expert making legal arguments about other Program decisions and their import, this case has no direct relevance, since it involves a different vaccine, and since there is no analogous Table claim providing an onset timeframe that arguably bears on the present circumstances.

With respect to the issue of onset and its medical acceptability, Dr. Kang noted that Petitioner had received the flu vaccine on the morning of September 24, 2019, with onset of neurologic, GBS-oriented symptoms later the next day. Kang Rep. at 16. But Dr. Kang maintained that "no compelling evidence in the literature" supported the conclusion that the GBS variant experienced by Petitioner could clinically manifest in such a short time frame "following an immunogenic exposure." *Id.*

In support, Dr. Kang stressed that "the adaptive immune response through development and production of human immunoglobulins (first IgM then IgG or IgG) in response to exposure to the influenza virus, for example, takes several days, peaking at about 7 days." Kang Rep. at 16; F. Krammer, *The Human Antibody Response to Influenza A Virus Infection and Vaccination,* 19 Nat. Reviews – Immunol. 383 (June 2019), filed as Ex. C Tab 9 (ECF No. 50-10), at 383 Box 3. But Petitioner had displayed GBS early symptoms (which would in theory be driven by the antibodies produced in reaction to receipt of the flu vaccine) too soon after vaccination for the vaccine to have been responsible for those antibodies. Kang Rep. at 16. As a result, "it is not plausible that the vaccine is the cause of the MFS variant GBS." *Id.*

2. Dr. William Hawse – Dr. Hawse is, like Dr. Akbari, an academic immunologist, and he offered an expert report for Respondent. Report, dated February 6, 2024, filed as Ex. A (ECF No. 49-1) ("Hawse Rep.").

Dr. Hawse is an Assistant Professor in the Department of Immunology at the University of Pittsburgh School of Medicine. *See* Curriculum Vitae, filed as Ex. B (ECF No. 49-16) ("Hawse CV") at 1. He earned his Ph.D. in Biophysical Chemistry at Johns Hopkins and currently runs a laboratory studying CD4+ T-cell generation and immune tolerance to inform therapeutic strategies for autoimmune diseases. Hawse Rep. at 1. Dr. Hawse has published multiple peer-reviewed articles on the subject. He is not, however, a medical doctor or experimental clinician, and thus does not offer commentary on diagnosis.

Much of Dr. Hawse's report addressed issues of causation that do not impact this claim's resolution. But he also discussed Dr. Akbari's contentions regarding *Althen* prong three. *See generally* Hawse Rep. at 11. Dr. Hawse emphasized that the record established an onset within a day of vaccination (not two days, as Dr. Akbari proposed). *Id.* at 11. He deemed it unlikely GBS could manifest in so short a timeframe. He also observed that the record revealed that prior to vaccination, Petitioner had both likely experienced a URI, and that she had been diagnosed with an infection-associated sepsis—either of which could have triggered her subsequent GBS, and in a timeframe more reasonable than the immediate one proposed for vaccine causation. *Id.*

Dr. Hawse also attempted to rebut some of Dr. Akbari's specific contentions about points in the human immunologic response that could have contributed to a short onset. ILLs, Dr. Hawse maintained, *could* be quickly stimulated by vaccination. But the existing scientific and medical literature on the topic was too sparse to conclude either that vaccines likely *do* stimulate these

immune cells, or (and more importantly) that they lead to GBS (and it was speculative for Dr. Akbari to assume this explained instances in which individuals reported short onset of GBS after vaccination). *Id.*

Similarly, Dr. Hawse noted that Dr. Akbari had shown (in citing articles like Crooke) only that there is *some* inflammasome stimulation attributable to receipt of the flu vaccine—but not that this stimulation would be sufficiently aberrant to cause a disease process leading to GBS. Hawse Rep. at 4–5. In fact, literature suggested that vaccine-provoked inflammasome stimulation could result in the production of *inflammation-modulating* cytokines. *Id.* at 5; S. Mohanty et al., *Prologued Proinflammatory Cytokine Production in Monocytes Modulated by Interleukin 10 After Influenza Vaccination in Older Adults,* 211 J. Infect. Dis. 1174 (1 Apr. 2015), filed as Ex. A Tab 5 (ECF No. 49-6). And other studies observed that receipt of the flu vaccine suppressed some innate responses that would be otherwise pro-inflammatory. Hawse Rep. at 5–6; F. Wimmers et al., *The Single-Cell Epigenomic and Transcriptional Landscape of Immunity to Influenza Vaccination,* 184 Cell 3915 (2021), filed as Ex. A Tab 6 (ECF No. 49-7).

III. Procedural History

This matter began approximately four years ago. After "pre-assignment review" (the Program's process for ensuring sufficient documents relevant to the claim have been filed for analysis), the matter was assigned to the "Special Processing Unit" ("SPU"), since it alleged the Table claim of GBS due to the flu vaccine—an oft-settled and common Vaccine Act claim. However, Respondent's June 2022 Rule 4(c) Report noted an issue with the claim—the fact that the filed vaccination record (a facially-cursory document) suggested Petitioner had received *three* vaccine doses in a short timeframe—one the night of September 23, 2019, and two more early the next morning of the 24th. Rule 4(c) Report (ECF No. 18) at 7; Ex. 1 at 3. And even if the latest dose were deemed the sole vaccination event at issue, Petitioner's onset of the evening of September 25th would still be too short, measured from vaccination, to meet the Table requirements. Rule 4(c) Report at 7.

In reaction, I ordered Petitioner to show cause why the Table claim should not be dismissed. Order, dated Jun 15, 2022 (ECF No. 19). Petitioner in reaction, however, maintained that because it appeared she had received three doses of vaccine within 24 hours, a claim was still viable (given the unusual circumstances—which might make a short onset medically acceptable)—and based on that contention, I determined the matter would be transferred out of SPU for expert input. Order, dated July 26, 2022 (ECF No. 22).

After several months of records filing and some initial expert input, Respondent raised again the fact that it did not appear from the totality of the filed records (as of that time) that Petitioner could corroborate receipt of *any* flu vaccine doses, let alone three. In reaction, I ordered the parties to brief this issue. Order, dated February 9, 2023 (ECF No. 27). After the parties briefed the question, it was my initial determination that the fact of vaccination had not been proven, and

I dismissed the claim on that basis in June 2023. Petitioner thereafter, however, moved *twice* for reconsideration of my dismissal determination, and in the course of so doing was eventually able to identify and offer a previously-unfiled document[11] confirming that she received one vaccine dose at 2:20 a.m. on September 24, 2019. *See* Order Granting Second Motion for Reconsideration, dated July 26, 2023 (ECF No. 37 ("Reconsideration Order").

In my Reconsideration Order, however, I noted that despite due opportunity, Petitioner had utterly failed to establish receipt of more than one dose of the flu vaccine. Reconsideration Order at 2. I also found that the Table onset for a flu-GBS claim could be established, since Petitioner's onset seemed to have begun sooner than three days post-vaccination. *Id.* I otherwise ordered Petitioner to file a revised expert report in light of my determination.

The parties thereafter filed the expert reports discussed above. Final reports were filed in the summer of 2024, and in November of that same year I ordered Petitioner to show cause why the claim should not be dismissed, for failure to meet prong three of the test set forth for causation-in-fact claims by *Althen*. The parties filed the briefs cited above, completing the process in mid-March 2025, and the matter is ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner maintains that the flu vaccine can cause GBS *outside* the 3–42-day timeframe—first noting the importance of Dr. Akbari's reliance on ILLs, and several newly identified cells within this category: invariant natural killer cells ("iNKT"), innate like lymphoid cells, and gamma delta T cells. *Id.* at 43, 46; Akbari First Rep. at 9. Dr. Akbari explained, "ILLs are fast-acting cells and upon stimulation can produce cytokines and cause protection or cause pathologies (such as adverse effects) within a few hours. Br. at 46–47; Akbari First Rep. at 9. Thus, he argued that ILLs are understood to be "key participants in early response after immunization that would suggest the involvement of these fast-acting immune cells in the induction of demyelinating diseases such as GBS." *Id.*; *see also* G. Borsellino et al., *Phenotypic and Functional Properties of μδ T Cells from Patients with Guillain Barré syndrome*, 102 J. Neuroimmunology 199 (2000), filed as Ex. 38 (ECF No. 44-1).

Similarly, according to Dr. Akbari, "ILCs have been shown to 'exert a profound influence in CNS inflammatory disease' and [] these resident cells within the nervous system can be activated early in disease to manifest disease-modifying cytokines and chemokines." Br. at 47 (citing M. Brown & R. Weinberg, *Mast Cells and Innate Lymphoid Cells: Underappreciated Players in CNS Autoimmune Demyelinating Disease*, 9 Frontiers Immunology 1 (2018), filed as Ex. 39 (ECF No. 44-2). Lastly, Petitioner relies on an article to support the notion that iNKT cells are "associated with GBS, [and] suggesting a central role of these fast-acting T cell types in

[11] I note that this confirmation of vaccination was only discovered *two years* after the case's filing.

inflammatory neuropathies varying between acute and chronic subtypes." Br. at 48 (citing M. Heming et al., *Immune Cell Profiling of the Cerebrospinal Fluid Provides Pathogenetic Insights into Inflammatory Neuropathies*, 10 Frontier Immunology 1 (2019), filed as Ex. 41 (ECF No. 44-4). Petitioner argues that these articles establish how these specific types of cells function within the hyperacute phase of inflammation, and thus, can lead to an onset of injury within hours or a few days. Br. at 48.

Here, Petitioner maintains that she began exhibiting symptoms of her GBS, Miller-Fisher variant between 36- and 55-hours post-vaccination (based on the evidence establishing that she received the vaccine in question on September 24, 2019, at 2:20 a.m.). Br. at 52, 53; Ex. 15 at 6; Ex. 3 at 313–14. She further notes that she reported no prior neurological symptoms at the time she was initially hospitalized for abdominal pain. *Id.* She underwent the ECRP at 2:40 p.m. and was NPO for the following two hours. Br. at 53; Ex. 3 at 304. By 9:25 p.m. that evening, medical records indicate that Petitioner was "resting comfortably at [the] time and [was] not disturbed." Ex. 3 at 307. Thus, she further maintains that her medical records would not document her condition as such had she been experiencing weakness or neurological symptoms. Br. at 53. Moreover, Petitioner notes that many of the reports following Petitioner's ECRP do not mention neurologic complaints until 9:30 a.m. the day after (meaning her onset would be longer than 48 hours post-vaccination). Ex. 3 at 289 (documenting complaint of fingertip numbing and dizziness on September 26, 2019, at 9:30 a.m.); 256 (describing visit with Dr. Hernandez who noted Petitioner's progressing neurologic symptoms).

Accordingly, and relying on the above-mentioned studies, and other supported and well-established medical literature, Petitioner contends that she has not only provided a sound and reliable medical theory of causation, but that her experts, Drs. Akbari and Jeret, have preponderantly proposed how the flu vaccine can trigger an earlier onset of GBS between one and three days. *Id.* at 51.

Respondent

Respondent has offered a succinct brief in reaction to my Order to Show Cause, maintaining that the case turns on Petitioner's inability to show that a one-day post-vaccination onset is medically acceptable. Opp. at 9–13. In so arguing, he notes my prior fact finding, contrasting it with the view (reflected in Petitioner's briefing) that her onset may have been closer to three days post-vaccination. *Id.* at 10. But as Dr. Kang proposed, there is record evidence of an onset as early as the morning of the ECRP procedure (which would make onset even closer-in-time to vaccination). *Id.* at 11.

Dr. Kang, Respondent argues, has persuasively opined that the MFS GBS variant would not be expected to begin within a day or two of a trigger like vaccination. Opp. at 11. In response, Petitioner relies on case series like Kazi, which in fact do not establish the medical acceptability

of a short onset. *Id.* at 11–12. And case reports generally are low-value evidence of causation. Opp. at 12 (citations omitted).

By contrast, Dr. Kang established that the production of autoantibodies that would likely drive GBS would occur during the adaptive immune response, and would take days to a week or so to occur—longer than the onset in this case. Opp. at 12. And that timeframe was more consistent with the likelihood (corroborated by the record evidence of Petitioner's pre-hospitalization symptoms) that Petitioner had experienced an infection that resulted in her GBS. *Id.* at 12–13. Dr. Akbari attempted to invoke ILLs as capable of causing GBS in a shorter timeframe, but the independent support he offered for this contention was too general, and did not address the specific issues in dispute relating to onset of GBS due to vaccination. *Id.* at 13. Thus, his opinion was highly speculative.

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*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] There is a Table claim for GBS after receipt of the flu vaccine, but (as discussed herein) it requires proof of an onset no sooner than *three days* post-vaccination—and onsets too close-in-time to vaccination can be fatal even to non-Table claims that the flu vaccine caused a person's GBS.

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*,

[12] 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. 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).

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 at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

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 even a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (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 v. Sec'y of Health & Hum. Servs.*, 107 Fed. Cl. 280, 245 (2012).

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 Cerrone v. Sec'y of Health & Hum. Servs.*, No. 24-1281, slip op. at 9 (Fed. Cir. July 29, 2025); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL

2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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. *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*, 618 F.3d at 1347 (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. *Determination to Resolve Case without a Hearing*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human 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 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. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

The failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient grounds for a claim's dismissal (and therefore the three prongs need not *all* be addressed in cases where a claimant clearly fails to satisfy at least one). *Dobrydnev v. Sec'y of Health & Hum. Servs*., 566 Fed. App'x. 976, 980 (Fed. Cir. 2014). The primary deficiency in Petitioner's claim is her inability to satisfy the third *Althen* prong. *Althen*, 418 F.3d at 1281. Petitioner has not preponderantly established that her GBS developed within a medically-acceptable timeframe after receipt of the flu vaccine.[13]

It is well understood in the Vaccine Program that the onset of an alleged vaccine injury is marked by the "first symptom or manifestation of onset." *See* Section 16(a)(2). As the Federal Circuit makes clear in *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1357 (Fed. Cir. 2007), there is a difference between a "symptom" and "manifestation of onset"—but because of the Act's use of the disjunctive "or," *either* can constitute the start of a disease process (even though a symptom could be nonspecific, or hard to link to what was later viewed as a full disease). *Markovich,* 477 F.3d at 1357–59. As a result, the date of official diagnosis, and/or when treaters were *able* to reach a conclusion as to the proper diagnosis, does *not* mark the onset of an alleged vaccine injury. *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013) (stating that "it is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations under § 300aa–16(a)(2)."). Nor is onset deemed the date an injured party *recognizes* the subsequent disease has begun, or even understands the symptom to be concerning. *See Markovich*, 477 F.3d at 1357 ("[a] symptom may be indicative of a variety of conditions or ailments, and *it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury*") (emphasis added). Onset can predate the time when a disease could be accurately diagnosed. *Id.*[14]

As determined in my 2023 Fact Order, Petitioner's GBS onset likely began in the evening hours of September 25, 2019—most likely after her ECRP procedure, but not quite two days post-vaccination. Fact Order at 2; Ex. 3 at 256; Br. at 56 (acknowledging that "Petitioner began exhibiting symptoms of her GBS/Miller-Fisher variant between 36 and 55 hours after her flu vaccination"). Thus, even though the parties may not *precisely* agree on when onset began, they both accept a post-vaccination of less than three days—and the record preponderates in favor of

[13] I do not deem it reasonably disputed that the flu vaccine *could cause* GBS (prong one)—based on the Table presumption, as well as my familiarity with the ample medical science on the subject. I do not reach the second, "did cause" prong, since all three prongs must be met to establish entitlement to damages—and in any event, an onset too soon in time post-vaccination to be medically acceptable precludes a finding the flu vaccine "did cause" her GBS.

[14] Although the injured child in *Markovich* was not diagnosed with a seizure disorder until August 2000, it was determined in that case that the onset of the disease dated back a month earlier, when the child suffered from an eye-blinking episode that was later determined to be the first symptom of her seizure disorder. *Markovich*, 477 F.3d at 1357, 1360.

an onset occurring sooner (35 to 40 hours post-vaccination). Accordingly, the Table elements for a flu-GBS claim (3–42 days after vaccine administration) cannot be met. 42 C.F.R. § 100.3. Petitioner could only succeed in her claim by showing that her less than two-day onset constituted a medically-acceptable timeframe for vaccine-instigated GBS.

Petitioners alleging a non-Table, causation-in-fact flu vaccine-GBS claim are of course not formally limited, in any "bright line" sense, by the Table's timeframe element. They can always attempt to prove that a shorter or longer onset is still medically acceptable, given the facts of the case. Yet the medical science *behind* a Table claim—the *raison d'etre* for its existence—should not be ignored simply because the claim can no longer succeed as a Table matter. That medical/scientific foundation (which led the Government to presume causation when certain facts are proven) remains meaningful, and should still be taken into account to some degree when deciding claims that "fall out" of the Table.

Often, giving some regard to the elements of an analogous Table claim inures to a claimant's benefit, and avoids unnecessary expenditure of judicial resources and needless burdens on the petitioner. It would, for example, be temporally wasteful and judicially picayune to demand that a petitioner "prove" prong one causation in a flu vaccine-GBS case with the filing of opinions and items of literature, just because he cannot meet Table timeframe onset. But Petitioner seems to suggest this is exactly what should occur. Br. at 37–38.

So—should I simply don blinders, declare that the Table version of the flu vaccine-GBS claim has no bearing herein, and proceed accordingly? Should I demand that Petitioner "prove" the flu vaccine *can cause* GBS, as if I have no prior knowledge at all of the Table presumption of causation? Should I require exhibits filed and hear expert testimony? And what if I were to find that Petitioner *in this case* failed to prove an association? Should I issue decisions of that sort going forward? Would every single non-Table case involving the flu vaccine and GBS come down to a battle of the experts, with some petitioners prevailing because they made the effort, and others losing when Respondent's counsel goes to the "full nine yards," as it were, to rebut causation?

To do so would be to open the door to a range of perverse outcomes contrary to the Program's goals of expedient case resolution. Were I to engage in such an overly rigid application of prong one in failed flu vaccine-GBS Table claims, I would risk creating a "parallel universe" of decisions in which petitioners had failed to prove something the Program otherwise *presumes* to be so.[15] I reasonably hesitate to make such a world a reality.

[15] Indeed (and as I have learned from other cases), there is *ample* evidence that the modern version of the flu vaccine may *not* be reasonably associated with GBS, in comparison to the version administered during the swine flu epidemic in the 1970s (the timeframe from which the most persuasive evidence of an association was generated). If Respondent were allowed to litigate this issue without regard to the existence of the Table claim, inconsistent outcomes on such claims would become common.

But "sauce for the goose is sauce for the gander," as the adage goes—and this means that if I am to give weight to *some* Table presumptions when evaluating a non-Table claim analog, I should do the same with others. Here, that means that special masters should not disregard the science behind the Table timeframe element. For that timeframe *best captures* the most likely period in which flu vaccine-caused GBS would begin, based on the most persuasive and reliable science available when the terms of the Table claim were struck. *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). Otherwise, special masters risk stretching the Table's timeframe period to fit a claim, and on the mere say-so of an expert. *Velasquez v. Sec'y of Health & Hum. Servs.*, No. 19-1703V, 2024 WL 829599, at n.13 (Fed. Cl. Spec. Mstr. Jan. 31, 2024). Failed Table claims would still succeed if onset were "close" enough.

This does not mean that petitioners like Ms. Beckwith seeking to prove the medical acceptability of a shorter (or longer) onset timeframe than what the Table allows for GBS are doomed to failure. Rather, what they must do is establish (via evidence) what about *the specific facts of their medical history* or personal circumstances suggests a faster onset due to vaccination could occur. This has been done in prior cases, where petitioners were able to establish that some synergistic combination of causes involving the vaccine and the claimant's own preexisting health likely resulted in a faster immune process. *See,* e.g., *Lehrman v. Sec'y of Health & Hum. Servs.*, No. 13-901V, 2018 WL 1788477, at *16–19 (Fed. Cl. Spec. Mstr. Mar. 19, 2018) (finding a 24-hour onset post-vaccination was medically acceptable because petitioner's expert persuasively explained how a preceding upper respiratory infection acted synergistically with the flu vaccine, leading to a rapid onset of GBS).

Where that evidence is lacking, however, it is reasonable to find the third *Althen* prong has not been satisfied. *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 that a 30–36-hour onset in elderly petitioner was medically acceptable). And here, the kind of special/personal factors that would render a short onset more acceptable are absent. The medical record in this case instead reveals no reaction to the vaccination, and establishes merely onset of GBS-like neurologic symptoms after performance of the ECRP. These facts do not suggest a faster aberrant immune response leading to GBS was more likely in Petitioner's case (no matter how *plausible* it might be), or did occur for the reasons alleged.[16]

[16] The record evidence in this case actually provides other explanations for Petitioner's close-in-time onset that are more likely than vaccination to have impacted onset's timing. For example, Petitioner was vaccinated after experiencing a resolved URI—and in a timeframe that (if that infection was causal) would be consistent with a medically-acceptable process instigated by infection that began more than a week before. There is also the possibility that the ECRP was associated with Petitioner's subsequent GBS—if the flu vaccine could cause GBS within two days,

None of the arguments of Petitioner's experts have persuasively rebutted my finding that onset of flu vaccine-caused GBS is *unlikely* to occur within two days of vaccination. Dr. Jeret, for example, repeatedly identifies literature relying on passive surveillance reports of GBS *beginning* in a comparably-short timeframe—but which do not opine as to the meaningfulness of these occurrences, for purposes of causation. This is no different than relying on case reports—a kind of evidence that takes note of a temporal association between an adverse event and vaccination, but says very little about whether that relationship reflects more than mere chance. *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) (stating that "[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value compared particularly to formal epidemiological studies").

More importantly, these independent items of literature do not provide any reliable basis for concluding that the biologic process necessary to result in the production of antibodies capable of causing the harm to myelin that characterizes GBS *could* occur in less than two days. The flu vaccine is thought to be able to instigate GBS because it is believed to be capable of prompting, via molecular mimicry, the creation of autoantibodies that (due to similarity with myelin self-structures, like gangliosides) can cross-react, damaging the myelin as a result. That process of antibody creation is not something that likely occurs within a day or two of vaccination. *Rowan,* 2020 WL 2954954, at * 17 (noting that antibodies are created during the adaptive immune process, and that this phase is not likely to result in production of damaging antibodies within a few days—even if the body "recognizes" foreign antigens, for purposes of generating antibodies against them, in as little time as one day).

The specific items of literature referenced by Dr. Jeret are also worthy of little evidentiary weight for other reasons. Park, for example, relies on outcomes from a foreign vaccine injury compensation program, and thus could reflect a policy decision to resolve "close" cases. It therefore does not stand for the proposition that an onset of less than two days *has been found* to be medically acceptable, based on methodologically-sound research. I have for this reason rejected Park when invoked in other cases to support a short onset comparable to what Ms. Beckwith experienced. *See, e.g.*, *Flowers v. Sec'y of Health & Hum. Servs.,* No. 20-285V, 2024 WL 2828211 (Fed. Cl. Spec. Mstr. May 8, 2024), at *13, *mot. for review den'd*, 173 Fed. Cl. 613 (2024); *Block v. Sec'y of Health & Hum. Servs*., No. 19-969V, 2021 WL 2182730 (Fed. Cl. Spec. Mstr. Apr. 26, 2021), at *5, 8–9. Relying on Park to prove the third *Althen* prong is little different from contending that *Vaccine Program* damages decisions (particularly cases in which a short onset of GBS post-vaccination occurred) substantiate the medical acceptability of the onset timeframe at issue.[17]

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why would a procedure performed hours prior to onset also not be potentially causal? (Admittedly, Petitioner has specifically contested the latter speculation on my part; I reference it only to illustrate that the facts of this case provide more *alternative* explanations for Petitioner's GBS than they support the flu vaccine as causal).

[17] Petitioners often attempt to do just that—offering in their briefing lengthy lists of cases in which compensation was awarded in comparable cases as proof that they are entitled to compensation. *See, e.g.*, *Howard v. Sec'y of Heath & Hum. Servs.,* No. 16-1592V, 2022 WL 4869354 (Fed. Cl. Spec. Mstr. Aug. 31, 2022), at *22–23, *mot. for review*

Other items are similarly distinguishable, or of limited probative value. Articles like Polakowski and Vilar-Perez all rely on passive surveillance data (and thus are not robust evidence of the degree of actual risk), and do not propose to evaluate the relative risk of vaccine-caused GBS over timeframes comparable to this matter (say, two days versus a week), but instead merely consider larger timeframes parallel to the flu vaccine-GBS Table period of 3–42 days. Moreover, they either find no greater risk from vaccination, or limit their findings of risk to specific infectious seasons and/or vaccine formulations then in use. All that I have been provided of Kazi is a summary abstract, making it difficult to assess its actual findings—and while it seems to identify a greater risk of the GBS variant at issue within the same timeframe applicable to a Table claim (and arguably a meaningful risk within even two weeks of vaccination), it does not stand for the proposition that onset *within a day or two of vaccination* is as likely as within a week or more.

Dr. Akbari's science-heavy opinion proved no more persuasive on the disputed timeframe question. To start, it reflects the same kind of overarching, generalized view that I have rejected when encountering his expert opinions in other cases. *See generally Efron v. Sec'y of Health & Hum. Servs.,* No. 20-1405V, 2025 WL 408219, at *22 (Fed. Cl. Spec. Mstr. Jan. 2, 2025); *Ampofo-Addo v. Sec'y of Health & Hum. Servs.*, No. 21-1231V, 2025 WL 2463643 (Fed. Cl. Spec. Mstr. July 31, 2025). In effect, Dr. Akbari offers a large-scale overview of the entirety of the immune response, soup to nuts, proposing within it numerous points when vaccines could have a negative impact. While this description may be biologically correct and/or supported by reliable independent evidence in many respects, it founders in implicating vaccination as an "x factor" leading to injury, and does not identify with enough reliable specific evidence *where and how* this occurs. And it repeatedly speculates about certain aspects of the immune response that have not been evaluated enough to deem those aspects of his opinion reliable.

Dr. Akbari's specific arguments were also inadequately bulwarked with sufficient reliable evidence. While he clearly offered *numerous* literature citations, and provided an explanation about how different aspects of the immune response work (or are speculated to work in some faster contexts—such as with ILLs), his opinion amounted to the contention that it was plausible that GBS could be triggered in a shorter time than commonly understood. This is not equivalent to evidence that GBS *likely* occurs in a day or two of vaccination—and the sheer amount of literature he filed in connection with his reports does not constitute a preponderant showing on the timeframe question. It simply remains *more likely than not* that it takes more than two days for flu vaccine-caused GBS to produce autoantibodies sufficient to result in manifestation of outward, clinically-observable symptoms.

Otherwise, Dr. Akbari mistakenly assumed the onset timeframe element of a Table flu vaccine-GBS claim reflects legalistic presumptions of the special masters, when instead its terms

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den'd, 2023 WL 4117370 (Fed. Cl. May 18, 2023), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). But only *reasoned* Program determinations—decisions explaining why a particular outcome was supported by the evidence—have guidance value. *Howard,* 2022 WL 4869354, at *23. Determinations to settle claims say nothing at all about the merits of the causation theory presented.

are the product of *Respondent's* evaluation of the science. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132-01 at 45144–45146 (July 29, 2015). That medical science suggests that it is *unlikely*, absent factors specific to a given claimant, that vaccine-caused GBS will occur sooner than *three* days post-vaccination (since the presumption of causation subsequently evaporates under such factual circumstances). And no special factors have been proven that would explain why Petitioner *in this case* experienced a faster onset. The circular logic that because the Petitioner's onset *did* occur in short timeframe, some unknown genetic or personal immunologic propensity exists that "explains" vaccine causation, is nothing more than the kind of *post hoc ergo propter hoc* reasoning rejected by the Vaccine Program.

Petitioner's experts have unquestionably vouched for the medical acceptability of a one to two-day onset of GBS post-vaccination, but I am not bound by their *ipse dixit*. I found the counter-opinions of Drs. Kang and Hawse far more persuasive. Respondent's experts relied on what is known about GBS and its autoantibody propagation, and the fact (consistent with the Table timeframe) that in *most* cases GBS will *more likely than not* take a few days to manifest clinically after an environmental trigger (whether infection or vaccination), given the time it takes for the body to manufacture the pathogenic, cross-reactive antibodies. Petitioner has otherwise not shown than her personal health or other circumstances made a fast onset likely.

CONCLUSION

Vaccine Act claimants must carry their burden of proof to be entitled to damages. Because Petitioner cannot show by preponderant evidence that her GBS began in a medically-acceptable timeframe, I deny entitlement.

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.[18]

IT IS SO ORDERED

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

[18] 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.