

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 17-760V
(to be published)

DENIS J. ROWAN, *as the personal* *
representative of the estate of *
*
DOROTHY A. ROWAN, *
Petitioner, *
*
v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
Respondent. *

Chief Special Master Corcoran

Filed: April 28, 2020

Influenza vaccine; onset;
Non-Table claim; Elderly
immune system; Antigen
response; *Althen* prong three;
Medically-acceptable timeframe;
Guillain-Barré syndrome

Curtis Webb, Twin Falls, ID, for Petitioner.

Voris Johnson, U.S. Dep’t of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION¹

On June 8, 2017, Dorothy Rowan, now deceased,² filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”)³ alleging that

¹ This Decision will be posted on the Court of Federal Claims’ website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id.*

² Counsel filed a status report on November 7, 2019, informing me of Ms. Rowan’s passing in September 2019, and also stating that her estate would be continuing to prosecute the claim. ECF No. 34. Earlier this month, counsel indicated that an estate representative had finally been appointed, and the caption has been revised to reflect the new petitioner. Order, dated April 16, 2020 (ECF No. 36).

³ The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter “Vaccine Act” or “the Act”). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

she developed Guillain-Barré syndrome (“GBS”) following receipt of the influenza (“flu”) vaccine on September 27, 2016. Petition (ECF No. 1) at 1.

It is largely undisputed⁴ that Ms. Rowan experienced GBS, an injury that has been credibly associated (for purposes of establishing Vaccine Act entitlement) with the flu vaccine. But the matter is nevertheless contested, because her onset occurred within thirty-six hours of vaccination—shorter than the three-day minimum onset period for a flu-GBS claim as set forth in the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(D). Accordingly, Petitioner advances a causation-in-fact, non-Table claim that Ms. Rowan’s short-onset GBS was vaccine-caused, and occurred in a medically-reasonable timeframe.

Both parties submitted expert/treater reports and briefs. *See* Petitioner’s brief, dated February 28, 2019 (ECF No. 24) (“Brief”); Respondent’s Opposition, dated March 21, 2019 (ECF No. 25) (“Opp.”); Petitioner’s Reply, dated April 19, 2019 (ECF No. 26) (“Reply”). They also obtained supplemental expert reports at my request, addressing the extent to which Ms. Rowan’s age might have impacted the expected timeframe for onset. Now, having had an opportunity to review the filings and medical records, I deny entitlement. As set forth in greater detail below, Petitioner has not established by preponderant evidence that it is medically acceptable to conclude that the flu vaccine could likely cause GBS within a 36-hour timeframe, or that it did so in this case. The fact that Ms. Rowan was elderly at best has no bearing on the onset question—and at worst suggests that flu vaccine-induced GBS would more likely take *longer* than a few days to begin (and thus likely longer than it did so in her specific case).

I. Factual Background

Ms. Rowan received the flu vaccine on September 27, 2016, at the Brookdale Parkcenter Independent Living Center—a Boise, Idaho assisted living facility where she had resided for some time (“Brookdale”). Ex. 1 at 1–2; Ex. 2 at 2; Ex. 7 at 3. She was then 91, with a prior medical history that included hypertension, triple cardiac bypass surgery, high cholesterol, osteoarthritis, alcohol dependence, depression, and anemia. Ex. 7 at 4, 14, and 43. The medical record does not establish the precise time of day the vaccination occurred, but because Ms. Rowan’s name is third-to-last on the list of thirty flu shots administered that day, it can be inferred that she was among the last individuals that day to receive the vaccine, and therefore likely received it in the afternoon of the 27th. Ex. 2 at 2.

A bit more than a day later, Ms. Rowan began experiencing symptoms that arguably

⁴ As noted herein, Respondent originally accepted the GBS diagnosis, but appears to have since backed away from it. However, because my decision turns on the third *Althen* prong, I need not decide also if the GBS diagnosis is preponderantly-determined, and thus do not do so herein.

constituted onset of her GBS. She went to the emergency room at St. Luke's Boise Medical Center on September 29, 2016, at which time she reported receipt of the flu vaccine two days before. Ex. 3 at 107–08. As the ER note from her arrival states, “she felt at baseline yesterday morning [September 28th] upon waking,” but that by “yesterday evening she began to feel as if she could not walk.” *Id.* at 108. Specifically, Ms. Rowan informed nurse practitioner Dawn Aiken, NP, that the night prior she had been ambulating with a walker, but then, when she attempted to stand after having been seated for 30 minutes, she felt profoundly weak and almost fell. She was able to get to bed that evening, but when she awoke the morning of the 29th she still felt very weak and called her daughter, who transported her to the ER. She denied any recent illnesses, and reported no associated numbness or tingling. Ex. 3 at 19–22.

Ms. Rowan's lab tests on admission were unremarkable, including a complete blood count. An MRI of her brain showed prominent atrophy and extensive small vessel ischemic white matter change. Ex. 3 at 6, 97. An MRI of Petitioner's spine showed mild/moderate degenerative changes with no cord abnormalities. *Id.* at 16, 95–96. The next day (September 30, 2016), Ms. Rowan saw neurologist Sergei Kashirny, M.D., and reported a history consistent with the above—again placing onset of her weakness on the evening of September 28, 2016 and claiming difficulty in ambulating when compared to her usual baseline, despite some improvement since being admitted. An exam showed mild questionable left facial asymmetry, normal eye movement, mild proximal weakness (arms/legs not specifically mentioned), difficulty coordinating the legs, severely diminished reflexes in the legs, and an inability to stand. Ex. 3 at 21–22. Dr. Kashirny did not obtain a lumbar puncture, noting that her age alone made elevated protein possible, thus diminishing the value of a positive result. Regardless, based on her total presentation Dr. Kashirny proposed that Ms. Rowan had GBS, and prescribed four days of IVIG treatment. *Id.* at 24–25.

On October 1, 2016, Dr. Kashirny now noted that Ms. Rowan showed significant improvement, and he decreased her IVIG dosage, observing that hospital discharge might soon be possible. Exam showed “no obvious weakness,” although she did display absent lower extremity reflexes and weak upper extremity reflexes. Ex. 3 at 33. A case manager began preparing a plan for home health physical therapy at Brookdale once Ms. Rowan returned from the hospital. *Id.* at 66. The next day, Ms. Rowan revealed additional improvement in her ambulation, and an occupational therapy (“OT”) assessment recommended rehabilitation for balance and training in performing activities of daily living. *Id.* at 38, 50.

On October 3, 2016, treaters opted to delay slightly Ms. Rowan's discharge in light of the rehab recommendations, along with reports that she had experienced falls even pre-vaccination, but otherwise noted that the weakness that had led her to seek emergency medical intervention appeared to have largely resolved. Ex. 3 at 51–52. She was finally discharged on October 4, 2016, after six days as an inpatient at St. Luke's. Ex. 1 at 2; Ex. 3 at 15–16, 19–22. Discharge records confirm the view that her “mild GBS” began the evening of September 28, 2016—between 30 to

36 hours post-vaccination. Ex. 1 at 1–2; Ex. 3 at 15–16, 19, 24–26.

After discharge, Ms. Rowan was transferred for rehab to the Valley View Life Care Center in Boise, Idaho. Ex. 3, pp. 16–17. She was an inpatient there from October 4, 2016 through November 4, 2016. Ex. 4 at 2–3. She subsequently returned to live at Brookdale, where she remained until March 19, 2017. Ex. 1 at 2–3. Even when back at Brookdale, she required the assistance of a nurse's aide for 12 hours a day, 7 days a week, going up to 24 hours per day for two weeks in March 2017. Ex. 8 at 1–49. The cost for such round-the-clock care eventually made it impossible for Ms. Rowan to continue to live in her own apartment at Brookdale, forcing her to move to other assisted living facilities in Boise. Ex. 9 at 1–6 (Past Unreimbursed Expenses for Assisted Living Care). Ms. Rowan passed away on September 23, 2019. Status Rep., filed on Nov. 7, 2019.

II. Expert and Treater Opinions

A. Dr. Lawrence Steinman

Dr. Steinman submitted two expert reports on behalf of Petitioner's claim. Expert Report of Lawrence Steinman, M.D., filed as Ex. 13 on July 9, 2018 (ECF No. 16-1) ("Steinman Rep."); Supplemental Expert Report of Lawrence Steinman, M.D., filed as Ex. 26 on October 8, 2019 (ECF No. 32-1) ("Steinman Supp. Rep."). Dr. Steinman opines that the onset of Ms. Rowan's symptoms, approximately 30 to 36 hours after receipt of the flu vaccine, was medically acceptable—and that her elderly status was not inconsistent with this opinion.⁵

As shown in his CV, Dr. Steinman received his B.A. from Dartmouth College and his M.D. from Harvard Medical School. Ex. 14 at 1, filed July 9, 2018 (ECF No. 16-2) ("Steinman CV"). He then completed residencies in neurology and pediatrics at Stanford University. *Id.* He has worked as a professor of neurology and pediatrics at Stanford for the past thirty-eight years. *Id.* Dr. Steinman has also published hundreds of peer-reviewed publications on neurology and autoimmune disease. Steinman CV at 5–45. He holds several patents related to the diagnosis and treatment of autoimmune and demyelinating diseases. *Id.* at 2–3. He presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics at Stanford University. *Id.* at 1.

Dr. Steinman's first report discussed the immune processes involved in reaction to a vaccine, and the timeframes in which that reaction would be medically expected to occur. Citing

⁵ As noted below, prior to the filing of Dr. Steinman's first expert report I had informed the parties of my view that a primary question in dispute in this case was whether Ms. Rowan's onset was medically acceptable—and therefore this was the issue that experts should focus on. Dr. Steinman's report accordingly does not go into detail about the capacity of the flu vaccine to cause GBS (and it did not need to either).

a report from the Institute of Medicine, Dr. Steinman observed that the “lag phase” from primary (meaning first-time) antigen exposure to start of immune response (during which time the body is either producing antibodies or sending T cells to react to the antigen) is 7 to 10 days, but will be shortened to 1 to 3 days for subsequent exposure to the same antigen, with the subsequent immune response—the logarithmic or “log” phase—occurring in 3 to 5 days. Steinman Rep. at 3 (*citing* Chapter 3: Evaluating Biological Mechanisms of Adverse Events, *in* *Adverse Effects of Vaccines: Evidence and Causality* 457–62, 91–101 (Stratton et al., eds., 2012) (“IOM Report”)). Because Ms. Rowan appears to have received the flu vaccine before in her life, Dr. Steinman surmised that her lag response would also be expected to be brief. Steinman Rep. at 3–4.

Besides the IOM, Dr. Steinman invoked an item of literature that could well be the single most cited article in the entirety of the Program (excluding certain articles referenced in the Omnibus Autism Proceeding). Steinman Rep. at 3-4, *citing* L. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Program, United States, 1976-77*, 110 *Am. J. Epid.* 2:105-123 (1979), filed as Ex. 21 (ECF No. 18-7) (“Schonberger”). Schonberger is an epidemiologic study performed in the wake of the 1970s swine flu epidemic, and considers the impact of the immunization program initiated by the federal government in response. The study evaluated over 1,000 individuals who experienced GBS in the 1976–77 timeframe, comparing those who received the particular vaccine utilized by the program versus those who did not, and found that the incidence rate for GBS was higher among those who had *received* the vaccine. Schonberger at 121–22. Schonberger is consistently cited in the Program by virtually *any* claimant seeking to establish how the flu vaccine could cause a demyelinating autoimmune disease of the peripheral or central nervous (“CNS”) system.

Dr. Steinman maintained that Schonberger established that GBS was more likely to begin in a short timeframe, comparable to what Ms. Rowan experienced, than longer—although he admitted that “[n]o statistics are available” to corroborate the acceptability of this proposed timeframe. Steinman Rep. at 4. In specific support of this contention, Dr. Steinman referenced Schonberger’s Figure 5, which sets forth distribution of onset for approximately 500 GBS cases by two-day intervals, measured from date of vaccination. Schonberger at 112. Schonberger specifically cites Figure 5 to illustrate what its authors deemed a “nonrandom” distribution of onset timeframes, ultimately observing that expected peak onset (for the population of cases considered) occurred 16 to 17 days post-vaccination, although the majority of all GBS cases considered in the chart (72 percent) began within four weeks. *Id.* at 110–11. Dr. Steinman, however, drew attention to the fact that (a) the chart evidenced *some* early cases of GBS (approximately 12 in the initial, zero to one post-vaccination interval, and 16 in the one to three-day interval) and (b) more cases were observed in that timeframe than days 35 and beyond. Steinman Rep. at 3. Thus, although Schonberger does not *on its own* say (either directly or indirectly) that the flu vaccine can cause GBS in a timeframe of less than two days (and in fact, could be interpreted to mean, as

Schonberger's authors seem to suggest, that the most likely timeframe for GBS is longer), Dr. Steinman interpreted it as so saying.

In his supplemental report, Dr. Steinman attempted to address my question regarding the role age might play in increasing the likelihood of experiencing vaccine-caused GBS in a faster-than-usual timeframe. *See generally* Steinman Supp. Rep. In a single page with two references, Dr. Steinman opined that an elderly individual's recall response to the flu vaccine could in fact occur within two days. Noting the significance of the anti-ganglioside antibody in the mechanistic processes resulting in GBS,⁶ Dr. Steinman referenced an article that (based on its title alone) seems to *undercut* Petitioner's claim generally. D. Wang et al., *No Evidence of a Link Between Influenza Vaccines and Guillain-Barré Syndrome-Associated Antiganglioside Antibodies*, 6 *Influenza and Other Respiratory Viruses* 3:159–66 (2011), filed as Ex. 28 (ECF No. 33-2) ("Wang").

Wang sought to evaluate the extent to which certain anti-ganglioside antibodies (believed to play a key pathogenic role in propagating GBS) were induced by the flu vaccine. To do so, the article considered pre and post-vaccination sera from nearly 650 human and 30 mice subjects, with the human serum samples derived from different time periods in which the flu vaccine was administered. Wang at 159, 160. The relevant serum samples were screened to determine if they contained the relevant antibodies after immunization. *Id.* at 161. Although many of the subgroups of tested human sera did not show the presence of the anti-ganglioside antibodies after vaccination, 15 subjects known to be derived from individuals 60 years old or more tested positive for the antibodies, a determination Dr. Steinman emphasized as supporting his conclusions. *Id.* at 162; Steinman Supp. Rep. at 2.

But (as the block quote from Wang in Dr. Steinman's report reveals) only four of these 15 subjects showed antibody positivity *after* vaccination, with the majority showing the presence *both* before and after. Wang at 62. The article ultimately characterized the amount of these antibodies found in the few elderly samples as "very low," and while admitting that the possibility that the flu vaccine might induce anti-ganglioside-mediated GBS in rare instances, also noted that "there has been no link to increased risk of GBS and receipt of influenza vaccination in older adults." *Id.* at 164. Thus, Wang's authors did not conclude that the flu vaccine was likely to induce this antibody in *any* group, young or old. More importantly, Wang says nothing about the *timeframe* in which this vaccine-induced production of anti-ganglioside antibodies would be expected to occur, or whether the elderly would likely experience production of these antibodies

⁶ R. Yu et al., *Ganglioside Molecular Mimicry and its Pathological Roles in Guillain-Barré Syndrome and its Related Diseases*, 74 *Infection and Imm.* 12:6517–27 (2006), filed as Ex. 27 (ECF No. 33-1).

in a faster timeframe.⁷

B. *Dr. Waj Nasser*

Petitioner also offers a treater statement, although it says less about causation than about the impact GBS had on Ms. Rowan's life. Ms. Rowan's primary care physician, Dr. Nasser, of St. Luke's Clinics - Capital City Family Practice, Boise, Idaho, prepared a letter in support of her claim. *See* Letter, dated March 28, 2018, filed as Ex. 11 (ECF No. 14-1) ("Nasser Ltr."). Dr. Nasser represents that he was Ms. Rowan's primary care physician since 2013, providing him insight into her pre versus post-vaccination health. Nasser Ltr. at 2. He deems her overall condition to have been "dramatically and adversely affected" by GBS, noting what a negative impact the disease has had on her ability to independently perform a variety of daily life activities. *Id.* He does not, however, opine as to any relationship between the flu vaccine and her GBS.

C. *Dr. Arnold Levinson*

Dr. Levinson acted as Respondent's expert, and filed two written reports in the matter. Expert Report, filed as Ex. A on November 30, 2018 (ECF No. 21-1) ("Levinson Rep."); Expert Report, filed as Ex. E on October 8, 2019 (ECF No. 30-1) ("Levinson Supp. Rep."). Dr. Levinson opined that the onset of Ms. Rowan's GBS symptoms (within 36 hours of vaccination) was not medically acceptable for vaccine-induced GBS, and that an elderly individual like Ms. Rowan would experience "impaired immune responsiveness," making it even *less* likely that she could incur a vaccine-caused injury in such a short timeframe. Levinson Rep. at 5; Levinson Supp. Rep. at 3.

Dr. Levinson currently serves as Emeritus Professor of Medicine and Neurology at the Perelman School of Medicine at the University of Pennsylvania (in addition also being a consultant to other biotech and pharmaceutical companies). *See* Curriculum Vitae, filed as Ex. B (ECF No. 21-5) ("Levinson CV") at 2–5. During his career with the Perelman School, Dr. Levinson held a number of positions: Chief of the Allergy and Immunology Section, Director of the Fellowship Training Program in Allergy and Immunology, and Director of the Center for Clinical Immunology. Levinson CV at 1–2. He received his undergraduate degree and medical degrees from the University of Maryland. Levinson CV at 1. He is also currently board certified in internal medicine and allergy and clinical immunology, and holds a medical license in the state of Pennsylvania. *Id.* at 2–3.

Following a review of the undisputed facts derived from the relevant medical records, Dr.

⁷ In fact, the procedures used to test the blood serum samples reveal that the largest group of samples (approximately 612 subjects living in British Columbia, Canada or the State of Connecticut) involved a *four-week* delay between pre and post-vaccination testing—not a few days, further diminishing the extent to which Wang could reach any conclusions as to anticipated onset timing. Wang at 160.

Levinson's report considers whether Ms. Rowan's GBS onset (which he places on the evening of September 28, 2016, approximately 36 hours after vaccination) was medically acceptable. Although Dr. Levinson expressed doubts about the validity of the very diagnosis of GBS in this case,⁸ he did not accept that GBS could ever begin in a 24 to 36-hour post-vaccination timeframe. In so doing, he noted that the particular chart from Schonberger cited by Dr. Steinman only involved (for each relevant post-vaccination two-day interval) a "handful of cases," making it impossible for him to give its findings the degree of scientific/statistical significance Dr. Steinman urged. Levinson Rep. at 5.

In addition, Dr. Levinson questioned the "biological plausibility" of GBS actually manifesting clinical symptoms in less than two days from trigger. In his view, it was not scientifically reliable to contend that the leg of the autoimmune process that would actually cause "peripheral nerve destruction" sufficient to elicit clinical symptoms in a person could begin in such a short timeframe. Levinson Rep. at 5. In so maintaining, he pointed out that Dr. Steinman's report did not explain the literal mechanistic process (and the timeframe in which it would occur) by which antigens in the flu vaccine would induce immune mechanisms sufficient to cause a peripheral nerve injury. *Id.*

Like Dr. Steinman's supplemental report, Dr. Levinson's second report only addressed my question about whether an elderly individual's immune response would be expected to be faster than normal (which, if true, might bulwark Petitioner's contention that Ms. Rowan's GBS began in a shorter-than-usual timeframe). However, Dr. Levinson devoted considerably more time to consideration of the question than Dr. Steinman, characterizing it the "subject of immunosenescence." *See generally* Levinson Supp. Rep. He began by noting that aging causes impairment to both the innate and adaptive immune systems, with the latter characterized by a decrease generally in the production of B and T cells responsive to foreign antigens. *Id.* at 1. As a result, the elderly face more serious risk from infection, prompting efforts in the pharmaceutical industry to develop "new vaccination strategies" designed to account for the "frailty of the elderly host's immune system." *Id.* at 2.

In order to specifically address whether an elderly individual like Ms. Rowan might have (due to her naturally-impaired immune system) mounted a less effective response, leading to a faster onset of GBS, Dr. Levinson looked for epidemiologic evidence, but found only two articles that he felt addressed the temporal question. One such article was filed with his original report. S. Peric et al., *Guilain-Barré Syndrome in the Elderly*, 21 J. Periph. Nerv. Syst. 105–10 (2016), filed as Ex. A Tab 2 (ECF No. 21-3) ("Peric"). Peric compared 250 "young" (meaning

⁸ Other than Schonberger, Dr. Levinson filed only two additional items of literature, both of which he referenced in connection with his contention that Ms. Rowan may not have had GBS. As previously noted, however, because I find this case turns on the onset timing issue, I do not address whether in fact she was properly diagnosed given the medical record, despite the fact that Respondent appears to have raised this as a possible secondary objection to the claim.

younger than 60) with 153 “old” (above 60) GBS patients, finding that the latter (especially those older than 80) had a more severe disease process overall. Peric at 108; Levinson Supp. Rep. at 2. But the mean timeframe from a presumed precipitating disease trigger to clinical onset was roughly the same for both—in each case taking longer than one week. Peric at 106.

There are, however, some limitations to Peric’s findings that affect how much weight it should be given. First, Peric *excluded* from consideration any subject whose presumed antecedent event precipitating the patient’s GBS occurred earlier than three days prior to onset—exactly the circumstances of this case. Peric at 106. Second, the mean time for the elderly from trigger to onset was literally 12 *plus or minus* 12 days—consistent with the conclusion that some individuals *might* experience onset in the timeframe Ms. Rowan experienced (although Peric also observed a similar, secondary timeframe from onset to requiring hospitalization, thus further extending the timeframe for GBS beyond what Petitioner claims is medically acceptable). *Id.*

Dr. Levinson additionally referenced an article considering a group of 70 elderly GBS patients in India. Levinson Supp. Rep. at 3–4 (citing M. Nagappa et al., *Guilain-Barré Syndrome in the Elderly: Experience from a Tertiary-Care Hospital in India*, 46 J. Clinical Neuroscience 45–49 (2017), filed as Ex. E Tab 3 (ECF No. 30-4) (“Nagappa”). As with Peric, Nagappa’s authors observed elderly patients to experience overall a more severe course of GBS, both in terms of symptoms and length of illness. Nagappa at 47–48. However, the interval between antecedent infection believed to have triggered the GBS and onset was *longer* than when compared to an adult group of younger patients, albeit by only three to four days. *Id.* at 47. Dr. Levinson thus maintained that what literature existed addressing the question I had posed did not support the conclusion that GBS onset would inherently be faster in the elderly, despite their otherwise-compromised immune systems (and in fact might be slower, precisely *because* of the age-induced impairment to their immune response). Levinson Supp. Rep. at 3.

III. Parties’ Respective Arguments

Petitioner forthrightly acknowledges that this claim does not satisfy the requirements for a Table flu-GBS claim, due to the short onset, but nevertheless proposes that the actual timeframe is sufficiently medically acceptable to meet the third prong of the Federal Circuit’s causation-in-fact test set forth in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); Brief at 4, 12. To support this contention, he makes a number of arguments. He notes that as a general matter, the flu vaccine is associated with an increased risk of GBS up to six weeks post-vaccination, a timeframe inclusive of the 36-hour onset period relevant herein. *Id.* at 12–13. He emphasizes Dr. Steinman’s opinion about the medically-acceptable nature of an onset as early as 24 hours post-vaccination. *Id.* at 14–15. And in so doing, he references Dr. Steinman’s invocation of the Figure 5 from Schonberger revealing cases of post-vaccination GBS less than two days post-vaccination. *Id.* at 15.

Respondent's opposition cites the medical record in detail in order to bulwark his contention that onset was no later than 36 hours post-vaccination, and perhaps even sooner. Opp. at 8. From this, Respondent argues that Dr. Steinman's opinion on onset is scientifically unreliable, for several reasons. *Id.* at 9–10. First, he observes that it is speculative to conclude that Ms. Rowan would likely have experienced a swifter immunologic “recall response” to the 2016 version of the flu vaccine merely because she claimed to have received it in the past, noting that every year the vaccine's formula (and specifically its viral components) changes. *Id.* at 10.

Second, and focusing closely on the contents of the IOM Report, Respondent notes that Dr. Steinman appeared to have conflated aspects of the immune response process. Although Dr. Steinman spoke about the “lag” phase, and seemed to suggest that the time from a presenting foreign antigen (whether in a vaccine or infection) to clinical response was a single part of that process, in fact the IOM Report observed *three* parts of the process: (1) the lag phase (during which the presenting antigen initially activates an adaptive immune response—here, production of antibodies associated with GBS's occurrence); (2) the logarithmic phase (when the antibody response begins to impact the body); and (3) a subsequent plateau (when the maintenance of peak antibody levels for a length of time is followed by a decline in the serum antibody levels). *Id.* at 11, *citing* IOM Report at 58. As a result, even if the initial lag phase is shorter due to prior antigenic exposure, that phase *plus* the “log” phase means that clinical manifestations of a pathogenic, vaccine-induced process would take well longer than 24 hours to appear, and likely longer than even three or four days. Opp. at 11–12 (citing IOM Report at 321–34).

Respondent similarly takes aim at Dr. Steinman's reading of Schonberger, noting Dr. Levinson's reaction to its scientific significance regarding onset timeframe. Opp. at 13. And Respondent observes that the short timeframe proposed as medically acceptable herein by Dr. Steinman has been rejected in several other recent Vaccine Program decisions, albeit in not exactly the same circumstances. *Id.* at 13–14 (citing *Forrest v. Sec'y of Health & Human Servs.*, No. 14-1046V, 2019 WL 925495 (Fed. Cl. Spec. Mstr. Jan. 28, 2019) (noting that researchers in Schonberger did not specifically examine whether a two-day-onset occurred more frequently than expected and therefore “the two events (vaccination and onset of GBS) may be a coincidence”); *Palattao v. Sec'y of Health & Human Servs.*, No. 13-591V, 2019 WL 989380, at *34 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (36-hour timeframe rejected for onset of transverse myelitis due to alleged innate immune response). At bottom, Respondent argues that Petitioner effectively asks me to abrogate the Table's three-day limit for early onset of vaccine-caused GBS. Opp. at 15–16.

In reply, Petitioner (accepting the fact that the claim largely turns on resolution of the timeframe issue) reviews again the various items of evidence supporting the conclusion that the incidence of vaccine-caused GBS is highest within six weeks of vaccination (a timeframe which obviously includes the first 36 hours, at least literally). Reply at 1–4. He also reemphasizes Dr. Steinman's opinion that onset in a single day is medically acceptable, along with the evidentiary

support for the contention (relied upon by Dr. Steinman) that Ms. Rowan previously received the flu vaccine and therefore would have more likely than not experienced a faster recall response. *Id.* at 8, 11–13.

In addition, Petitioner draws attention to Dr. Steinman’s basis for finding Figure 5 from Schonberger persuasive on the timing issue, based upon his contrast of the higher number of cases of reported early-onset GBS against later. Reply at 15–17. He also distinguishes the onset/timeframe cases pointed to by Respondent, arguing that they involve CNS demyelination—a pathologic process that would *inherently* take longer than peripheral nervous system demyelination, since it would entail breach of the blood-brain barrier. *Id.* at 17–19. And he emphasizes that this claim does not seek the Table to be revised to include onsets of GBS occurring less than three days from vaccination; rather, Petitioner accepts that the claim is non-Table, and therefore relies on scientific and medical evidence beyond the mere facts of the case. *Id.* at 19–21.

IV. Applicable Law

A. Standards for Vaccine Claims

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a “Table Injury”); or (2) they suffered an injury actually caused by a vaccine (i.e., 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 & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim—mainly because onset of the claimed injury, GBS, unquestionably occurred outside of the defined time period for such a claim. 42 C.F.R. § 100.3(a)(XIV)(D) (listing requirement that manifestation of first symptom for a flu-GBS table claim cannot occur before three days).

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) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, 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 & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Human 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 *Althen* prong requires a different showing and is discussed in turn along with the parties’ arguments and my findings.

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 & Human 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. This standard was recently clarified by the Federal Circuit. *See Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1359–60 (Fed. Cir. 2019) (correct standard for *Althen* prong one is “reputable,” and “sound and reliable,” not a “lower reasonable standard” (internal quotations omitted)).

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 & Human 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. This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).⁹

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 & Human 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

⁹ Although there has been some confusion in the past as to whether the first *Althen* prong is *itself* subject to a preponderant standard, ample controlling authority stands for the more straightforward proposition that the first *Althen* prong is subject to a preponderance standard. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

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 & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views 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 & Human 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 also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Human 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 Health & Human 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, 356–57 (2011), *aff’d without opinion*, 475 F. App’x. 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 & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide 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 & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

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 & Human 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).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and “complete” (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human 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 & Human Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people 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 & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human 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 & Human Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally 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 & Human 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, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human 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 & Human 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 & Human 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 & Human 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 & Human 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 & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Human 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).

However, in the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings—e.g., 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 & Human 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 of her own 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 & Human 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 & Human 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 & Human 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 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 & Human 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 & Human 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. *Consideration of Prior Vaccine Program Decisions*

In reaching a decision in this case, I have considered other decisions issued by special masters involving similar injuries, vaccines, or circumstances. I also reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decision in different cases do not *control* the outcome herein.¹⁰ *Boatmon*, 941 F.3d at 1358–59 (Fed. Cir. 2019); *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined *elsewhere*, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner’s injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec’y of Health & Human Servs.*, 76 Fed. Cl. 328, 338–39 (2007) (“[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*”) (emphasis added). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases, but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to “reinvent the wheel,” so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value – and why special masters often explain how a new determination relates to such past decisions.¹¹ Even if the

¹⁰ By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

¹¹ Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury, and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after the flu vaccine as not requiring extensive proof on *Althen* prong one “can cause” matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners—and I have in fact done so *in this very case*.

Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon*, 941 F.3d at 1358), it is still *wise* to do so.

F. *Determination of Case Without Hearing*

The parties have acquiesced to my determination that resolution of this case on the papers, rather than by holding a hearing, is the most appropriate means of its disposition. 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 & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *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 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 & Human 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 & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

As noted, Petitioner has satisfied the first, “can cause” *Althen* prong, since (for Program purposes) the flu vaccine has credibly been associated with GBS.¹² I also am assuming for sake of argument that Ms. Rowan’s GBS diagnosis is not in question.¹³ Accordingly, the primary issue presented for disposition is whether her approximately 30 to 36-hour onset (with symptoms beginning the evening of September 28, 2019—the day after vaccination) is medically

¹² Petitioner somewhat misstates my view of this matter, however, when he asserts that I “have said that the Secretary of Health and Human Services’ decision to add Guillain-Barré syndrome after seasonal influenza vaccination to the Vaccine Injury Table satisfies *Althen* prong 1.” Brief at 4. It is well understood in the Program that a non-Table vaccine injury claimant *cannot* overtly leverage a comparable Table claim’s requirements to establish entitlement by a preponderance. *Grant*, 956 F.2d at 1148; H.R. Rep. No. 99–908, Pt. 1, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344. Of course (and as Petitioner later notes accurately), the *science* that underlies the grounds for the Table amendment, along with any existing well-reasoned Program decisions on the matter, can be referenced in support of a non-Table claim, and where the weight of this evidence has consistently resulted in prior determinations by other special masters that a particular vaccine is reliably associated with an injury sufficient to meet the first prong, there is no need to require a detailed and extensive evidentiary showing going over the same well-plowed ground (especially in the absence of new research undercutting prior determinations). Brief at 5 (referencing scientific data relied upon by HHS in promulgating flu-GBS Table claim).

¹³ Earlier in the case, Respondent seemed to concede the appropriateness of the GBS diagnosis. Rule 4(c) Report, filed on Jan. 4, 2018 (ECF No. 11), 9 n.3 (“respondent does not dispute the diagnosis of GBS in this case”). More recently, however, Respondent has questioned it. *See, e.g.,* Opp. at 8 n.2. Regardless, for purposes of the present decision I will assume that the diagnosis is not contested (although I acknowledge that this remains a potentially disputed issue that might require resolution if my determination in this case on timing were overturned on appeal).

acceptable.

I. Reference to Table Requirements When Adjudicating Non-Table Claims

I accept Petitioner's assertion that he does not formally seek to expand the Table's early-onset requirements in flu vaccine-GBS cases from a three to a two or even one-day minimum. Certainly he is entitled to seek damages for a Vaccine Act non-Table claim that is "like" an existing Table claim, even if he cannot meet one of the Table version's elements. Section 11(c)(1)(C)(ii)(II). Here, Petitioner has attempted to establish his causation-in-fact claim with a variety of scientific and medical evidence, and thus embraces his proper evidentiary burden. Nor does he explicitly, or even implicitly, assert that the minimal temporal difference between Ms. Rowan's onset (30 to 36 hours) and the Table-defined onset (no less than 72 hours) is a basis for a favorable determination. Nevertheless, the interplay between the evidence necessary to establish comparable Table and non-Table claims merits some comment.

Given the Program's oft-noted remedial goals and focus on fairness, when faced with a "close-to-Table" claim it is always tempting for special masters to give a petitioner the benefit of the doubt—especially when the onset timeframe is the primary disputed matter.¹⁴ This is a temptation that must be resisted, for controlling and persuasive Program precedent does not permit claimants to rely on the Table requirements, or even the mere *existence* of a Table version of a claim, in proving a non-Table claim. *See, e.g., Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("similarity of a petitioner's injury to those listed on the Table does not show causation in fact"); H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), *reprinted in* 1988 U.S.C.C.A.N. 6344, 6356 ("the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation").

Much of the reason for this distinction flows from what a Table claim actually represents: a concession by the Government that when medical record facts are established pertaining to certain post-vaccination injuries, causation is presumed. *See de Bazan*, 539 F.3d at 1351; *Grant*, 956 F.2d at 1147 (quoting H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359). That presumption has consequences, for it obviates the need to litigate the kinds of thorny causation questions (such as the association of a vaccine with a particular injury, or the timeframe the injury would be expected to occur post-vaccination) that normally characterize the adjudication of non-Table claims. It also means, more importantly, that a claimant who can prevail on a Table claim simply by meeting its factual requirements *will*

¹⁴ This dilemma arises less commonly when Respondent disputes a petitioner's satisfaction of the Table's *definition* of a particular injury - although such questions can be difficult to resolve, and often require expert input.

receive damages.¹⁵

As a result, Respondent vigilantly patrols the “borders” of a Table claim’s requirements, especially when invoked in non-Table cases. The Government only endorses Table amendment when it believes the basis for adding such a claim has sufficient scientific support. It stands to reason that claims that cannot meet a particular Table requirement (here, that GBS onset post-vaccination have occurred in no less than three days) face a more difficult path in establishing causation. Thus, a claimant’s inability to meet the Table requirements of a particular claim mean that his burden will be heightened in part, even if he *can* meet other part of the Table version’s requirements (as here).

Special masters have dismissed non-Table claims for failure to offer sufficient preponderant evidence where a petitioner’s onset fell just outside the Table requirements. *See, e.g., Orton v. Sec’y of Health & Human Servs.*, No. 13-631V, 2015 WL 1275459, at *3–4 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (one-day onset of GBS after flu vaccine administration not substantiated with expert opinion). And flu-GBS claims have otherwise been dismissed where the onset timeframe was not demonstrated to be medically acceptable. *Orton*, 2015 WL 1275459, at *3–4; *Corder v. Sec’y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *29 (Fed. Cl. Spec. Mstr. May 31, 2011) (denying entitlement of flu-GBS claim because Petitioner’s onset was four months post-vaccine).

At bottom, a petitioner may certainly rely on the same kinds of evidence that led to addition to the Table of a particular claim in seeking to prove a non-Table version of the same claim. In many cases, such evidence might be especially persuasive, depending on the *Althen* prong at issue (although it is also possible that the evidence relied upon for the Table requirements is unhelpful as well). But Vaccine Act claimants *cannot* meet their preponderant burden of proof in a non-Table claim context merely by noting how close they are to satisfying the Table requirements.

II. Petitioner Did Not Establish Ms. Rowan’s Onset Occurred in a Medically Acceptable Timeframe

Even though Petitioner offered several scientifically-reliable items of evidence to support the argument that a 30 to 36-hour onset of GBS post-vaccination was medically reasonable, his overall showing did not preponderate in his favor.

First, his contention (which was substantiated with reliable evidence) that GBS is more

¹⁵ In addition, the limited circumstances for when this presumption obtains is a product of the long-standing legal directive that waivers by the federal sovereign of immunity to suit (which the Vaccine Act reflects) are to be strictly construed. *See Sebelius v. Cloer*, 569 U.S. 369, 380–81 (2013) (explaining that the cannon favoring strict construction of waivers of sovereign immunity gives way when the words of a statute are unambiguous).

likely to occur within six weeks of vaccination than after, and therefore any onset *within* that larger time frame is also medically acceptable, was unpersuasive. While the greater timeframe inherently includes the lesser, citation to the outmost time period in which medical science arguably allows for the possibility that the flu vaccine could cause GBS is insufficient by itself to establish that a short timeframe is also medically acceptable. *de Bazan*, 539 F.3d at 1352 (“we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked”). In making this argument, Petitioner seems to be conflating the evidence that supports a flu vaccine-GBS relationship under *Althen* prong one with evidence necessary to show how or why a short onset timeframe could be acceptable. But even though the first and third prongs of the *Althen* test are unquestionably related, evidence supporting one does not necessarily carry the same weight when offered with respect for the other.

Second, Petitioner has not offered sufficient preponderant evidence reliably supporting the medical acceptability of the short onset at issue. Almost the *only* item of independent evidence Petitioner relies on to defend Ms. Rowan’s short onset is Schonberger, but it does not perform as intended. There is no doubt that, despite having been published more than 40 years ago, Schonberger remains a persuasive piece of epidemiologic evidence supporting the general contention that the flu vaccine can cause GBS. It is for this reason that Schonberger continues to be referenced by petitioners who seek to leverage its findings about one kind of autoimmune-oriented, vaccine-caused demyelination as relevant to *all* kinds. *See, e.g., Greene v. Sec’y of Health & Human Servs.*, No. 11-631V, 2019 WL 4072110, at *9 (Fed. Cl. Spec. Mstr. Aug. 2, 2019), *mot. for review den’d*, 2020 WL 702241 (Fed. Cl. 2020), *appeal docketed*, No. 20-1544 (Fed. Cir. Mar. 6, 2020) (denying entitlement for a brachial neuritis claim in which Dr. Steinman relied on Schonberger to support his *Althen* prong three onset opinion).

But Schonberger is not the “Ur-text” of scientific articles for purposes of all Vaccine Act claims. In particular, it loses persuasive heft when offered in disparate contexts, such as when invoked to prove a CNS injury (rather than peripheral nerve injury) was vaccine-caused. *See, e.g., L.Z. v. Sec’y of Health & Human Servs.*, No. 14-920V, 2018 WL 5784525, at *18 n.18 (Fed. Cl. Spec. Mstr. Aug. 24, 2018) (“[p]etitioner’s evidentiary showing regarding the timing prong is similarly deficient based on the scientific literature submitted” because it relied on the Schonberger study on GBS, which was “distinguishable from MS”); *see also Jones v. Sec’y of Health & Human Servs.*, No. 15-1239V, 2018 WL 7139212, at *16 (Fed. Cl. Spec. Mstr. Dec. 21, 2018) (“Schonberger’s timeframe [] is much less persuasive when used by way of analogy to a different condition that purportedly resulted from different vaccines”).¹⁶ And the fact that Schonberger is strong evidence for the first *Althen* prong in this case does not mean that it is

¹⁶ Indeed, Petitioner recognizes the distinction, at least with respect to the relevant timeframe issue, between peripheral nerve system demyelinating illnesses and CNS demyelination, given the difficulties a vaccine-induced process would face in reaching CNS nerves. Reply at 17-19.

also equally strong on the other prongs—especially to the extent its focus or findings are inapposite for the purpose cited.

This is the case herein. Figure 5 from Schonberger, which Dr. Steinman references in support of his onset opinion, was included in Schonberger (as its text reveals) to illustrate that (a) most of the individuals referenced in the chart experienced onset within four weeks of vaccination, and (b) ten percent of the total sample experienced onset on the 16th or 17th day post-vaccination. Schonberger at 112. Even though Figure 5 unquestionably observes *some* GBS cases beginning in a timeframe comparable to what Ms. Rowan is purported to have experienced, Schonberger draws no conclusions at all about whether these cases *were* vaccine caused, or (more importantly) if a shorter timeframe is medically acceptable. In fact, the thrust of Figure Five is that an onset *longer* than what Ms. Rowan experienced is to be expected for most cases, all things being equal.

Schonberger thus simply does not stand for the proposition asserted. Rather, the small number of cases of GBS that Figure 5 identifies as having begun within two days of vaccination illustrate the kind of temporal association long rejected in the Program as preponderant evidence supporting causation. Schonberger does not otherwise comment on the question of onset, or whether the early cases identified might be vaccine-caused. *Forrest*, 2019 WL 925495, at *7 (Schonberger did not examine “whether the incidence of GBS within two days of vaccination occurred more frequently than expected”).

Third, Petitioner’s timing argument unpersuasively relies on conflating different stages of the adaptive immune response timeframe (which under a theory of molecular mimicry would occur, as the flu vaccine triggered the production of sufficient numbers of anti-ganglioside antibodies to cause peripheral nerve demyelination) into a single process. However, as observed in *Forrest* by Special Master Moran, the IOM Report cited by Petitioner in this case discusses a lag and “log” phase in the adaptive immune response, which involve *different* processes that occur sequentially. Lag begins the process, and is the time during which the body encounters foreign antigens and through recognition of them initiates an adaptive process, while log is the phase when those antibodies are actually produced. *Forrest*, 2019 WL 925495, at *6; IOM Report at 58. Under a theory of an autoimmune cross-reactive attack sufficient to cause demyelination, the pathologic phase resulting in clinical symptoms could not begin until the *end* of the lag phase at the earliest, and likely would occur sometime *within* the log phase. Thus, even if recall to a previously-encountered antigen could occur as fast as 24 hours, as Dr. Steinman argues, it is unlikely the pathologic period of the autoimmune response would progress enough to produce clinical symptoms *immediately* thereafter. In effect, as Dr. Levinson persuasively established, Dr. Steinman has “squashed” together these connected phases of the immune process into a single shortened timeframe.

The above underscores the deficiencies in Dr. Steinman’s opinion. It is indisputable that

a special master need not accept at face value an expert's *ipse dixit*. *Snyder*, 88 Fed. Cl. at 743. Thus, Petitioner cannot establish that a 36-hour onset was reasonable on the basis of Dr. Steinman's mere say-so. He instead needed to demonstrate *why* that say-so should be embraced—and thus Dr. Steinman's opinion needed to demonstrate that it arose from sufficient reliable scientific basis. But other than Schonberger (which alone was not enough to reliably establish the medical acceptability of a 36-hour onset), his opinion was lacking in this regard. And despite his overall testimonial qualifications, Dr. Steinman cannot point to any personal research or direct expertise on the question of the timeframe for vaccine-induced GBS onset. By contrast, Dr. Levinson's views of the medically acceptable timeframe for an adaptive immune response *were* supported by the IOM Report, and overall seemed more consistent with what is known about immunology generally.

Ms. Rowan's age also likely impacted the timeframe in which her adaptive immune process (here, directly relevant to her injury)¹⁷ unfolded. Because she was over ninety years old at the time she received the flu vaccine at issue,¹⁸ I asked the parties' experts to provide an opinion whether an elderly individual's immune response would be expected to be swifter—whether generally or specifically in response to GBS.¹⁹ Dr. Steinman's supplemental report, however, avoided direct comment on whether the elderly immune response is likely faster. Moreover, Dr. Steinman cited an item of literature, Wang, that not only did not support Petitioner's claim in a greater sense (since it discounts the possibility that the flu vaccine can cause GBS), but says nothing about the timeframe in which elderly GBS patients would be expected to generate the anti-ganglioside antibodies associated with the disease. Wang at 159–65.

Dr. Levinson, by contrast, directly addressed the question presented, offering some literature that reliably supported the conclusion that although elderly GBS patients will likely experience a more severe form of the disease, the fact that their immune systems are less sensitive when responding to foreign antigens means that the adaptive response timeframe will

¹⁷ GBS is understood to be mediated by an autoimmune process that is attributable to the erroneous functioning of the adaptive immune system. Antibodies produced by B cells as part of the adaptive response to the antigens presented (whether through foreign infection or here, vaccine) attack the myelin sheath of peripheral nerves. *Perez v. Sec'y of Health & Human Servs.*, No. 10-659V, 2015 WL 9483680, at *8–9 (Fed. Cl. Spec. Mstr.) (“Dr. Steinman contends that one of the infections from which Petitioner suffered, or the flu vaccine she received, elicited an adaptive immune response that resulted in the molecular mimicry process and an attack on the myelin sheaths”).

¹⁸ There is no evidence in this case that Petitioner received the higher-dose Fluzone vaccine—a factor that other special masters have deemed significant when evaluating an elderly patient's immune response (especially one with existing comorbidities). See *Halverson v. Sec'y of Health & Human Servs.*, No. 15-227V, slip op. at 38 (Fed. Cl. Spec. Mstr. Feb. 4, 2020) (higher dose Fluzone vaccine coupled with petitioner's upper respiratory infection “significantly aggravated her preexisting heart disease, resulting in her death”).

¹⁹ There is little Program case law addressing this point (other than a single case that indirectly discusses the issue, *Miles v. Secretary of Health & Human Services*, No. 12-254V, 2018 WL 3990987, at *49 (Fed. Cl. Spec. Mstr. June 28, 2018), *mot. for review denied*, 142 Fed. Cl. 136 (2018), *aff'd*, 769 F. App'x 925 (Fed. Cir. 2019)).

likely be *longer* than one or two days. Admittedly, some of the literature Dr. Levinson cited (Peric in particular) was unhelpful to his argument, and overall the evidence discussing the timeframe in which elderly GBS patients might be expected to experience onset of GBS is limited. But at a minimum, and consistent with my charge to weigh the evidence presented in an effort to evaluate if it preponderates in favor of a claimant, I find that Dr. Levinson's contentions on these matters were more pertinent, persuasive, and substantiated than those of Dr. Steinman.

A petitioner armed with better and more reliable evidence—say, a treater willing to opine that the vaccine caused a shorter-than-usual disease onset,²⁰ some literature discussing the onset issue in the relevant context, a differently-aged injured party, or an expert with direct experience in evaluating timeframes for immune-mediated illnesses—might be able to substantiate preponderantly the claim that a timeframe for flu vaccine-caused GBS shorter than envisioned by the Table could be medically acceptable. But that has not been accomplished here.

CONCLUSION

Petitioner's claim must be dismissed because it has not been demonstrated that the flu vaccine could cause GBS in a 30 to 36-hour timeframe. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.²¹

IT IS SO ORDERED.

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

²⁰ The treater letter from Dr. Nasser obtained in this case does not accomplish this. It says nothing about the flu vaccine's role in causing Ms. Rowan's GBS.

²¹ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.