

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**No. 17-1494V**  
(not to be published)

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JESSICA WATTS, \*  
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                    Petitioner, \*  
\*  
                    v. \*  
\*  
SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*  
\*  
                    Respondent. \*  
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Special Master Corcoran  
Filed: August 13, 2019  
Residual Effects of Vaccine  
Injury; Six Months Severity  
Requirement; Corroborative  
Record Evidence

*Randall G. Knutson*, Knutson & Casey Law Firm, Mankato, MN, for Petitioner.

*Heather L. Pearlman*, U.S. Dep’t of Justice, Washington, DC, for Respondent.

**ENTITLEMENT DECISION**<sup>1</sup>

Jessica Watts filed a petition on October 11, 2017, seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”).<sup>2</sup> ECF No. 1. Petitioner alleged that the influenza (“flu”) vaccine she received on October 12, 2014, caused her to develop Guillain-Barré syndrome (“GBS”). *Id.* at 1 ¶ 13. This case was originally assigned to the Office of

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<sup>1</sup> Although this Decision has been formally designated “not to be published,” it will nevertheless be posted on the Court of Federal Claims’ website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012).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.*

<sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–37 (2012) (hereinafter “Vaccine Act” or “the Act”). Individual section references hereafter shall refer to § 300aa of the Act.

Special Masters's Special Processing Unit (which is intended for claims deemed likely to settle or be easily resolved), but was transferred to me in December 2018.

Respondent's Rule 4(c) Report, dated November 30, 2018 (ECF No. 23), disputed Petitioner's entitlement to a Vaccine Program award. Specifically, although Respondent conceded that Ms. Watts did experience GBS, he noted that proof of vaccination had not been established, and also that the medical record did not preponderantly support the conclusion that she suffered the residual effects of the allegedly vaccine-caused injury for more than six months. Rule 4(c) Report at 6–8 (citing Section 11(c)(1)(D)(i)).

I ordered the parties to brief these two issues, and they have done so. Petitioner's Brief, dated May 13, 2019 (ECF No. 30) ("Mot."); Respondent's Response, dated May 29, 2019 (ECF No. 31) ("Opp."). As Petitioner filed the relevant vaccination record, Respondent now agrees that Petitioner has established sufficient proof of vaccination. Opp. at 1. However, Respondent maintains his position that Petitioner did not suffer the residual effects of her GBS for more than six months, meaning that the Vaccine Act's "severity" requirement cannot be met under the facts of this case. *Id.* at 1–2. Having reviewed the parties' respective filings and the medical record, I find that Respondent's remaining objection is well-taken, and therefore (for the reasons discussed below) dismiss the claim.

## **I. Factual Background**

On October 11, 2014, Ms. Watts (then twenty-three years old) was admitted to Indiana University Health Methodist Hospital ("IUH") in Indianapolis, Indiana, for the birth of her son. Ex. 4 at 3–6, filed Oct. 19, 2017 (ECF No. 7-4). She received the flu vaccine on October 12th before being discharged. Ex. 13 at 3, filed Feb. 4, 2019 (ECF No. 28-1). Almost two weeks later on October 23rd, Petitioner went to the office of her primary care physician complaining of a three-day history of headache and a two-day sore throat. Ex. 5 at 4, filed Oct. 19, 2017 (ECF No. 7-5). She tested negative for strep throat and was instead diagnosed with pharyngitis. *Id.* Then, on October 25th, she went to IUH complaining of a three-day history of headaches plus lower extremity numbness and weakness, with a progressively worsening inability to move her legs. Ex. 4 at 89.

Petitioner was subsequently admitted to the hospital, and initial testing supported the conclusion that she was experiencing a demyelinating process. Ex. 4 at 57, 82. An MRI showed nerve root enhancement and tests revealed a protein level of 257. She was diagnosed with GBS and started on intravenous immunoglobulin treatment for five days. *Id.* at 93–94, 97, 106. By October 29, 2014, Ms. Watts showed enough improvement to be discharged from the hospital and transferred to an inpatient rehabilitation hospital for therapy. *Id.* at 82–84. She remained at the rehabilitation facility until November 12th, at which time her condition was deemed to have further improved. Ex. 6 at 134, filed Oct. 19, 2017 (ECF No. 7-6).

On December 1, 2014, Petitioner had a follow-up visit with an IUH neurologist. Ex. 4 at 126. While her strength had improved, she noted continued weakness in her hips, although she no longer felt the need to use a walker and had not had any falls. *Id.* Her sensory symptoms had resolved entirely, however, and her facial strength was improving as well. *Id.* Petitioner was instructed to begin outpatient physical therapy and occupational therapy, and follow up with the neurology department in three months. *Id.* at 128. At this point, assuming an onset of October 22, 2014 (three days prior to her return to IUH, at which time she was hospitalized), Petitioner's symptoms had at that time been present for forty days, or just under six weeks.

At the end of January 2015, Petitioner saw a new primary care physician, Allison Burke, M.D. Ex. 5 at 10. She reported to Dr. Burke that she had fully recovered, with the exception of weakness in her hips. *Id.* (“[s]he states these issues resolved and she is off medication for this”). Importantly, her neurologic exam was normal, and she displayed full strength with no focal deficits. *Id.* at 11. A final note recorded that Ms. Watts was scheduled for a follow-up neurology visit in three months, or by the end of April 2015. *Id.* It does not appear from the records filed in this case, however, that Petitioner followed through with this planned visit.

Chronologically, the next record of a medical visit is from May 2015 (more than six months from the onset of Petitioner's GBS-related symptoms). On May 6, 2015, Petitioner had a dental emergency (an abscess) for which she sought treatment at IUH. Ex. 4 at 129–34. No reference was made in this record to her prior neurologic symptoms, although the nature of this hospital visit may reasonably explain this absence. *See id.* Second, Ms. Watts saw a nurse practitioner to obtain family planning advice on May 14, 2015. Ex. 5 at 13–14. This record reflects that Petitioner's GBS had “now resolved,” and included no other complaints about ongoing neurologic symptoms, although it also does not indicate that any neurologic evaluation was performed. *Id.* at 13.

The medical record is subsequently silent for over *two years*, with no intervening incident in which Petitioner either complained of any symptoms she believed related to her GBS or other symptoms that might have been neurologic in character. The next time Petitioner appears to have sought treatment for any medical issue at all was on June 7, 2017, when she sought an osteopath's evaluation for a six-month history of nausea and vomiting. Ex. 10 at 1, 5–7, filed Mar. 28, 2018 (ECF No. 11-2). No reference was made to her 2014 GBS diagnosis, no complaints of neurologic problems were raised, and the neurologic exam that was performed at this time produced normal results. *Id.* at 6.

In addition, the record establishes that Ms. Watts required treatment in August 2017 after a motor vehicle accident in which she was injured but did not appear to suffer any symptoms that might resemble those associated with GBS (e.g., numbness or weakness). Ex 10 at 24–29. She subsequently saw a pulmonologist in early September 2017 for follow-up after testing in the wake

of her accident revealed possible respiratory issues. Ex. 11 at 6–8, filed Mar. 28, 2018 (ECF No. 11-3). Once again, Petitioner complained of no GBS-like symptoms, did not mention the diagnosis, and otherwise showed no neurologic abnormalities on examination. *Id.* at 7.

The very first record after January 2015 in which any reference at all is made to Petitioner’s 2014 GBS is from September 28, 2017, when she saw another osteopath, Molly Binkley, D.O. Ex. 7 at 1, 6, filed Oct. 19, 2017 (ECF No. 7-7). By this time, and as Petitioner has acknowledged, she was consulting with present counsel about the filing of this action, who had advised her of the need to obtain an updated medical evaluation. Mot. at 3–4. At the September 28th visit with Dr. Binkley, Petitioner maintained that she had in fact suffered persistent weakness, numbness/tingling, and pain since her GBS in the fall of 2014 (despite the fact that these claims were unsupported by her medical records from the interim period). Ex. 7 at 1. Tests performed at this time revealed no cranial nerve or sensory deficits, but did establish some reduced grip strength and finger abduction and adduction. *Id.* at 5. The sequelae set forth in the record are “some residual weakness in hands, and this affects [patient’s] ADLs [activities of daily living].” *Id.* Dr. Binkley did not propose referring Petitioner to a neurologist for follow-up, however. *See id.*

## **II. Procedural History and Parties’ Respective Arguments**

As noted above, Petitioner filed her claim on October 11, 2017. Medical records were filed over the coming months. Respondent’s Rule 4(c) Report raising questions about the severity requirement was filed in late November 2018, with the case transferred to me not long after. The parties subsequently briefed the issues raised by the Rule 4(c) Report, and the matter is now ripe for resolution.<sup>3</sup>

Petitioner argues that, although it is clearly the case that the September 28, 2017 record from her visit with Dr. Binkley was obtained after she began preparing to file this claim, it still stands as legitimate objective proof of her GBS sequelae. In so maintaining, she takes pains to state that her counsel was not somehow complicit in obtaining a medical evaluation that would assist her, stating that he had no prior relationship with Dr. Binkley. Mot. at 4. She otherwise characterizes this evidence—the only post-six months evidence of ongoing GBS sequelae offered in this case—as grounded in “objective testing” and therefore providing “ample evidence of continuing GBS issues.” *Id.*

Respondent, by contrast, emphasizes that Petitioner relies heavily on her own allegations of ongoing sequelae rather than objective evidence. Opp at 1. He also notes that the single September 2017 medical record is not corroborated by any prior-in-time evidence for the period

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<sup>3</sup> As noted above, although Respondent initially questioned whether Petitioner could establish she had in fact received the flu vaccine as alleged on October 12, 2014, he had since conceded that Ex. 13 (filed in February 2019) satisfied this concern. Opp. at 1.

of time more than six months after vaccination, during which Petitioner did not once mention or seek treatment for any ongoing sequelae, and otherwise appeared well from a neurologic standpoint. *Id.* at 1–2. As a result, the mere fact that some deficits may have been legitimately observed in September 2017 did not mean that such complaints could reasonably be linked to Petitioner’s 2014 GBS. *Id.* at 2.

### III. Applicable Legal Standards

#### A. 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 11(c)(1), 13(a)(1)(A), 14(a); 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).<sup>4</sup> Furthermore, a petitioner must show that he has “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.” Section 11(c)(1)(D).

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(a)(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 Enters. 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 & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & 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).

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<sup>4</sup> Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Human 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 & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x 712 (Fed. Cir. 2004); see also *Spooner v. Sec’y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at \*7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005): “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Id.* at 1278.

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 & 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.

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. 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 & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory’s biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States*, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner’s overall burden); *Contreras*, 121 Fed. Cl. at 245 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant’s success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g., Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master’s determination that expert “had not provided a ‘reliable medical or scientific explanation’ *sufficient to prove by a preponderance of the evidence a medical theory linking the [relevant vaccine to relevant injury]*”) (emphasis added). Regardless, petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant

evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (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 & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” an 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 & 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 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); *Caves v. Sec’y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at \*17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff’d without op.*, 475 Fed. 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 align with the theory of how the relevant vaccine can cause the injury in question. *Id.* at 1352; *Shapiro v. Sec’y of Health & Human Servs.*,

101 Fed. Cl. 532, 542 (2011), *recons. denied 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 denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

#### B. *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) (it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, 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. 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).

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. denied sub. nom. 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”)).

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, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### ANALYSIS

Program claimants not asserting a vaccine-related death or other injury requiring a specific kind of medical intervention generally must demonstrate that they suffered the residual effects or complications from their vaccine-related injury for more than six months. Section 11(c)(1)(D).<sup>5</sup> I am mindful that (in keeping with the generosity of the Vaccine Program generally, and how that policy concern impacts interpretation of the Act’s provisions) severity is not something that should be so rigidly enforced that claims are dismissed simply because the claimant’s injury “trails off” toward the conclusion of the six-month period. *See Wright v. Sec’y of Health & Human Servs.*, No. 16-498V, slip op. at 10–11 (Fed. Cl. July 16, 2019).<sup>6</sup> At the same time, Vaccine Act claims are frequently, and properly, dismissed for failure to satisfy this requirement. *See, e.g., Wagner v. Sec’y of Health & Human Servs.*, No. 17-1388V, 2019 WL 3297509 (Fed. Cl. Spec. Mstr. May 8, 2019), *mot. for review denied*, 2019 WL 2866786 (Fed. Cl. June 4, 2019); *Gerami v. Sec’y of Health & Human Servs.*, 127 Fed. Cl. 299 (2014) (upholding dismissal of case on basis of failure to meet severity requirement, where record did not establish injury lasted more than three months, and Petitioner could not persuasively vary record with physician letter prepared in anticipation of lawsuit that was not otherwise corroborated by record evidence).

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<sup>5</sup> Many decisions measure this time period from the date of vaccination, relying on a plain-language reading of the Act. *E.g., Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at \*2 (Fed. Cl. Spec. Mstr. July 18, 2014). However, I believe a more reasonable interpretation is that, since the six-month period measures severity of injury, it cannot begin *before* the time of injury, and hence is properly measured from the date of *onset*. Other special masters have also employed this rule in assessing whether the severity requirement has been satisfied. *E.g., Gerami v. Sec’y of Health & Human Servs.*, 127 Fed. Cl. 299, 305 (2014) (citing *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011)). This distinction in interpretation of the Act does not bear on the outcome of this case, however, since Petitioner’s alleged onset was close in time to vaccine administration, and the evidence offered to support severity came long after *either* time period would have expired.

<sup>6</sup> The fact that a petitioner will not be able to show extensive residual impact from a vaccine injury can properly be taken into account in damages calculation, and hence claimants are not “rewarded” for being able to satisfy the severity requirement with weak proof that the injury’s sequelae extended only a bit beyond the six-month timeframe.

Here, it appears that Petitioner's GBS had resolved within six months of onset in October 2014. No medical record in the two-plus year period thereafter—from late January 2015 (approximately three months after onset) until September 2017—demonstrates any instance in which (a) Petitioner complained of GBS-related symptoms connected to what she first experienced, (b) sought treatment for such symptoms, (c) obtained a neurologic evaluation of any kind that might corroborate either of these points, or (d) a treater proposed *any* symptom complained of by Petitioner was GBS-related. She also did not continue to see a neurologist to monitor her condition, thus differentiating this case from those where a petitioner's health may have improved but ongoing preventative treatment is deemed to satisfy the severity requirement. There is not even evidence that Petitioner was symptom-free but was nevertheless taking medication prophylactically to evade recurrence—circumstances that have usually been found to be an insufficient basis for satisfying the severity requirement in any event. *See, e.g., Toebe v. Sec'y of Health & Human Servs.*, No. 91-1623V, 1992 WL 101638 (Cl. Ct. Spec. Mstr. Apr. 23, 1992) (taking anti-seizure medication for several months following vaccine-related seizures did *not* constitute a residual effect or complication of the petitioner's injury); *Parsley v. Sec'y of Health & Human Servs.*, No. 08-781V, 2011 WL 2463539, at \*5 (Fed. Cl. Spec. Mstr. May 27, 2011) (“an increased risk of recurrence without an actual recurrence of a condition is not medically recognized as a ‘residual effect’ and is not a residual effect within the meaning of § 300aa-11(c)(1)(D)(i) of the Vaccine Act”).

The September 2017 record does not resolve this dispute in Petitioner's favor. First, although the circumstances in which the visit occurred may not be suspect in a larger sense, the fact that Petitioner only sought to obtain treatment for alleged ongoing sequelae (after failing to do so for the prior two years) right before filing this claim greatly reduces the probative value of such evidence. *See, e.g., Milik v. Sec'y of Health & Human Servs.*, No. 01-64V, 2014 WL 6488735, at \*12 n.16 (Fed. Cl. Spec. Mstr. Oct. 29, 2014) (giving less weight to physician record created for purposes of litigation than to earlier records to the contrary, especially when later record was offered “without a persuasive explanation of how or why the original record was incorrect”), *mot. for review denied*, 121 Fed. Cl. 68 (2015), *aff'd*, 822 F.3d 1367 (Fed. Cir. 2016). Second, the document itself (which was not obtained in consultation with a neurologist) is weak proof of sequelae, since the degree of deficits measured do not appear to be significant (and could well be attributable to any number of occurrences in the intervening period). And third, not only is the September 2017 medical record *not* corroborated by any earlier contemporaneous records (which, in a case in which a Petitioner *had* experienced residual effects of her injury, would “tell a story” of the claimant's ongoing treatment to manage those effects and ameliorate the pain they caused her), but it is *contradicted* by the overall record, which strongly suggests Petitioner's condition had improved long before six months had passed from onset.

This case simply does not describe the kind of circumstances that would constitute ongoing treatment for Petitioner's GBS. In cases in which I have found that the severity requirement was met despite a medical treatment "gap" arising after it appeared the injured party had mostly recovered, the length of the gap was significantly shorter. *See, e.g., Grieshop v. Sec'y of Health & Human Servs.*, No. 14-119, 2015 WL 4557620, at \*5–6 (Fed. Cl. Spec. Mstr. June 5, 2015) (denying Respondent's motion to dismiss on basis of Section 11(c)(1)(D) severity requirement). *Grieshop*, for example, involved a shoulder injury that arose after a May 15, 2012 vaccination, with onset reported within forty-eight hours. *Id.* at \*1. The petitioner in that case sought medical treatment for the injury for three months, then did not return for a follow-up visit until May 2013 (nearly nine months from the time he last saw the doctor). *Id.* at \*2. Although the evidence of the injury's ongoing nature was not particularly robust, I nevertheless found that the May 2013 record (one year from the time of vaccination and onset) was enough to establish severity. Here, by contrast, the gap is longer, with several intervening records that do not memorialize GBS-related or other neurologic complaints.

It is regrettable that Petitioner experienced GBS at all—although it is also heartening that her illness does not appear to have resulted in the kind of ongoing and lingering effects that often plague many other Vaccine Program claimants. Regardless, because the Petitioner cannot satisfy the severity requirement, she has not established entitlement to a damages award and I must **DISMISS** her claim. 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 accordance with this decision.<sup>7</sup>

**IT IS SO ORDERED.**

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

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<sup>7</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.