In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1231V

(to be published)

* *
DONALD RANDOLPH, *
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Petitioner, *
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v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
*
* *

Chief Special Master Corcoran

Filed: January 2, 2020

Influenza Vaccine; Guillain-Barré Syndrome; Onset; Table Injury; Lookback Provision

Lawrence R. Cohan, Anapol Weiss, Philadelphia, PA, for Petitioner.

Claudia Gangi, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION[1]

On August 16, 2018, Donald Randolph filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] alleging that he developed Guillain-Barré syndrome ("GBS") from receipt of the influenza ("flu") vaccine on September 22, 2014. Petition (ECF No. 1) at 1. The Petition specifically alleges an onset of October 29, 2014—37 days post-vaccination, and thus sufficient to fall within the 3-42 temporal period requirement of a flu-GBS Table claim (in light of the Table's March 2017 amendment to

[1] This Decision shall 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. *Id*.

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

include that as a cognizable Table injury). Petition at 2 ¶ 4; 42 C.F.R. § 100.3(a)(XIV)(D) (2019).

Petitioner's claim was filed nearly four years from the alleged onset date, and therefore was facially untimely under the Vaccine Act's 36-month statute of limitations. *see* Section 16(a)(2) (statute of limitations for alleged vaccine injuries not resulting in death). However, because the claim arises under the recent Table amendment, it was governed by the Act's "lookback provision" that kicks in whenever the Table is amended, and therefore was (initially) deemed timely—allowing its consideration herein. Section 16(b)(1) & (2).

After consideration of the medical records filed in this case, Respondent submitted his Rule 4(c) Report (filed on May 31, 2019), and in it requested dismissal of the case for untimeliness. ECF No. 11 ("Mot."). Respondent maintained that onset of Petitioner's GBS symptoms occurred *more* than 42 days after vaccination, and therefore a Table claim was not tenable. Mot. at 7–8. He further argued that even if Petitioner subsequently wished to maintain the claim as a non-Table, causation-in-fact claim (under which circumstances the 42-day timeframe requirement would no longer be a factual prerequisite for success), such a claim was not protected by the lookback provision. *Id.* at 8–10. Petitioner has opposed the dismissal request, arguing that (a) the evidence supports a late-October 2014 onset, and thus satisfies the Table's timeframe requirement, and (b) the lookback provision applies to the claim. *See generally* Petitioner's Response to Motion to Dismiss, dated August 22, 2019 (ECF No. 12) ("Opp.").

Based upon a thorough review of the record and all submissions, I hereby GRANT Respondent's motion. As discussed in greater detail below, the record preponderantly supports the conclusion that Mr. Randolph's symptoms began more than 42 days after vaccination—meaning he cannot substantiate the requirements of a flu-GBS Table claim. Moreover, although the lookback provision permitted my evaluation of his Table claim (as reflected in the present Decision) despite its untimely filing, once I determined that the claim could not satisfy the Table requirements, the lookback provision no longer applied—and therefore the claim could not be subsequently maintained in *any* form, given its untimeliness.

I. *Factual Background*

Mr. Randolph (a surgical technician) received the flu vaccine on September 22, 2014. Ex. 1 at 319; Ex. 4 at 10. His medical history includes some symptoms that had appeared neurologic in nature, but he received treatment for spinal stenosis in 2012, which was ultimately determined to be the most likely cause of such symptoms, and before vaccination he was not otherwise diagnosed with any peripheral neuropathy akin to what he experienced post-vaccination. Ex. 1 at 89–90, 418–19. There is no medical record evidence of any immediate subsequent reaction to the vaccine, or initial symptoms within four weeks of vaccination.

Petitioner alleges that his GBS symptoms first manifested on October 29, 2014 (37 days post-vaccination), when he purportedly fell at work due to numbness and weakness in both of his legs. Ex. 1 at 113, 163. The documents in which he reported this onset, however, are not contemporaneous with the purported fall, but were instead generated nearly four months later. *See,* e.g., Ex. 1 at 113 (February 18, 2015 handwritten physician's insurance report) and 163 (notes from February 26, 2015 visit to Dr. Allen Nielsen). Indeed, Mr. Randolph saw his primary care physician for follow-up evaluation of his diabetes and hypertension a week after purported onset, on November 5, 2014, but did not mention the fall or any associated symptoms. *Id.* at 318–20. This record notes Petitioner's receipt of the flu vaccine in September and includes a reference to his activity levels as well, thus somewhat belying any claim that this visit did not provide Petitioner the opportunity to disclose any recent injury or experience of a related sort, like the purported October fall due to leg numbness/weakness. *Id.* at 319.

The next records are from mid-December 2014. On December 15, 2014, Petitioner went to see Dr. David Primrose at Virginia Mason Medical Center in Seattle, Washington. Mr. Randolph was familiar with Dr. Primrose due to the work he had performed as a surgical technician. The record from this visit indicate that Petitioner was inspired to see Dr. Primrose by an experience approximately one week before (and hence in December 2014), when he felt a "pop" in his back, followed by intense left leg pain, while pushing a cart during his work day. Ex. 1 at 316. Dr. Primrose (who had previously operated on Petitioner's back in 2012, and who apparently encountered Petitioner on occasion at the Medical Center) had discussed the incident with Petitioner a few days before the visit, and had encouraged Petitioner to see him about it. *Id.*

From examination, Dr. Primrose determined that Petitioner's back had largely healed from his surgery, and that he displayed "really full motor power everywhere," although he displayed some sensory changes on his thigh. Ex. 1 at 316. Petitioner also revealed limited reflexes at the knee and ankles, but otherwise appeared to ambulate normally. *Id.* An MRI performed at Dr. Primrose's direction was also unremarkable, although he felt it might have revealed a protruding piece of disk that could explain Petitioner's symptoms. This record, which is quite detailed, makes no mention at all of any purported October 2014 fall or associated weakness and numbness.

Dr. Primrose subsequently proposed that Mr. Randolph go see Dr. Andrew Friedman, a physiatrist, who could help him with anything that was the product of post-surgical rehabilitation, but whose department at the hospital (physical medicine and rehabilitation) also had the capacity to perform an electromyogram ("EMG") or other related nerve function tests, in the event Petitioner's symptoms were deemed attributable to something else. Ex. 1 at 316–17. As a result, Petitioner saw Dr. Friedman the next day - December 16, 2014. *Id.* at 314.

At this visit, Petitioner reiterated his assertion that his new symptoms had arisen that same month (and not two months before) as a result of physical movement at work. Ex. 1 at 314. After examination and review of the new MRI images, Dr. Friedman characterized Petitioner's

symptoms as the product of a "recurrent left lower extremity radiculopathy," but added that he could not tell if the symptoms were truly "new" or associated with the problems that had resulted in Petitioner's surgery two years prior. *Id.* Dr. Friedman proposed that Petitioner be treated with a course of oral steroids, with a steroidal injection (an epidural) to be tried depending upon how Petitioner responded. *Id.*

Petitioner ended up requiring the injection by the end of that month, because his symptoms progressed to reoccurring anterior thigh numbness and occasional left leg weakness. Ex. 1 at 163, 311. Immediately after receiving the injection, he felt a negative reaction that caused his legs to give out. *Id.* at 163. Thereafter, in early 2015 Petitioner reported some improvement, but also that his symptoms were overall becoming progressively more painful and noticeable. By February 2015, Petitioner was seeking medical intervention on a more serious level. It was by this time (as noted above, in reference to Petitioner's visit to Dr. Neilsen) that the medical records first began to record an onset of symptoms in late October 2014 (even though prior records record a later onset). *Compare* Ex. 1 at 316 (December 15, 2014 record stating that Mr. Randolph was "doing well until just about a week ago") *with* Ex. 1 at 304 (February 18, 2015 record stating Petitioner's "back gave out" on October 29, 2014).

Treaters now proposed additional imaging, and performance of an EMG, to rule out denervation and/or a neurologic injury. Ex. 1 at 307. A nerve conduction study performed on February 20, 2015, revealed "evidence of symmetric bilateral sensory peripheral neuropathy" and "asymmetric motor demyelination and axon loss, left greater than right." *Id.* at 236. Then, Petitioner saw Dr. Nielsen again in March 2015, who affirmatively proposed that Petitioner's symptoms (especially in light of the nerve testing) might reflect an inflammatory polyneuropathy associated with the flu vaccine. *Id.* at 292. A subsequent lumbar puncture also produced results that Dr. Nielsen felt were consistent with a common GBS variant, acute inflammatory demyelinating polyneuropathy, and he reiterated his view of a possible association with the flu vaccine. *Id.* at 59, 286, 1280.

Mr. Randolph thereafter received IVIG treatments into the spring of 2015, and Dr. Nielsen continued to maintain Petitioner likely had experienced a post-vaccination AIDP. Tr. at 283. Despite the treatments, certain symptoms (in particular, areflexia) lingered on. *Id.* at 285–86.

II. ***Relevant Law***

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

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative; or (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).[3] Here, Petitioner primarily seeks to establish a Table claim, and he therefore must make a precise factual showing sufficient to meet the Table's relevant definitions, as set forth in the Table's "Qualifications and aids to interpretation" ("QAIs"). Section 14(b). If he is successful, he need not establish vaccine causation, as it is presumed if the Table requirements for a particular claim are met. Section 14(a).

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).

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, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d 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.

[3] 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).

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 ("Plausibility . . . 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, one thing remains: 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; *see also 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 at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical 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).

Medical records and/or statements of a treating physician's views, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here 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) (finding that it is not arbitrary or capricious for special masters 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 denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without op.*, 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.*; *see also 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. *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) (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; *see also Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("Given 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"); *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. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.") (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948)).

There are, however, 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) ("[L]ike 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 ("Written 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. *Ruling Without Hearing or Argument*

I have opted to decide the issue of onset in this case based on written submissions and evidentiary filings, and thus am not acceding to Petitioner's request for oral argument. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions (or components of a claim) on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

I. The Record does not Support Petitioner's Assertion that his Symptoms Began within the 3-42 Day Period under the Table Version of a Flu-GBS Claim

Assuming Petitioner was accurately diagnosed in the spring of 2015 with GBS, the record does not preponderantly support the conclusion that Mr. Randolph's symptoms began any sooner than December 8, 2014—76 days post-vaccination,[4] and approximately one week before he first saw Dr. Primrose.

In this case, the initial contemporaneous records from December 2014 are the best evidence of onset, as reflected in Vaccine Program case law. *See Caron v. Sec'y of Health & Human Servs.*, 136 Fed. Cl. 360, 384 (Fed. Cl. 2018) (affirming the special master's finding that "[p]etitioner's testimony and multiple affidavits of relatives and friends, and her date book do not overcome the presumption in favor of the information contained in the contemporaneous medical records"). Moreover, Petitioner's first meeting with Dr. Primrose provides factual context for the visit. The December 15, 2014 record notes that the visit was the product of the two only recently running into each other—in effect, further pinning the onset as having occurred in December 2014. Ex. 1 at 316. The record does not say that this informal interaction occurred outside the month of December, nor does it say Petitioner's symptoms began in October as alleged. There is otherwise *no* record evidence from the fall of 2014 that places onset in October, and the record closest in time to the alleged onset is also silent on the purported instigating injury. Ex. 1 at 318–20. The above records therefore support the conclusion that subsequent records erred in reporting, and then repeating, that October was the onset.

Petitioner's arguments in opposing Respondent's motion to dismiss are not persuasive. He does note some reasonable grounds for giving the intervening November 2014 record less weight, accurately pointing out that the purpose of this visit was primarily to check on Mr. Randolph's diabetes and hypertension, along with the fact that the record itself from this time is somewhat summary in nature. Opp. at 6–9. I give credence to Petitioner's suggestion that a person seeing a treater about a particular injury might not inform the treater of other symptoms or problems he was experiencing, even if the treatment visit in question occurred close-in-time to the disputed symptoms onset.

However, such an argument runs headlong into the fact that the next set of medical records, from December 2014—generated at a time Petitioner *did* wish to complain of symptoms involving what could arguably be the first presenting signs of GBS (weakness sufficient to cause a fall or other injury while Petitioner was engaged in physical activity at work)—do *not* refer in any way to an October onset. Rather, they consistently reference the fact that Petitioner informed

[4] Arguably, Petitioner's actual symptoms may have begun even later, if Petitioner's claim of a December 2014 "pop in his back" is deemed distinguishable from how GBS typically presents. Ex. 1 at 316. Petitioner's pre-vaccination history of back problems could well explain these initial symptoms, meaning that his actual onset of GBS did not occur until 2015. But in either case, the timeframe for onset is after the Table period.

Drs. Primrose and Friedman that his symptoms had just arisen that month, rather than two months prior. Petitioner makes virtually no effort in opposing the present motion to engage with the references in these December 2014 records, or explain why they are in error, while the records from February 2015 (two months later) are correct.

All in all, the record preponderantly supports the conclusion that the earliest Petitioner's possibly GBS-related symptoms began was the first week of December 2014. This means that if we assume (for purposes of taking the evidence in the light most favorable to Petitioner) that onset was December 8, 2014, it occurred 76 days post-vaccination—well outside the 3-42-day window set by the Table for a flu-GBS claim. Indeed, *any* date from that first week of December is still more than four weeks beyond the timeframe cut-off.

II. The Lookback Provision Does Not Save the non-Table Version of Petitioner's Claim

Because I have found that onset of Petitioner's GBS symptoms did not fall within the Table's timeframe for a claim of post-flu vaccine GBS, the cause of action cannot succeed as a Table claim. Under other circumstances, a *non-Table* version of such a claim (which would lose the causation presumptions applicable to a Table claim) could nevertheless proceed,[5] based on the contention that a 77-day onset of flu vaccine-caused GBS was still medically reasonable.[6] But Petitioner's claim was unquestionably filed in August 2018, more than three years from the onset I have found to have evidentiary support (December 2014). Although there is a "lookback" provision of the Act that permits a category of otherwise-untimely claims to be asserted in a defined timeframe after a Table amendment is enacted, I find that this provision does not save a non-Table version of a flu-GBS claim.

Vaccine Program petitioners have been able to assert claims based upon an injury allegedly due to receipt of the flu vaccine since 2005. *See* 70 Fed. Reg. 19,092–01, 2005 WL 828323. And they have previously argued that the vaccine caused GBS. *See, e.g.*, *Corder v. Sec'y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *1 (Fed. Cl. Spec. Mstr.

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[5] I have made just such a determination in other cases, after finding that facts required to support a Table claim were absent. *See, e.g.*, *Greene v. Sec'y of Health & Human Servs.*, No. 11-631V, 2019 WL 4072110, at *22 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (dismissing Table claim of brachial neuritis after Td vaccine because claimant could not show onset in 41 days, but allowing claim to go forward as non-Table claim), *appeal docketed,* No. 1:11-VV-00631 (Fed. Cl. Sept. 3, 2019).

[6] A causation-in-fact version of the current claim would still face significant obstacles that are already self-evident. GBS is widely understood to be acute and monophasic. *See Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *31 (Fed. Cl. Spec. Mstr .Mar. 15, 2019) (dismissing Petitioner's non-Table flu-GBS claim). For this reason, in most cases it will begin after being triggered (whether by infection or vaccination) in no longer a timeframe than four to six weeks. *Chinea,* 2019 WL 1873322, at *29. Most current special masters will not entertain a GBS injury case with an onset of more than six to eight weeks after receipt of the flu vaccine. *See id.* at *1, 29. Accordingly, my determination that onset of Petitioner's symptoms could not have begun sooner than the first week of December *still* makes onset in this case about *eleven weeks post-vaccination*—far too long to deem the vaccine causal. It is therefore extremely likely the claim would be dismissed on this basis even if it had been timely filed.

May 31, 2011) (petitioner alleging that the flu vaccine caused her to suffer from GBS). Effective March 21, 2017, however, the Vaccine Table was amended to include GBS as recoverable injury for individuals receiving the flu vaccine. 82 FR 6294-01, 2017 WL 202456 (Jan. 19, 2017).

Under Section 16(b) of the Act, where the vaccine injury table is amended, and that amendment makes the petitioner "eligible" or "significantly increase[s] the[ir] likelihood of obtaining compensation," then the petitioner may take advantage of the lookback provision. The enacting regulations specified that this new Table claim was subject to the Act's existing three-year limitations period, but also invoked the Act's lookback provision, which provides that any individual who alleges to have experienced an injury occurring not more than eight years before the effective date of revision (March 21, 2017) could file suit based on the new Table claim within two years of the effective date of amendment. Section 16(b).

Petitioner's claim was filed in August 2018, clearly within two years of the March 2017 Table amendment to include the flu-GBS claim. Moreover, he alleges GBS as his injury, with onset in October 2014—a date within eight years of the amendment's effective date. Thus, Petitioner's Table claim was timely under the lookback. The question, however, is whether it *continues* to be so once it is determined, as here, that it is not a proper Table claim.

There are recent Program cases in which even facially-deficient flu-GBS Table claims that were not filed within the otherwise-governing three-year statute of limitations period have nevertheless been deemed timely (and thus maintainable as a non-Table claim) under the lookback provision. *See,* e.g., *Simpson v. Sec'y of Health & Human Servs.*, No. 17-944V, *slip op.* (Fed. Cl. Spec. Mstr. Aug. 7, 2019) (46 to 47-day onset of GBS after flu vaccine too long to constitute Table claim, but non-Table claim deemed timely filed based on lookback). Special masters deciding such cases have reasoned that the very fact of amending the Table to add flu-GBS as a cause of action made it globally "easier" to succeed on *any* such claim, Table or not, since amendment constitutes the Government's embrace of this kind of claim. Therefore allowing operation of the lookback period to save an otherwise-untimely non-Table claim (especially one that was only four or five days outside the Table timeframe) was within the Act's definition of the effect of the lookback. *Simpson* at 8–9. These decisions have also invoked the oft-considered remedial nature of the Program as a reason for this interpretation, along with the fact that the lookback provision *itself* says nothing about its scope being restricted to Table claims. *Id.* at 7-8.

However, other, equably well-reasoned decisions rendered years before this recent Table amendment, but discussing the function of the Act's lookback provision, suggest a narrower reading of the lookback provision is appropriate. *See generally Gorski v. Sec'y of Health & Human Servs.,* No. 97-156V, 1997 WL 739497 (Fed. Cl. Spec. Mstr. Nov. 13, 1997). *Gorski* provides a particularly cogent analysis of the current question, and therefore is deserving of some

consideration. In it, a petitioner filed a claim in March 1997 asserting that she developed rheumatoid arthritis after receipt of the MMR vaccine seven years prior, with her symptoms manifesting within weeks of vaccination. *Gorski*, 1997 WL 739497, at *1. Former Special Master Hastings considered whether a March 1995 Table amendment that established "chronic arthritis" as an injury for the MMR vaccine "saved" a non-Table version of the claim under the Act's lookback provision.

There, as here, the lookback would operate to make the claim timely, since (a) it had been filed within two years of the amendment, and (b) the alleged injury occurred within eight years of the Table revision. *Gorski,* 1997 WL 739497, at *2–3. However (and also like the present case), Petitioner's Table claim was wanting, since he had offered no medical records that could establish he suffered from "chronic arthritis" as defined by the Table. *Id.* at *4. This left the question of whether a non-Table form of the same claim (MMR-caused arthritis) was equally entitled to benefit from the lookback.

After careful consideration of the provision's terms, Special Master Hastings concluded that the lookback provision did not save the claim. In his reading, the provision (as reflected by the post-enactment "extension" it provided) allowed individuals who might now have a potentially compensable claim "a fresh two-year period, from the effective date of the revision," to file that claim. *Gorski,* 1997 WL 739497, at *1. But only two kinds of otherwise-untimely claims could be filed - newly "eligible" claims, or claims where Table amendment "significantly increased" the likelihood of success - and Petitioner's claim met neither definition. Section 16(a) & (b).

First, Special Master Hastings observed that prior to amendment, claimants were permitted to assert a variety of non-Table-specified injuries based on the MMR vaccine, which was a "covered" Vaccine Program vaccine. Thus, because the new amendment only added a Table claim for a defined injury (chronic arthritis), petitioners were not now, for the first time since amendment, literally "eligible" to assert such a claim. *Gorski*, 1997 WL at *5. Second, he noted that while it could be argued that adding "chronic arthritis" as an MMR-associated Table claim might lend "credence to the *general theory* that the rubella vaccine can cause chronic arthritis," this did not mean that the likelihood of success in establishing a claim based on such a theory was in fact "significantly increase[d]." *Id.* In doing so, he paid heed to the irrelevance of similarity to Table claims when adjudicating a non-Table claim—that claimants with the latter sort of claim did not get to "piggyback" on the Table requirements, let alone their very existence. *Id.* He therefore dismissed the claim as untimely. *Id.* at *6.

I am sympathetic to the reasoning of decisions like *Simpson* (and certainly take note of their sound emphasis on the Program's policy goals of petitioner leniency and generosity).

However, I find the reasoning of *Gorski* far more persuasive.[7] Flu vaccine-GBS claims were litigated, often successfully, before the March 2017 amendment, and thus the amendment did not create out of whole cloth a new kind of cognizable injury. *See, e.g.*, *Corder*, 2011 WL 2469736, at *1 (petitioner alleging that the flu vaccine caused her to suffer from GBS). It is also well-accepted in the Program, as observed in *Gorski*, that petitioners cannot leverage the Table requirements, or their ability to satisfy certain of them, when asserting a non-Table claim - and thus may not, for example, take advantage of the fact that onset of a particular injury is only a day or two outside the Table's definition. *See Gorski*, 1997 WL 739497, at *6 ("the benefit of the extended limitations period would be available only if petitioner could show that her injury fits within the new 'Table Injury' category"); *Greene*, 2019 WL 4072110, at *16 n.18 (determining that a petitioner could not "rely on the Table claim timeframe for a non-Table claim").

It may be that addition of flu-GBS to the Vaccine Table "lends credence" to a non-Table version of the same claim, since the Table would not have been amended had the Department of Health and Human Services not determined that there was reliable science to support the concept. *Greene*, 2019 WL 4072110, at *16 n.18 ("Program law instead requires petitioners (and Respondents in seeking to rebut a Vaccine Act non-Table claim) to rely on *evidence* to bulwark the reasonableness of the proposed period—independent of the Table timeframe []although evidence used to establish that timeframe may still be relevant." (emphasis in original)). But even if a non-Table claimant can marshal the same literature or scientific/medical findings to support his causation-in-fact claim, this does not mean, as a general matter, that *all* non-Table versions of the claim are now significantly more likely to prevail.[8] Only claims that can meet the Table's exacting requirements will fit that bill.

It is therefore inaccurate to suggest that the mere fact of amendment of the Table means that the "atmosphere" for flu-GBS claims becomes more clement, and therefore *any* claimant who has an otherwise untimely, but arguably-valid Table claim, and who subsequently is unable to meet the Table requirements, should still obtain the lookback's benefits. Rather, a logical reading of the lookback provision in connection with the circumstances of its triggering (the

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[7] My construction of the lookback provision is also governed by "'sovereign immunity' principles of statutory construction." *O'Connell v. Sec'y of Health & Human Servs.*, 63 Fed. Cl. 49, 57 (2004), citing *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed.Cir.2000) (quoting *Block v. North Dakota*, 461 U.S. 273, 287 (1983)). Such principles require me to "interpret the 'Government's consent to be sued' under the Vaccine Act 'strictly in favor of the sovereign' and not 'enlarged . . . beyond what the language requires.'" *Id.* (quoting *United States v. Nordic Vill., Inc.*, 503 U.S. 30, 34 (1992)).

[8] A person, for example, whose GBS began six months post-vaccination will still likely fail even after Table amendment. *See, e.g.*, *Chinea*, 2019 WL 1873322 at *32 ("[t]he most reliable medical literature offered in this case establishes that a reasonable timeframe for onset of GBS after vaccine administration is no more than six to eight weeks. This is echoed by the timeframe set for the Table version of the claim, which is grounded in scientific observation of *how* the flu vaccine would result in harmful demyelination." (internal citations omitted) (emphasis in original)).

Table's amendment) suggests that the lookback *only* "saves" claims that, but for their untimeliness, *would satisfy the Table's requirements*.[9] As a result, and following the sound reasoning of *Gorski*, I find that the lookback provision does not save an untimely non-Table version of the Petitioner's flu-GBS claim.

I emphasize that (consistent with my interpretation of the lookback's operation) Petitioner *has already received the benefit of the lookback*. Ordinarily, nearly *any* claim[10] that was filed more than three years after symptoms onset would be subject to prompt dismissal. Here, that is unquestionably the case, whether onset is measured from October 2014 or December 2014, since the filing of this action was at least approximately nine months late. But I have nevertheless evaluated the Table claim as if it had been filed in a timely manner, and considered the evidence to determine if in fact the Table's requirements were met. Once it was evident that the claim could not stand on its own two feet as a viable Table claim, the lookback ceased to "save" it.

Admittedly, my reading of the Act's lookback provisions means that some claims that just barely fail the Table's requirements—for example, an onset that is 45 days, or a claim where the alleged GBS injury finds some record support but cannot satisfy the Table's strict definitional requirements—may appropriately be dismissed as untimely, even though had the claim been filed within three years of onset, it might have been permitted to go forward. But such claims will have *still* benefitted from the lookback, since (to the extent they present a factual dispute that cannot be facially resolved) they will obtain consideration by a special master under the "fresh start" occasioned by enactment of the amendment.

III. This Case was Properly Resolved without a Hearing.

In deciding onset based on the record and written filings, I am declining Petitioner's request that I conduct a hearing or allow counsel the opportunity for oral argument. The choice of how best to resolve this case is a matter that lies generally within my discretion, but given Petitioner's objections I shall explain my reasoning.

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[9] Petitioner's opposition brief largely seems to concur with this interpretation of *Gorski*. Opp. at 16 ("[i]n order for a table revision to "significantly increase" a person's "likelihood" of receiving compensation under the Act, the person must have suffered the new Table Injury and be able to satisfy all of the corresponding newly-established criteria for the injury as well.").

[10] The narrow and limited circumstances in which claimants in the Vaccine Program may invoke the doctrine of equitable tolling to extend the limitations period (for example, due to intervening mental incapacity) have not been invoked by Petitioner, and are otherwise inapplicable here. *See Cloer v. Sec'y of Health & Human Servs*., 654 F.3d 1322 , 1344-45 (Fed. Cir. 2011) (holding that the petitioner could not invoke doctrine of equitable tolling because she had put forth no argument that she had "been the victim of a fraud, or of duress").

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, oral argument and/or witness testimony would not have helped resolve the matter. The question of onset was discrete and clearly addressed by the medical records most contemporaneous to the purported start of Petitioner's injury. While Petitioner might have preferred that I allowed him a chance to try to explain away record inconsistencies, assessing his credibility in the process, it is my experience that live testimony is not particularly helpful in cases like this, where the contemporaneous record proof is so unambiguous and persuasive. This was not a case where the record truly allowed for an alternative conclusion, and therefore made witness testimony or attorney argument necessary. In addition, the legal issues posed by the application of the Act's lookback provision could be resolved without attorney argument.

I also reiterate (as noted in footnote 6 above) that I discern clear substantive weaknesses with even a non-Table version of this claim, thus further counseling a summary disposition of the claim. My onset determination largely renders this a non-tenable non-Table flu-GBS claim, since onset would be approximately 11 weeks post-vaccination. In addition, even an earlier onset would not convert the claim into one likely to result in a favorable entitlement award. For the medical record reveals an individual whose symptoms at best slowly evolved from early November until February (a three-month period) before becoming acute and suggesting to treaters that he had some form of GBS. This does not describe how GBS typically unfolds, as I have noted in other cases where I rejected claims of a lingering GBS "variant" like this. *See Chinea*, 2019 WL 1873322, at *30-32 (dismissing claim that petitioner's GBS "smoldered" for several months before an acute presentation nearly four months post-vaccination).

CONCLUSION

Petitioner cannot sustain a flu-GBS Table claim in this case because the evidence does not preponderantly support a finding that his onset occurred within 42 days of vaccination. Because the claim is otherwise untimely, it also cannot proceed as a non-Table claim. Accordingly, the claim is hereby DISMISSED.

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.[11]

IT IS SO ORDERED.

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

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