

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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MARK CROSBY,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* * * * *

Michael Galasso, Robbins, Kelly, Patterson, & Tucker, LPA, Cincinnati, OH, for petitioner;

Althea Davis, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS¹

Mark Crosby alleged that a trivalent influenza ("flu") vaccination he received on October 21, 2016, followed by a pneumococcal (Prevnar 13) vaccination he received on January 25, 2017, caused him to develop Guillain-Barré syndrome ("GBS"). Pet., filed Sept. 26, 2018, preamble. After he moved to dismiss his petition, a decision found he was not entitled to compensation. Unpublished Decision Denying Compensation, No. 18-1478V, 2020 WL 4728849 (Fed. Cl. Spec. Mstr. July 16, 2020).

¹ The E-Government Act, 44 § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website (<https://www.uscfc.uscourts.gov/aggregator/sources/7>). Once posted, anyone can access this decision via the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will be reflected in the document posted on the website.

As the Vaccine Act permits, Mr. Crosby seeks an award of attorneys' fees and costs. To establish his eligibility for attorneys' fees and costs, Mr. Crosby must demonstrate that the claims set forth in his petition were supported by reasonable basis. The Secretary objects, maintaining that the objective evidence does not support a finding of reasonable basis.

The totality of evidence is insufficient to conclude that the claims in the petition were supported by reasonable basis. Accordingly, the motion for attorneys' fees and costs is DENIED.

I. Events in Mr. Crosby's Life²

On October 21, 2016, Mr. Crosby received a flu vaccination. Exhibit 1 at 1. Mr. Crosby later received a Prevnar 13 vaccination on January 25, 2017. Exhibit 2 at 18.

On or about February 1, 2017, Mr. Crosby manifested symptoms consistent with a viral upper respiratory infection.³ By February 3, 2017, petitioner started experiencing left hip pain. Over the next two days, his leg weakness and numbness worsened to the point that he was unable to walk.

On February 5, 2017, Mr. Crosby was admitted to an inpatient neurology service. He reports that he was unable to walk due to leg weakness and was experiencing numbness and tingling from the neck down. He was then admitted to the ICU at Premier Health Miami Valley Hospital, where an EMG suggested he likely suffered GBS. Exhibit 3 at 6. He received two five-day rounds of IVIG.

Mr. Crosby was discharged from the hospital on March 17, 2017. He had shooting pains and required 24-hour assistance for transfers and walking. Exhibit 3 at 3937. From then until April 5, 2017, Mr. Crosby underwent rehabilitation at a skilled nursing facility. Exhibit 6 at 3.

Mr. Crosby then saw Dr. Brammer on April 17, 2017. In his notes, Dr. Brammer wrote that Mr. Crosby was hospitalized about two months prior for acute

² The parties' briefs identify relatively few medical records relevant to the question of reasonable basis. Thus, the recitation of events is concomitantly short.

³ Mr. Crosby "steadfastly denies having a cold or reporting such symptoms and reports this as allergy like symptoms that have been present throughout his medical history." Pet'r's Br., filed Sept. 28, 2020, at 6. The Secretary comments that "[n]otably, petitioner has not personally denied these complaints." Resp't's Resp, filed Dec. 7, 2020, at 4.

onset of GBS. He had normal arm strength and mild weakness of the legs and feet. Exhibit 2 at 22-23.

On May 2, 2017, Mr. Crosby went to a follow-up appointment with his neurologist. He had arm and ankle weakness, pain in his extremities, and could not drive. Exhibit 7 at 26-36. In August 2017, the neurologist noted that Mr. Crosby's numbness had improved, and his strength had returned, though he still felt shooting electric pain in his feet.

On October 10, 2017, Mr. Crosby was examined by a different neurologist. Residual sensory deficits in the extremities were noted. Exhibit 8 at 11-12.

On December 6, 2017, Mr. Crosby's EMG indicated evidence of continued demyelination, supporting a GBS diagnosis. Exhibit 9 at 17.

In May 2018, Mr. Crosby had normal strength and gait, but lingering and persistent sensory disturbances. Exhibit 8 at 30. He reported continued generalized fatigue in October 2018, as well as decreased sensations, subjective muscle weakness, and numbness of extremities.

Additional medical records do not affect the determination of whether reasonable basis supports the claim set forth in Mr. Crosby's petition.

II. Procedural History

Mr. Crosby filed a petition on September 26, 2018. Mr. Crosby alleged he suffered from GBS "resulting from adverse effects of a trivalent influenza vaccination administered on October 21, 2016 followed by a pneumococcal (Prevnar 13) vaccination on January 25, 2017." Pet. at preamble. He contends that his injuries and GBS were "caused-in-fact" by the flu and pneumococcal vaccines. Id. at ¶ 21. Mr. Crosby's case was assigned to the Chief Special Master as part of the Special Processing Unit based upon the allegations raised in the petition.

On the same day that Mr. Crosby filed his petition, he also filed medical records and his affidavit. Exhibits 1-11. In his affidavit, Mr. Crosby states that his symptoms started "approximately 106 days" after his flu shot and "approximately 10 days" after his pneumococcal vaccine. Exhibit 11 at 1. He described his symptoms as bilateral shoulder pain radiating to his back, followed by numbing and aching from shoulder to hips and leg weakness. Id.

A status conference was held on December 19, 2018, to discuss Mr. Crosby's petition and evidence. The Chief Special Master ordered Mr. Crosby to

file all medical records for the three-year period before vaccination and an amended statement of completion. After Mr. Crosby produced more records on February 4, 2019, the Secretary filed a status report on April 4, 2019, stating that he completed a review of the records and did not identify any missing records.

Approximately eight months later, the Secretary filed his report. The Secretary contested Mr. Crosby's entitlement to compensation. The Secretary raised two obstacles: (1) the onset of petitioner's GBS symptoms was more than 15 weeks after his flu vaccination, and (2) petitioner did not submit an expert opinion causally connecting the Prevnar vaccine to his GBS symptoms. Resp't's Rep., filed Oct. 4, 2019, at 5-6.

This case was reassigned to the undersigned special master on October 9, 2019. In a subsequent scheduling order on October 21, 2021, Mr. Crosby was directed to file additional affidavits. Mr. Crosby filed affidavits regarding damages and onset on December 2, 2019, although he did not assign them exhibit numbers.

In the following status conference, petitioner's counsel stated that he was consulting Dr. Eric Gershwin to address respondent's Rule 4 report. Counsel further stated that if Dr. Gershwin were unable to provide a supportive opinion, he would likely move for dismissal. The undersigned ordered petitioner to file a status report indicating whether Dr. Gershwin would provide a supportive opinion. Order, issued Dec. 17, 2019.

After multiple motions for enlargements of time, petitioner reported on April 27, 2020 that he would not be utilizing opinion testimony from Dr. Gershwin. In a status conference on May 15, 2020, petitioner again stated he was considering voluntarily dismissing his petition but required more time to decide. He announced his intention to move for dismissal on June 15, 2020.

Mr. Crosby moved for a decision dismissing his petition on July 15, 2020. His case was then dismissed. Crosby v. Sec'y of Health & Human Servs., No. 18-1478V, 2020 WL 4728849 (Fed. Cl. Spec. Mstr. July 16, 2020).

Mr. Crosby requested an award of his attorneys' fees and costs. Pet'r's Mot., filed July 15, 2020. The following day, Mr. Crosby was ordered to file a brief explaining why there was reasonable basis for the petition. Before the Secretary addressed the reasonable basis for Mr. Crosby's claim, the Federal Circuit issued Cottingham v. Secretary of Health & Human Services, 971 F.3d 1337 (Fed. Cir. 2020), a new precedent regarding reasonable basis determinations.

After the Federal Circuit issued Cottingham, the parties were given time to file briefs stating their positions. To advance his argument that reasonable basis supports the claim set forth in the petition, Mr. Crosby initially identified four pieces of support: (1) his medical records, which included a GBS diagnosis from his treating physicians, (2) his affidavits, (3) his retention of Dr. Eric Gershwin, and (4) medical literature.⁴ Pet’r’s Br., filed Sept. 28, 2020, at 2-4. Although not raised prior to the September 28, 2020 brief, Mr. Crosby suggests he might have actually suffered from chronic inflammatory demyelinating polyneuropathy (“CIDP”) “based upon a forensic evaluation by an opinion witness.” Id. at 1.⁵ Mr. Crosby contends that he was not required to categorize his injury between GBS and CIDP to meet the reasonable basis threshold.⁶ Id. at 6-7.

The Secretary disagrees. The Secretary notes that although petitioner was diagnosed with GBS, the petition for an Off-Table Injury claim was an acknowledgment that the onset of petitioner’s GBS symptoms occurred well beyond the 3 to 42 day onset period codified in the Vaccine Injury Table for the flu vaccine. Regarding Prevnar 13, the Secretary states that it “is not causally linked to the injury alleged.” Resp’t’s Resp., filed Dec. 7, 2020, at 11. The Secretary maintains that “there was nothing in the record when the petition was filed or thereafter that provides even a scintilla of support for petitioner’s allegations” Id. at 13. The Secretary concludes: Mr. Crosby’s “claim lacked a reasonable basis when filed, and one was never established.” Id.

In his reply brief, Mr. Crosby argues he had reasonable basis to bring the claims in the petition “based only on the medical literature suggesting causation between the Prevnar 13 vaccine and his injuries.” Pet’r’s Reply filed Dec. 24, 2020, at 3. Next, Mr. Crosby argues he had reasonable basis based upon potential causation by the flu vaccine, shown in his medical records and the table. Additionally, he states he had a reasonable basis to investigate with Dr. Gershwin whether there was a link between the combination of vaccines and the injury as well as to explore differential diagnoses. Id. Mr. Crosby asserts that under the

⁴ In his brief, Mr. Crosby cited—but did not file—Ravishankar, Nidhi, *Guillain-Barre Syndrome Following PCV Vaccine*, Clinical Surgery (April 20, 2017), http://www.clinicsinsurgery.com/pdfs_folder/cis-v2-id1413.pdf.

⁵ Mr. Crosby did not identify the person who performed this “forensic evaluation.”

⁶ The potential of a CIDP diagnosis / theory had not been discussed by Mr. Crosby prior to this fees’ applications filings. The Secretary notes that no medical records or expert reports discuss a diagnosis of CIDP. Resp’t’s Resp., filed Dec. 7, 2020, at 8, n.6.

totality of these circumstances, he had a reasonable basis to assert the claims in his petition until the point when he moved for dismissal.

After the issuance of the Federal Circuit's decision in James-Cornelius v. Secretary of Health & Human Services, 984 F.3d 1374 (Fed. Cir. 2021), the parties were subsequently provided with an additional opportunity to submit supplemental briefs on the issue of reasonable basis in light of the developments from this case. Mr. Crosby filed his supplemental brief on March 9, 2021, and the Secretary filed his response on March 23, 2021.

In his brief, Mr. Crosby reiterates the sufficiency of the combination of his medical record and affidavit evidence to support reasonable basis, as well as circumstantial evidence suggesting causation. Mr. Crosby argues (1) his medical records contain objective evidence supporting a reasonable basis because the records demonstrate the vaccines were administered and his treating physicians diagnosed him with GBS. Similarly, Mr. Crosby argues (2) his affidavits are objective evidence supporting reasonable basis by further showing the vaccine administrations and injury. Analogizing to the petitioner in James-Cornelius who asserted "re-challenge" as supporting reasonable basis, Mr. Crosby notes (3) he investigated whether he actually suffered CIDP or an injury based upon a cytokine storm. Mr. Crosby also analogizes (4) the medical articles he submitted indicating possible causation to the submission of three medical articles in James-Cornelius.⁷ Pet'r's Suppl. Br., filed Mar. 9, 2021.

While the Secretary acknowledges that affidavits and medical records *can* constitute evidence supporting reasonable basis, he argues Mr. Crosby has not met his burden here. The Secretary maintains that the affidavits are consistent with the medical records but that they only establish the onset of GBS and describe Mr. Crosby's symptoms. Resp't's Suppl. Br., filed Mar. 23, 2021, at 7. The Secretary distinguishes the present case from James-Cornelius by noting in that case, a treating physician submitted a VAERS report, whereas here, Mr. Crosby's medical

⁷ In this brief, petitioner again cited the Ravishankar article, which remains unfiled. Petitioner also cited---but did not file---another article: Papathanasiou et al., *Clinical Heterogeneity of Guillain-Barre Syndrome in the Emergency Department: Impact on Clinical Outcome*, 2016 CASE REPS. IN EMERGENCY MED. 1 (Sept. 2016) (Article ID 4981274).

With petitioner's March 9, 2021 brief, petitioner filed two articles not previously submitted: Dimachkie et al., *Guillain-Barre Syndrome and Variants*, 31 NEUROLOGIC CLINICS 491 (May 2013); Fokke et al., *Diagnosis of Guillain-Barre syndrome and validation of Brighton Criteria*, 137 BRAIN, J. OF NEUROLOGY 33 (Jan. 2014). Petitioner did not assign the next consecutive exhibit number to either the Dimachkie or Fokke articles.

records contain no notations of treaters associating his vaccination(s) with his GBS. Id. at 6. The Secretary argues that petitioner's reasonable basis claim turns on whether objective evidence exists in the record to support vaccine causation. Id. at 5.

Mr. Crosby's motion is ready for adjudication.

III. Standards for Adjudication

Petitioners who have not been awarded compensation are eligible for an award of attorneys' fees and costs when "the petition was brought in good faith and there was a reasonable basis for the claim." 42 U.S.C. § 300aa—15(e)(1). As the Federal Circuit has stated, "good faith" and "reasonable basis" are two separate elements that must be met for a petitioner to be eligible for attorneys' fees and costs. Simmons v. Sec'y of Health & Human Servs., 875 F.3d 632, 635 (Fed. Cir. 2017).

"Good faith" is a subjective standard. Id.; Hamrick v. Sec'y of Health & Human Servs., No. 99-683V, 2007 WL 4793152, at *3 (Fed. Cl. Spec. Mstr. Nov. 19, 2007). A petitioner acts in "good faith" if he or she honestly believes that a vaccine injury occurred. Turner v. Sec'y of Health & Human Servs., No. 99-544V, 2007 WL 4410030, at * 5 (Fed. Cl. Spec. Mstr. Nov. 30, 2007). The Secretary has not challenged petitioner's good faith here and the undersigned finds the Secretary's position that good faith exists to be reasonable. Accordingly, Mr. Crosby's eligibility for compensation turns on the question of the reasonable basis for the petition.

Reasonable basis, in contrast, is purely an evaluation of the objective weight of the evidence. Simmons, 875 F.3d at 636. Because evidence is "objective," the Federal Circuit's description is consistent with viewing the reasonable basis standard as creating a test that petitioners meet by submitting evidence. See Chuisano v. Sec'y of Health & Human Servs., No. 07-452V, 2013 WL 6234660, at *12-13 (Fed. Cl. Spec. Mstr. Oct. 25, 2013) (explaining that reasonable basis is met with evidence), mot. for rev. denied, 116 Fed. Cl. 276 (2014).

In practice, it has proven difficult to define the modicum of evidence that confers reasonable basis. When the Federal Circuit and judges of the Court of Federal Claims have commented on the reasonable basis standard, they often do not speak of the amount of evidence that confers reasonable basis. Instead, they speak to the types of situations where reasonable basis cannot be said to exist. For example, a petition based purely on "unsupported speculation," even speculation

by a medical expert, is not sufficient to find a reasonable basis. Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994) (“Congress must not have intended that every claimant, whether being compensated or not under the Vaccine Act, collect attorney fees and costs by merely having an expert state an unsupported opinion that the vaccine was the cause in-fact of the injury.”). As another example, when “the medical and other written records contradict the claims brought forth in the petition,” a special master is not arbitrary in concluding that reasonable basis for the petition did not exist. Murphy v. Sec’y of Health & Human Servs., 30 Fed. Cl. 60, 62 (1993), aff’d without op., 48 F.3d 1236 (Fed. Cir. 1995) (table).

In Simmons, a judge found petitioner’s failure to submit a petition that complied with the Vaccine Act’s requirements supported a finding that reasonable basis for the petition did not exist. The judge reasoned that section 11(c) of the Vaccine Act requires that petitions “be accompanied with evidence of injury [to] ensure[] that petitioners and their counsel make some effort to establish that there was a vaccination and an injury that may be linked to the vaccine.” Simmons v. Sec’y of Health & Human Servs., 128 Fed. Cl. 579, 583 (2016), aff’d, 875 F.3d 632 (Fed. Cir. 2017).

The Federal Circuit clarified the reasonable basis standard, specifically materials that constitute objective evidence, in Cottingham v. Secretary of Health & Human Services, stating that “failure to consider objective evidence presented in support of a reasonable basis for a claim would constitute an abuse of discretion.” 971 F.3d 1337, 1345 (Fed. Cir. 2020). Furthermore, in categorizing medical records as objective evidence, the Federal Circuit stated, “[m]edical records can support causation even where the records provide only circumstantial evidence of causation.” Id. at 1346. The Federal Circuit in Cottingham specified that “[w]e make no determination on the weight of the objective evidence in the record or whether that evidence establishes reasonable basis, for these are factual findings for the Special Master and not this court.” Id. at 1347.

Finally, in its most recent opinion regarding the reasonable basis standard, the Federal Circuit stated that medical records, affidavits, and sworn testimony all constitute objective evidence which may support reasonable basis. James-Cornelius, 984 F.3d at 1379-81. The Federal Circuit further clarified that “absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has reasonable basis.” Id. at 1379 (citing Cottingham, 971 F.3d at 1346). These two most recent decisions guide the analysis regarding what types of evidence constitute objective evidence of reasonable basis, as originally articulated

in Simmons, though the ultimate weighing of such evidence is left up to the special master.

IV. Analysis

For the reasons set forth below, Mr. Crosby has not established a reasonable basis for his claim. Although Mr. Crosby presents some evidence to support his claim, the weight of the evidence—even at the standard that is lower than the preponderance of the evidence standard—is insufficient to support the claim that the administered vaccine(s) caused his injuries.

Through his briefs, Mr. Crosby has identified five points, which, to him, support a finding of reasonable basis. These are: (A) Mr. Crosby’s affidavit, (B) Mr. Crosby’s medical records, (C) his retention of Dr. Gershwin, (D) a potential misdiagnosis, and (E) medical literature. These topics will be discussed in turn.

A. Mr. Crosby’s Affidavit

In Mr. Crosby’s affidavit, he avers: “It is my belief that the injuries I have sustained including the diagnosis of Guillain-Barré Syndrome were caused by the trivalent influenza vaccination that I received on October 21, 2016 and the 13-valent pneumococcal conjugate vaccine on January 25, 2017.” Exhibit 11 (affidavit) ¶ 12. However, Mr. Crosby’s belief supports his good faith, a condition separate from reasonable basis required for eligibility for attorneys’ fees. See James-Cornelius, 984 F.3d at 1380 (“lay opinions as to causation or medical diagnosis may be properly characterized as mere ‘subjective belief’ when the witness is not competent to testify on those subjects.”). Mr. Crosby does not provide evidence to establish that he has the requisite knowledge, training, or education to opine on the cause of his GBS.⁸

If a petitioner, like Mr. Crosby, could establish the reasonable basis for the claim set forth in the petition simply by filing an affidavit, then the reasonable basis requirement would be meaningless. Thus, the undersigned declines to give much weight to Mr. Crosby’s affidavit opinion as to the cause of his alleged illness in determining whether reasonable basis supports the claim in his petition that the vaccination(s) caused his GBS.

⁸ On the other hand, Mr. Crosby’s affidavit can confirm when he received the vaccinations. See exhibit 11 ¶¶ 3-4.

B. Mr. Crosby's Medical Records and GBS Diagnosis

Similarly, the medical records here do not establish reasonable basis. Cottingham held that a petitioner “must point to evidence of a causal relationship between the administration of the vaccine and her injuries in order to establish that a reasonable basis for the claim existed when the petition was filed.” 971 F.3d at 1346. James-Cornelius added “the quantum of objective evidence needed to establish reasonable basis for a claim, including causation, is ‘lower than the preponderant evidence standard required to prove entitlement to compensation,’ but ‘more than a mere scintilla.’” 984 F.3d at 1379 (Fed. Cir. 2021) (quoting Cottingham, 971 F.3d at 1346).

Although the medical records show that Mr. Crosby received covered vaccines, and developed GBS after receiving two vaccinations, they do not provide evidence of causation. After Mr. Crosby's October 21, 2016 influenza vaccination and January 25, 2017 Prevnar 13 vaccination, on or about February 1, 2017, he reportedly developed symptoms consistent with a viral upper respiratory infection. Two days later he developed intense hip pain. Mr. Crosby was admitted to an inpatient neurology service on February 5, 2017. He was experiencing numbness and tingling from the neck down. Mr. Crosby was admitted to the ICU, where an EMG suggested a likely GBS diagnosis. After receiving two five-day rounds of IVIG, Mr. Crosby was discharged on March 17, 2017. Exhibit 3 at 3937. As such, the onset of Mr. Crosby's GBS would be 105 days after the influenza vaccination, nine days after the Prevnar 13 vaccination, and two days after an upper respiratory infection. Mr. Crosby also appears to rely on a note from Dr. Brammer on April 17, 2017, which states Mr. Crosby was hospitalized two months prior for acute onset of GBS. Exhibit 2 at 22.

The critical question is whether the medical records support the allegation in the petition that a vaccination *caused* Mr. Crosby's GBS. Chuisano, 116 Fed. Cl. at 287 (“Temporal proximity is necessary, but not sufficient.”). On this point, the collection of medical records is not dispositive about reasonable basis for two reasons. First, the onset of Mr. Crosby's GBS symptoms occurred more than 15 weeks after his flu vaccine. No evidence has been proffered in this case to support a finding that the flu vaccine can cause GBS more than six weeks after vaccination. See Caron v. Sec'y of Health & Human Servs., No. 15-777V, 2017 WL 4349189, at *10 (Fed. Cl. Spec. Mstr. Sep. 7, 2017) (rejecting five-month interval in context of multiple vaccines and the onset of a form of osteomyelitis), mot. for rev. denied, 136 Fed. Cl. 360, 389-90 (2018); Conte v. Sec'y of Health & Human Servs., No. 17-403V, 2020 WL 5743696, at *26 (Fed. Cl. Spec. Mstr. July 27, 2020) (rejecting

a twelve-week onset in a flu-CIDP case and remarking that eight weeks appears to be the maximum onset time frame deemed reasonable in the Vaccine Program); Pearson v. Sec'y of Health & Human Servs., No. 16-9V, 2019 WL 3852633, at *16 (Fed. Cl. Spec. Mstr. July 31, 2019) (finding, in a flu-TM case, that a “74-day onset period is medically and scientifically unacceptable”) (citing cases); Kamppi v. Sec'y of Health & Human Servs., No. 15-1013V, 2019 WL 5483161, at *11 (Fed. Cl. Spec. Mstr. July 24, 2019) (stating that “[s]pecial masters in the Program have not awarded compensation when onset occurs more than two months after vaccination” in flu-GBS cases) (citing cases). Second, the Secretary asserted that “petitioner did not cite to anything in his medical records to support his causation-in-fact claim, and none of his treating physicians indicated that there was a relationship – temporal or otherwise – between his flu and pneumococcal vaccines and his condition.” Resp’t’s Resp., filed Dec. 7, 2020, at 10. While Mr. Crosby has responded to other aspects of the Secretary’s challenge to reasonable basis, Mr. Crosby has not refuted this point.

In contrast, many petitioners are able to show evidence of causation in medical records based on the statements or opinions of their treating physicians. For example, see Bogdan v. Sec’y of Health and Human Servs., No. 16-1681V, 2019 WL 1528297, at *5 (Fed. Cl. Spec. Mstr. Mar. 13, 2019); Stewart v. Sec’y of Health and Human Servs., No. 06-777V, 2011 WL 3241585, at *8 (Fed. Cl. Spec. Mstr. July 8, 2011). Here, Mr. Crosby has not cited to any opinion by any of his treating physicians to suggest that they opined that his GBS was vaccine related.

C. Retention of an Expert Opinion Witness

Mr. Crosby retained Dr. Eric Gershwin hoping that he would provide a supportive opinion in this case. However, as counsel notes in the motion for attorneys’ fees, Dr. Gershwin “determined that he could not provide an opinion on causation as to GBS and either the influenza or pneumococcal vaccinations administered to [Mr.] Crosby based primarily on the temporal proximity between vaccination and injury.” Pet’r’s Mot., filed Sept. 28, 2020, at 3. Consultation with an expert who does not ultimately provide a supportive opinion is insufficient evidence to support reasonable basis for the claims in the petition. Chuisano, 116 Fed. Cl. at 291 (“Further undercutting petitioner’s assertion that she had a reasonable basis for bringing her claim is the refusal of the three consulted immunologists to opine favorably about causation”).

D. CIDP as an Alternative Diagnosis

In his briefs supporting attorneys' fees, Mr. Crosby raised the issue of potential misdiagnosis for the first time. He states he may have suffered CIDP "based upon a forensic evaluation by an opinion witness." Pet'r's Br., filed Sept. 28, 2020, at 1; see also Pet'r's Suppl. Br., filed Mar. 9, 2021, at 6. This argument fails for multiple reasons. First, an evaluation of reasonable basis must be based upon "objective" evidence. Simmons, 875 F.3d at 636. A statement by an attorney who represents a petitioner, referencing an out of court statement by an unidentified doctor, does not constitute evidence on which a finding of reasonable basis can be based. See Chuisano, 2013 WL 6234660, at *23.

Second, the assertion that Mr. Crosby suffers from CIDP and not GBS contradicts the multiple medical records in which doctors who treated Mr. Crosby diagnosed him with GBS. See exhibit 1 at 3 (stating "recovering from GBS"); exhibit 3 at 6 ("EMG revealed segmental demyelinating peripheral neuropathy consistent with AIDP (GBS)"); exhibit 6 at 40 (patient "admitted to the hospital in february and was dx with GBS"); exhibit 7 at 26 (patient "was diagnosed with GBS"); Pet. Ex. 8 at 3 (visit to discuss "current meds, recent GBS"); exhibit 10 at 3 ("Primary Medical Diagnosis: GBS").

Third, the petition alleges that the vaccinations caused Mr. Crosby to suffer GBS. Because reasonable basis is linked to the "claim for which the petition was brought," 42 U.S.C. § 300aa-15(e)(1), counsel's argument about a condition other than the condition identified in the petition is misplaced.

Fourth, even if Mr. Crosby properly pled that he suffered CIDP, Mr. Crosby's briefs fail to develop any remotely persuasive argument as to why a diagnosis of CIDP would make the claim that either vaccination caused him to suffer CIDP more plausible. Mr. Crosby's case would suffer from the same infirmities, such as lack of support from a medical professional, either a doctor who treated Mr. Crosby or one who presented an opinion in this litigation.

E. Mr. Crosby's Medical Literature

When ordered to file a brief explaining reasonable basis, Mr. Crosby cited (and sometimes filed) medical articles that he did not submit during the entitlement phase of the case. Mr. Crosby contends that he established reasonable basis "based only on the medical literature suggesting causation between the Prevnar 13 vaccine and his injuries." Pet'r's Reply, at 3.

Generally speaking, medical literature is objective evidence relevant to establishing a reasonable basis for a claim. Whether the medical literature is persuasive and whether it is sufficient to establish reasonable basis is a fact question for the special master. See Cottingham, 971 F.3d at 1347.

Across his various briefs, Mr. Crosby cites four articles, of which he filed two. The two articles he filed (but lack an exhibit number) are by Dimachkie and Fokke. The cited (but unfiled) articles are by Papathansiou and Ravishankar. These are discussed in turn.

The Dimachkie article, “Guillain-Barré Syndrome and Variants,” contains a discussion of broad aspects of the disease. Topics include the clinical features, laboratory features, treatment plans, and prognosis. The authors note that GBS is presumed autoimmune, but the precise molecular pathogenesis and its variants remains uncertain. Regarding vaccinations, the authors discuss the increased incidence of GBS after the 1976 swine flu vaccines and state that other vaccines have been associated with GBS, though less frequently than the flu vaccine. Six-weeks is suggested as the time in which GBS would develop following flu vaccination. The article does not discuss other vaccines, such as Prevnar.

The Fokke et al. article focuses on the Brighton diagnostic criteria for GBS. Primarily, the discussion focuses on the need for accurate diagnostic measures to improve patient care and research. The article discusses how Brighton criteria may be used to better identify patients for vaccine safety studies. However, the article is bereft of content discussing pneumococcal vaccines or GBS onset more than six weeks after flu vaccination.

The Papathansiou article discusses three case reports of GBS, highlighting the clinical heterogeneity of the presentation of GBS in these three people. It notes that clinical diagnosis of GBS in the emergency room can be challenging. The article does not discuss anything about vaccinations or the causes of GBS.

These three articles Mr. Crosby put forward do not provide the necessary support. None of these articles discuss pneumococcal vaccines causing GBS, or the flu vaccine causing GBS almost 15 weeks after vaccination. Thus, after the undersigned’s review of them, their relevance is not readily apparent. Furthermore, Mr. Crosby’s briefs do not persuasively illuminate why these articles are relevant to the issue of reasonable basis.

The other article Mr. Crosby referenced (Ravishankar) is a case report that discusses one 66-year-old female who developed GBS approximately seven weeks

after administration of a PCV-23 vaccine. See Nidhi Ravishankar, *Guillain-Barre Syndrome Following PCV Vaccine*, 2 CLINICAL SURGERY 1 (April 20, 2017), http://www.clinicsinsurgery.com/pdfs_folder/cis-v2-id1413.pdf. The article acknowledges that the literature discussing the association of GBS following pneumococcal vaccine is sparse but nonetheless proposes a possible etiology involving PCV vaccination. Mr. Crosby did not submit an accompanying statement from an expert explaining the significance of the article.

After considering the article, the undersigned declines to give substantial weight to this article for multiple reasons. First, the subject of the Ravishankar article received a different vaccine immediately before developing GBS, making reasoning from Ravishankar difficult. See *Deschler v. Sec’y of Health & Human Servs.*, No. 16-1070V, 2020 WL 4593162, at *5 (Fed. Cl. Spec. Mstr. July 1, 2020); see also Ravishankar at 2 (“There are two types of pneumococcal vaccines, plain and conjugated, that have different mechanisms”). Second, as a single report, the article carries less persuasive value than larger studies or meta-analyses. In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See *K.O. v. Sec’y of Health & Human Servs.*, No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

Third, Ravishankar does not conclude that there is a causal association between the PCV vaccination and GBS. Mr. Crosby did not submit any statement explaining the article or have Dr. Gershwin, or any other experts, submit a report explaining its significance. Without a statement from Dr. Gershwin, or another expert regarding how the article relates to his situation, Mr. Crosby is left to rely upon inferences about causation made by his attorney. But, an attorney’s argument carries less value than an opinion from an expert. See *Gilda Industries, Inc. v. United States*, 446 F.3d 1271, 1281 (Fed. Cir. 2006).

Fourth, even if the Ravishankar article could justify the finding that reasonable basis supports the assertion that the Prevnar vaccine can cause GBS, Mr. Crosby would face an additional gap. Mr. Crosby would still need some objective evidence to support the finding that the Prevnar vaccine caused his GBS specifically. While this evidence might come in a variety of forms, the evidence that Mr. Crosby has presented in this case is not enough.

Fifth, on a procedural note, Mr. Crosby did not file or cite this article during the entitlement phase. Indeed, Mr. Crosby has never *filed* the article. Even if it had been filed during the pendency of the underlying entitlement portion of the

case, it alone does not establish reasonable basis. Although the Ravishankar article counts as *some* objective evidence supporting causation, due to the facts of this case, its value is significantly limited.

In sum, the undersigned has considered each argument Mr. Crosby advanced both individually and holistically. Mr. Crosby has not carried his burden of establishing the reasonable basis that the vaccination(s) caused his GBS. This burden, as pointed out above, is less than the preponderance of the evidence, and, therefore, easier to satisfy. But, even under this lower burden of proof, the reasonable basis for Mr. Crosby's claim has not been established.

In setting the reasonable basis standard, Congress did not intend for every claimant to "collect attorney fees and costs by merely having an expert state an unsupported opinion that the vaccine was the cause in-fact of the injury." Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994). Based upon this Federal Circuit precedent, a judge of the Court of Federal Claims has stated: "Fee denials are expected to occur." Chuisano, 116 Fed. Cl. at 286.

V. Conclusion

Mr. Crosby's motion for attorneys' fees and costs is denied on the ground that he did not establish that he is eligible for an award. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master