# In the United States Court of Federal Claims office of special masters

MATHEW HENNINGS, \* No. 18-1336V Petitioner, Special Master Christian J. Moran v. \* Filed: July 8, 2021 SECRETARY OF HEALTH \* AND HUMAN SERVICES, attorneys' fees and costs; reasonable basis; lack of proof of vaccination; onset of disease Respondent. 

Mark T. Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for petitioner; Lara Englund, United States Dep't of Justice, Washington, DC, for respondent.

#### PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS<sup>1</sup>

Represented by Attorney Mark Sadaka, Mathew Hennings alleged that an influenza ("flu") vaccination given to him on or about October 1, 2015, harmed him. Mr. Hennings failed to establish that he received the allegedly causal flu vaccine. Hennings v. Sec'y of Health & Human Servs., No. 18-1336V, 2020 WL 2465730 (Fed. Cl. Spec. Mstr. Apr. 13, 2020).

Mr. Hennings filed a motion for attorneys' fees and costs, arguing that because a reasonable basis supported the claim set forth in his petition, he was eligible to receive attorneys' fees and costs as the Vaccine Act permits. The Secretary, however, disagreed, maintaining that Mr. Hennings did not have a reasonable basis. Adjudication of Mr. Hennings's motion was deferred while the Federal Circuit considered the factors contributing to an analysis of reasonable

<sup>&</sup>lt;sup>1</sup> The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Anyone will be able to access this decision via the internet (<a href="https://www.uscfc.uscourts.gov/aggregator/sources/7">https://www.uscfc.uscourts.gov/aggregator/sources/7</a>). 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 appear in the document posted on the website

basis. The Federal Circuit provided additional guidance in <u>Cottingham v. Secretary of Health & Human Services</u>, 971 F.3d 1337 (Fed. Cir. 2020). The parties reiterated their positions in additional briefs filed after <u>Cottingham</u>. The Federal Circuit then issued another decision regarding the reasonable basis standard in <u>James-Cornelius v. Secretary of Health & Human Services</u>, 984 F.3d 1374 (Fed. Cir. 2021). The parties were then afforded the opportunity to submit additional briefs in light of this most recent decision.

Mr. Hennings does not qualify for an award of attorneys' fees for two reasons. First, he has failed to establish a reasonable basis for the assertion that he received the flu vaccination. Second, he has not established a reasonable basis for the assertion that his neuropathy developed after he allegedly received the flu vaccination. Thus, his motion is DENIED.

#### I. Procedural History

The attorney's timesheets show that Mr. Hennings first consulted Mr. Sadaka on November 28, 2017. Pet'r's Mot. for Attorney's Fees and Costs, filed Nov. 6, 2020, exhibit A. Over the next nine months, Mr. Sadaka and/or his assistants communicated with Mr. Hennings multiple times to obtain information. Mr. Sadaka's office attempted to obtain "employee medical records" from Mr. Hennings's employer, VFI Corporation Finance, several times.

Several entries refer to attempts to obtain vaccination records. See, e.g., id. at 3-5 (entries for 5/24/2018, 6/13/2018, 6/20/2018, 7/12/2018, 8/29/2018). The last entry (8/29/2018) notes that Mr. Hennings and/or Mr. Sadaka were exploring obtaining information from the Utah Immunization Registry. In addition, the August 28, 2018 entry and other entries note the statute of limitations. <u>Id.</u> at 1-2, 4 (entries for 2/5/2018, 3/6/2018, 4/30/2018, 8/6/2018).

On behalf of Mr. Hennings, Mr. Sadaka filed the petition on August 31, 2018. Mr. Hennings alleged that he "received an influenza vaccination on or about October 1, 2015, and ... suffered shortly thereafter vaccine-induced polyneuropathy." Pet., filed Aug. 31, 2018, preamble. Mr. Hennings provided more context for the vaccination, alleging that he received the vaccination "at his place of employment, where it was being offered by a third party vendor." Id. ¶ 2. Mr. Hennings added that his attorney "is filing this case to preserve the statute of limitations, during the record collection process and plans on filing an amended complaint once all records have been received and reviewed." Id. ¶ 8. Mr. Hennings did not file any medical records with the petition. See CM/ECF No. 1.

Within approximately six weeks of filing the petition, Mr. Hennings sought to use formal discovery methods to gain information from his employer, VFI Corporate Finance. Pet'r's Mot. to Issue Subpoena, filed Oct. 10, 2018. Mr. Hennings was granted this authority. Order, issued Oct. 15, 2018.

Mr. Hennings filed the response of VFI Corporate Finance as exhibit 4.<sup>2</sup> VFI Corporate Finance's website states that "VFI has financed billions in assets worldwide. We specialize in meeting the financial needs of companies from the Middle-Market to Fortune 500 companies." See court exhibit 1001 (VFI Corporate Finance, About VFI Corporate Finance, <a href="https://www.vfi.net/about-vfi/">https://www.vfi.net/about-vfi/</a> (last visited Apr. 7, 2020)). A legal assistant from VFI Corporate Finance informed Mr. Hennings's attorney that "VFI has conducted a search of all records in its possession, and does not have information or documentation regarding VFI Corporate Finance sponsored employee vaccination events held from August 1, 2015, to December 31, 2015." Exhibit 4 (letter dated Nov. 7, 2018). The legal assistant also provided information about Intermountain Healthcare Pharmacy Services, "a third-party provider who would have information regarding flu vaccination events held from August 1, 2015 to December 31, 2015." <a href="https://www.vfi.net/about-vfi/">Id.</a>

Approximately six months after receiving this response from VFI Corporate Finance, Mr. Hennings filed a motion to authorize a subpoena to Intermountain Healthcare. Pet'r's Mot., filed May 22, 2019. This motion too was granted. Order, issued May 23, 2019.

Mr. Hennings submitted the results of the subpoena to Intermountain Healthcare on July 19, 2019. Exhibit 7. An unidentified person stated, "After an extensive search we are unable to find the type of record requested at this facility." Id. The letter continued "Intermountain Healthcare does not keep records from vaccination clinics held at off site locations. The patient signs a consent form for the vaccination, [is] given the vaccine, and then a paper with the vaccine's information for their own record." Id.

On the same day that Mr. Hennings filed the letter from Intermountain Healthcare, he also filed his employment records from VFI Corporate Finance. Exhibit 8. These records, which are 73 pages, do not refer to any immunization program. Supplemental information about Mr. Hennings's work schedule also provided no information. Exhibit 9.

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<sup>&</sup>lt;sup>2</sup> Mr. Hennings filed exhibit 4 on November 15, 2018, and December 21, 2018. But, exhibit 4 is the same in both filings.

Mr. Hennings also explored another source that could potentially document his receipt of vaccination. Utah, the state in which Mr. Hennings lives, maintains a "secure, confidential immunization information system that helps healthcare providers . . . and Utah residents maintain consolidated immunization histories." Court exhibit 1002 (Utah Department of Health, Utah Statewide Immunization Information System (USIIS), <a href="https://immunize.utah.gov/usiis/">https://immunize.utah.gov/usiis/</a> (last visited Apr. 7, 2020)). Mr. Hennings's query prompted a response that no immunization record could be found. Exhibit 10.

Mr. Hennings attested that he received a flu vaccination while employed as a manager at VFI Corporate Finance. This flu vaccination happened in the fall 2015, and he began having numbness and tingling in his left foot a few weeks after the vaccination. Exhibit 12 (affidavit).<sup>3</sup> The same day that Mr. Hennings filed this affidavit, January 24, 2020, he also filed his amended petition. With respect to factual allegations, the amended petition is not meaningfully different from the original petition, although the amended petition added Mr. Hennings's initial treatment details and his eventual diagnosis of polyneuropathy.

Mr. Hennings then requested a finding that he was vaccinated in the fall 2015. Pet'r's Status Rep., filed Jan. 24, 2020. Mr. Hennings relied upon his affidavit.

The Secretary opposed Mr. Hennings's proposed finding of fact. The Secretary relied upon the absence of any record of vaccination in material from VFI Corporate Finance, Intermountain Healthcare, or the Utah state registry. The Secretary also noted that the medical records, which began with records created approximately six months after vaccination, do not mention the flu vaccination. Resp't's Resp., filed Feb. 26, 2020.

Mr. Hennings maintained his position by developing various arguments in his reply. Pet'r's Reply, filed Mar. 19, 2020.

The April 13, 2020 Entitlement Decision found that Mr. Hennings had not presented preponderant evidence that he received a flu vaccination. Accordingly, Mr. Hennings's case was dismissed.

After judgment entered, Mr. Hennings filed a motion for attorneys' fees and costs. In response, the Secretary claimed a lack of reasonable basis in three respects: (1) a lack of evidence regarding vaccination, (2) the evidence suggests

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<sup>&</sup>lt;sup>3</sup> Mr. Hennings's previous affidavit provided information relevant to damages. Exhibit 2.

that Mr. Hennings's neuropathy started before the vaccination, and (3) a lack of evidence indicating that the alleged vaccination caused any adverse consequence. Resp't's Resp., filed Nov. 10, 2020, at 4. Mr. Hennings replied. After the decision in <u>James-Cornelius</u> was issued on January 8, 2021, the parties were again afforded an opportunity to submit supplemental briefs regarding reasonable basis in light of this new precedent. Mr. Hennings filed his supplemental brief with a new exhibit (exhibit 13) on March 9, 2021. The Secretary filed his response on March 22, 2021, and the Mr. Hennings again replied. Thus, the matter is now ripe for adjudication.

#### II. Standards for Adjudication

Petitioners who have not been awarded compensation (like Mr. Hennings here) 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). Here, the Secretary has not raised a challenge to Mr. Hennings's good faith. Thus, the disputed issue is reasonable basis.

In <u>Cottingham</u>, the Federal Circuit stated that the evidentiary burden for meeting the reasonable basis standard "is lower than the preponderant evidence standard." Something "more than a mere scintilla" might establish the reasonable basis standard. 917 F.3d at 1356. Petitioners meet their evidentiary burden with "objective evidence." <u>Id.</u> at 1344. 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." <u>Id.</u> at 1346. Finally, the Federal Circuit in <u>Cottingham</u> 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.

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 to support reasonable basis. <u>James-Cornelius v. Sec'y of Health & Human Servs.</u>, 984 F.3d 1374, 1379-81 (Fed. Cir. 2021). 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."

<u>Id.</u> at 1379 (citing <u>Cottingham</u>, 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 <u>Simmons</u>, though the ultimate weighing of such evidence is left up to the special master.

#### III. Analysis

In opposing the motion for attorneys' fees and costs, the Secretary raises three points against Mr. Hennings's argument that "there was a reasonable basis for the claim for which the petition was brought." 42 U.S.C. § 300aa–15(e). The Secretary's topics include: (A) a lack of reasonable basis for asserting that Mr. Hennings received a vaccination, (B) a lack of reasonable basis for asserting that Mr. Hennings developed a neuropathy after the alleged vaccination, and (C) a lack of reasonable basis for asserting that the alleged vaccination caused Mr. Hennings's neuropathy. These are discussed below.

#### A. Reasonable Basis for Asserting Vaccination

Although the Entitlement Decision dismissed Mr. Hennings's case because of a finding that Mr. Hennings did not establish that he received a vaccination, the outcome of the Entitlement Decision does not control the result of Mr. Hennings's pending motion for attorneys' fees and costs. The Entitlement Decision weighed the evidence according to the preponderance of the evidence standard. However, the evidentiary standard for determining reasonable basis is less than the preponderance of the evidence. Chuisano v. Sec'y of Health & Human Servs., No. 07-452V, 2013 WL 6324660, at \*12-13 (Fed. Cl. Spec. Mstr. Oct. 25, 2013), mot. for rev. denied, 116 Fed. Cl. 276 (2014).

Nevertheless, the reasoning in the Entitlement Decision regarding the weight of the evidence remains valuable. The Entitlement Decision found that Mr. Hennings had not established, with preponderant evidence, that he received a flu vaccination in October 2015. The Entitlement Decision looked at four potential sources that could contain information about vaccination. These included:

- Business records of Mr. Hennings's employer, VFI Corporate Finance, which allegedly hosted the vaccination clinic;
- Vaccination records from Intermountain Healthcare, which allegedly operated the vaccination clinic;
- Utah's vaccination registry;

 Mr. Hennings's medical records created within a year of the alleged vaccination

While the evidence in Mr. Hennings's case does not contain any affirmative evidence showing that he declined the vaccination, <u>cf. Gordon v. Sec'y of Health & Human Servs.</u>, No. 18-40V, 2021 WL 1957509 (Fed. Cl. Spec. Mstr. Apr. 16, 2021) (finding not reasonable basis when medical records indicated vaccinee denied the vaccination), none of the potential sources listed above affirmatively show that Mr. Hennings *did* receive a vaccination. Mr. Hennings, however, attested that he did receive the vaccination. Exhibit 12 (affidavit).

Mr. Hennings further argues that he supplied some corroborating evidence for his vaccination. In response to a subpoena Mr. Hennings issued, a legal assistant for VFI Corporate Finance stated it does not possess "any information or documentation regarding VFI Corporate Finance sponsored employee vaccination events held from August 1, 2015, to December 31, 2015." Exhibit 4. The legal assistant also provided information about Intermountain Healthcare Pharmacy Services "who would have information regarding flu vaccinations held from August 1, 2015 to December 21, 2015." Id. From this statement, Mr. Hennings draws the inference that VFI Corporate Finance sponsored events at which its employees could receive vaccinations because, in Mr. Hennings's view, if VFI Corporate Finance did not sponsor such events, VFI would have said so directly and would have not provided contact information. Pet'r's Mot., filed Nov. 6, 2020, at 3-4.

To develop this point further, Mr. Hennings also points to the response from Intermountain Healthcare, whose records Mr. Hennings also subpoenaed. Intermountain Health responded it "does not keep records from vaccination clinics held at off site locations. The patient signs a consent form for the vaccination, given the vaccine, and then a paper with the vaccine's information for their own record." Exhibit 7. Mr. Hennings argues that he is not responsible for the lack of record retention. Pet'r's Reply, filed Dec. 4, 2020, at 1-2.

Mr. Hennings's argument has some validity. The statements from VFI Corporate Finance and Intermountain Health constitute objective evidence that would support finding that there is reasonable basis for an assertion that Mr. Hennings's employer engaged Intermountain Health to offer vaccinations to its employees. Thus, Mr. Hennings has presented some evidence that a vaccine was available to him.

But, this argument gets Mr. Hennings only so far. Pharmacies and grocery stores also make vaccines available to their customers. Availability, however, is not the question. The question is whether Mr. Hennings received the flu vaccine.

Certainly, Mr. Hennings's affidavit constitutes *some* evidence on this topic. In James-Cornelius, the Federal Circuit explained: "While 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, the same is not true for sworn testimony as to facts within the witness's personal knowledge, such as the receipt of a vaccine and the timing and severity of symptoms." 984 F.3d at 1380. But, in cases decided before James-Cornelius, an affidavit regarding vaccination did not always carry petitioner's burden, at the lower than preponderant evidence standard, to present objective evidence in support of vaccination. Gomez v. Sec'y of Health & Human Servs., No. 17-1800V, 2019 WL 7480769, at \*5 (Fed. Cl. Dec. 6, 2019) (reversing a finding of reasonable basis and stating that "subjective recollections recorded in medical interviews" are "different in kind . . . from official vaccinations records"); Cole v. Sec'y of Health & Human Servs., No. 14-628V, 2015 WL 6149300 (Fed. Cl. Spec. Mstr. Sept. 14, 2015); Cortez v. Sec'y of Health & Human Servs., No. 09-174V, 2014 WL 1604002 (Fed. Cl. Spec. Mstr. Mar. 26, 2014) (citing cases and rejecting argument that a notation about an "injection" conferred reasonable basis to infer that a vaccine had been given when counsel could have investigated evidence before filing the petition); Rydzewski v. Sec'y of Health & Human Servs., No. 99-571V, 2007 WL 949759 (Fed. Cl. Spec. Mstr. Mar. 12, 2007), cited in Sebelius v. Cloer, 569 U.S. 369, 382 n.7 (2013); see also Van Houter v. Sec'y of Health & Human Servs., No. 90-1444V, 1992 WL 370270 (Fed. Cl. Nov. 18, 1992) (denying motion for review of decision that denied a motion for attorneys' fees and costs due to lack of proof of vaccination).

In <u>James-Cornelius</u>, the Federal Circuit's admonished special masters to consider affidavits in assessing reasonable basis for assertions on which the affiant could testify competently. (The undersigned has assessed Mr. Hennings's affidavit.) By way of contrast, <u>James-Cornelius</u> seems not to be stating that, as a matter of law, a special master must always accept the testimony of affiants that they received a vaccination. Whether a petitioner establishes receipt of vaccination is a question of fact, which special masters resolve on the basis of the entire record. <u>See Cortez</u>, 2014 WL 1604002, at \*2; <u>Riddick v. Sec'y of Health & Human Servs.</u>, No. 99-643V, 2006 WL 2990220 (Fed. Cl. Spec. Mstr. Oct. 4, 2006). If a petitioner's affidavit alone justified a finding that reasonable basis supported an

allegation of vaccination, then every petitioner would be able to satisfy this standard.<sup>4</sup>

The objective evidence concerning Mr. Hennings's vaccination does not rise to allow a finding that the petition's assertion that Mr. Hennings received a vaccination had a reasonable basis. (Again, the level for reasonable basis is lower than the preponderance of the evidence standard.) Mr. Hennings's affidavit regarding his receipt of vaccination is not supported in any respect. As noted above, the Utah immunization registry did not present any information showing Mr. Hennings received a vaccination. More importantly, even Mr. Hennings's medical records created when he began to seek treatment for a neuropathy in spring 2016 do not mention a vaccination. Somewhat farther afield, Mr. Hennings also did not present evidence from VFI Corporate Finance that grounds his assertion that he received a vaccination. For example, Mr. Hennings might have presented testimony from a co-worker who observed Mr. Hennings being vaccinated or an email regarding Mr. Hennings's scheduling of an appointment during the work day.

Ultimately, Mr. Hennings bears the burden of demonstrating that he had a reasonable basis for asserting he received a vaccination. McKellar v. Sec'y of Health & Human Servs., 101 Fed. Cl. 297, 305 (2011). Mr. Hennings's evidence on this point, consisting of his affidavit alone, was exceptional weak in the undersigned's experience. For a discussion of special master's reliance on their experience in determining whether a petitioner satisfies the reasonable basis standard, see Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2021 WL 347020, at \*40 (Fed. Cl. Spec. Mstr. Jan. 7, 2021), mot. for rev. granted, July 6, 2021. Under these circumstances, the undersigned finds that Mr. Hennings lacked a reasonable basis for asserting that he received a vaccination.

### B. Reasonable Basis for Asserting an Onset of Neuropathy after Vaccination

The petition asserted "Shortly after receiving the vaccination [in October 2015], petitioner developed numbness and tingling sensation in his left foot, which then progressed to his right." Pet. ¶ 3. During the entitlement phase after the Secretary pointed to the potentially early onset of Mr. Hennings neuropathy, see

<sup>&</sup>lt;sup>4</sup> In <u>James-Cornelius</u>, medical "records confirmed the dates of [the child's] three Gardasil® vaccinations." 984 F.3d at 1377. Thus, the Federal Circuit did not have occasion to consider cases, such as <u>Cortez</u>, in which a judicial officer found that petitioners did not have a reasonable basis for asserting they received a vaccine.

Resp't's Status Rep., filed Apr. 22, 2019, at 2, Mr. Hennings filed an affidavit. He averred that in his conversation with his primary care physician, Mr. Hennings "mentioned to him that the numbness began two weeks after I received the vaccination during the fall of last year. I think he either misunderstood me or misnoted which is why the record says the onset was 1 year ago." Exhibit 12 (affidavit) ¶ 10.

Because the Entitlement Decision found that Mr. Hennings did not establish with preponderant evidence that he received a flu vaccine and resolved the case on that basis alone, determining when Mr. Hennings developed neuropathy was not necessary. However, in arguing against a finding of reasonable basis for the claim set forth in the petition, the Secretary again contends that Mr. Hennings's neuropathy developed before the vaccination.

The factual basis for the Secretary's argument that Mr. Hennings developed a neuropathy comes from two medical records created in spring 2016. Resp't's Supp'l Br., filed Mar. 15, 2021, at 2. In the first instance on April 15, 2016, Mr. Hennings saw his primary care physician, and complained about numbness and weakness in both feet. The doctor recorded "Onset: 1 year ago." Exhibit 1 at 10. After assessing Mr. Hennings with a paresthesia, the doctor referred him to a neurologist.

The second record is from the neurologist, who saw Mr. Hennings on May 17, 2016. With respect to the history of present illness, the neurologist wrote that Mr. Hennings's numbness "slowly progressed along the bottom of his feet." Exhibit 11 at 1. The neurologist's impression included a statement that the numbness has been "present for more than a year." <u>Id.</u> at 3.

In challenging the reasonable basis for Mr. Hennings's petition that the alleged flu vaccination caused a neuropathy, the Secretary accepts the accuracy of these records. If these records are accurate, then the onset of Mr. Hennings's neuropathy was "several months" before October 2015, when he was allegedly vaccinated. Resp't's Resp., filed Nov. 10, 2020, at 4.

In supporting the reasonable basis of the claim set forth in the petition, Mr. Hennings presents an argument different from the one he advanced in his affidavit. He now argues that the statement "Onset: 1 year ago' could be read to say that it began the year prior, which it did." Pet'r's Reply, filed Dec. 4, 2020, at 2. Mr. Hennings adds "There are other discovery tools that could have been used to flesh out this issue, but it was decided to address the vaccination threshold question first." Id.

Mr. Hennings's assertion that his neuropathy began weeks after a vaccination in October 2015 is questionable. Mr. Hennings strains the usual meaning of "ago" to contend that the statement "Onset: 1 year ago" actually means some like "Onset: during the last calendar year." Even more problematically for Mr. Hennings, the neurologist's May 17, 2016 statement that the numbness has been "present for more than a year," exhibit 11 at 3, is straightforward. Mr. Hennings does not offer even a fanciful alternative explanation for the neurologist's record. The neurologist's record, therefore, reinforces and corroborates the primary care doctor's record. While it is possible that one doctor may have recorded a history incorrectly, the chances that two doctors independently erred in the same way is much more remote.

Mr. Hennings attempts to save his claim for an award of attorneys' fees and costs by arguing that he could have "fleshed out" this issue, using "other discovery tools." But, this argument is unsubstantiated. Mr. Hennings has not identified how he would have explored this issue. In the undersigned's experience, petitioners who challenge the accuracy of information from medical records present affidavits and oral testimony from people who were aware of the vaccinee's health and activities in the relevant time. Although Mr. Hennings presented his own affidavit in which he asserts numbness and tingling started a "few weeks after the vaccination," exhibit 12 ¶ 8, he has not filed affidavits from ancillary witnesses. Mr. Hennings should have been able to present any affidavits without resort to a formal discovery device. See Pet'r's Mot. for Attorneys' Fees and Costs, exhibit A, at 7 (entry for 10/10/2018 stating "Receive/review correspondence from client re: potential fact witnesses").

Accordingly, the undersigned finds that Mr. Hennings has not met his burden---a burden that is less than the preponderance of the evidence standard---to submit sufficient objective evidence supporting the assertion that his neuropathy started after a vaccination in October 2015. When a neuropathy precedes any vaccination, the vaccination cannot be the cause of the neuropathy. <u>See Locane v. Sec'y of Health & Human Servs.</u>, 685 F.3d 1375, 1380-81 (Fed. Cir. 2012).

## C. Reasonable Basis for Asserting the Alleged Flu Vaccination Caused Mr. Hennings's Neuropathy

The petition alleges that "As a direct result of receiving the influenza vaccination, petitioner suffered and continues to suffer from polyneuropathy and paresthesia." Pet. ¶ 7. In challenging Mr. Hennings's eligibility for attorneys' fees and costs, the Secretary argues that no evidence (such as a statement from a

treating doctor or an expert's report) indicates that the alleged flu vaccination caused the neuropathy. Resp't's Resp., filed Nov. 10, 2020, at 4.

Mr. Hennings does not dispute the premise that the record does not include a statement from a doctor that a flu vaccination caused his neuropathy. (Mr. Hennings did present the product information sheet for the flu vaccination as evidence of associated contraindications and adverse reactions. Exhibit 13.) Instead, Mr. Hennings asserts that he "could have, would have produced an expert report showing that influenza vaccine could cause the neuropathy that he suffered if this case proceeded. . . . The fact that we did not expend resources to get an expert report until we resolved key factual issues should not be held against petitioner." Pet'r's Reply, filed Dec. 4, 2020, at 2.

The issue regarding evidence of causation is a difficult question, about which the parties could have presented additional points for consideration. Mr. Hennings may well be correct that had disputes about factual issues (receipt of vaccination and onset of neurologic symptoms) resolved in his favor, then he would have retained a report from an expert. See Pet'r's Reply, filed Dec. 4, 2020, at 2. But, considering what Mr. Hennings might have done runs afoul of the Federal Circuit's holding that reasonable basis depends upon objective evidence. Simmons, 875 F.3d at 635.

Objective evidence, such as medical records, can often establish three foundational points: (1) the petitioner received a covered vaccine, (2) the petitioner developed a recognized and diagnosed injury, and (3) the petitioner's disease began after the vaccination. In such a case, the medical records effectively establish a sequence of events in which the vaccination preceded the disease. This sequence, in turn, is a basis for examining whether the vaccine caused the disease. In this context, petitioners might add medical literature suggesting that a vaccine can cause the relevant disease. Evaluating the reasonable basis for the assertion that the vaccine caused a disease in the absence of a record from a treating doctor or an expert retained for litigation is a challenging task. See Cottingham v. Sec'y of Health & Human Servs., No. 15-1291V, 2021 WL 347020 (Fed. Cl. Spec. Mstr. Jan. 7, 2021), mot. for rev. granted, July 6, 2021.

Here, the objective evidence relevant to the assertion that the flu vaccine harmed Mr. Hennings is sparse. Regarding the first point, the evidence favoring vaccination is limited to Mr. Hennings's affidavit. As discussed at length above, there is not a reasonable basis for the assertion that Mr. Hennings received the vaccination as he averred. Without a finding of vaccination, the remainder of any

analysis regarding whether there is a reasonable basis for asserting that the vaccine caused the injury is hypothetical.

If it is assumed for sake of argument that Mr. Hennings received a flu vaccination in October 2015, the next point in the paradigm outlined above is whether Mr. Hennings developed a disease. The medical records from April and May 2016 show that Mr. Hennings suffered from a neuropathy. Exhibit 1 at 10; exhibit 11 at 1.

The third point is whether the disease started after the (hypothetical) vaccination. The stronger evidence is that the disease started before the alleged vaccination. Mr. Hennings's basis for asserting that the disease afterwards is not reasonable as explained in section B, above.

Nevertheless, if---in contradiction of two medical records created by two different doctors---it is assumed that Mr. Hennings began having numbness and tingling after a vaccination in fall 2015, then Mr. Hennings would have met the foundational predicate for causation in that a vaccination preceded the onset of disease. But even a sequence of events has been found not adequate, by itself, to support a finding of reasonable basis for the assertion that a vaccine caused an injury. Chuisano v. United States, 116 Fed. Cl. 276, 287 (2014) ("Temporal proximity is necessary, but not sufficient.").

Beyond the construct in which Mr. Hennings's affidavit is the primary basis for a sequence of events, the objective evidence for Mr. Hennings's argument that the flu vaccine can cause a neuropathy rests upon the product information sheet for the flu vaccination. Exhibit 13. Undoubtedly, the product information sheet constitutes evidence that a special master must consider in evaluating whether a reasonable basis supports the claim asserted in the petition. Cottingham, 971 F.3d at 1345.

Via highlighting, Mr. Hennings focuses attention on two portions of the product information sheet. First, in section 5 ("Warnings and Precautions"), the product information sheet warns that the benefits and risks of Fluvirin should be considered carefully if the anticipated recipient developed Guillain-Barré syndrome within six weeks of receipt of prior influenza vaccine. That warning does little to advance Mr. Hennings's argument because his presentation in the spring 2016 does not resemble Guillain-Barré syndrome and Mr. Hennings has not identified any doctor who diagnosed him as suffering from Guillain-Barré syndrome.

Second, Mr. Hennings has highlighted a portion of section 6.3 Postmarketing Experience. This section begins: "The following additional adverse reactions have been reported during post-approval use of FLUVIRIN®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure." Exhibit 13 at 7. Following additional introductory language, the product information sheet lists many conditions of which Mr. Hennings has drawn attention to "neuropathy (including neuritis)." <u>Id.</u>

Information from the "postmarketing experience" generally carries little weight in determining whether a vaccine can cause an injury. Werderitsh v. Sec'y of Health & Human Servs., 99-319V, 2005 WL 3320041, at \*8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005); see also Cottingham, 2021 WL 347020, at \*23-26. Mr. Sadaka's attempt to interject his opinion similarly carries little weight because he is an attorney and not a doctor. See Williams v. Social Sec. Admin., 586 F.3d 1365, 1368 (Fed. Cir. 2009) ("We decide cases on the record before us, not on the basis of facts stated by counsel."); Chuisano, 116 Fed. Cl. at 289 ("The court also rejects petitioner's attempt to equate reasonable basis with an attorney's good faith or 'professional judgment' in pursuing a claim.").

On behalf of Mr. Hennings's motion for an award of attorneys' fees and costs, Mr. Sadaka, as noted earlier, maintained he "could have, would have produced an expert report showing that influenza vaccine could cause the neuropathy that he suffered <u>if</u> this case proceeded." Pet'r's Reply, filed Dec. 4, 2020, at 2. In point of fact, Mr. Sadaka could have submitted a report from an expert. He was not forbidden from having "a full and fair opportunity to present [his] case." Vaccine Rule 3(b)(2). Mr. Sadaka could have directed the expert to assume when Mr. Hennings received a vaccination and when Mr. Hennings developed a neuropathy. <u>See</u> Fed. R. Evid. 703 (permitting expert to opine on hypotheticals).

However, what Mr. Sadaka could have done and what opinion a retained expert might have presented remains speculative. Accordingly, these possibilities are not a form of objective evidence on which a decision regarding reasonable basis can be based. See Simmons, 875 F.3d at 635. But, the undersigned anticipates that judicial officers will be called upon to determine whether reasonable basis supports a claim, as set forth in a petition, that a vaccine harmed someone when the factual bases are undermined before the petitioner elects to retain an expert.

Ultimately, the lack of evidence that a vaccine harmed Mr. Hennings does not affect the outcome of Mr. Hennings's motion for attorneys' fees. Any finding on this issue would be superfluous because of two flaws within Mr. Hennings's case. First, the evidence, taken as a whole, does not support a finding that there was reasonable basis for the assertion that Mr. Hennings received a flu vaccine in October 2015. Second, the evidence, again taken as a whole, does not support a finding that Mr. Hennings's neuropathy developed after any vaccination in October 2015.

#### V. Conclusion

Mr. Hennings's eligibility for an award of attorneys' fees and costs depends upon his establishing a reasonable basis for the claim set forth in the petition. While the reasonable basis standard is easier to satisfy than the preponderance of the evidence standard, Mr. Hennings has failed to present sufficient objective evidence that would ground a finding of reasonable basis that he received a flu vaccine. He has also failed to present sufficient evidence that would ground a finding of reasonable basis that he developed a neuropathy in the fall of 2015, after receiving a vaccination. Accordingly, Mr. Hennings's motion for an award of attorneys' fees and costs is DENIED.

IT IS SO ORDERED.

s/Christian J. MoranChristian J. MoranSpecial Master