

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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NATACHA JACQUES, \*

Petitioner, \*

v. \*

SECRETARY OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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No. 19-1128V

Special Master Christian J. Moran

Filed: April 22, 2025

Robert Krakow, Law Office of Robert J. Krakow, P.C., New York, NY, for petitioner;  
Lynn Schlie, United States Dep't of Justice, Washington, DC, for respondent.

### **ORDER DENYING MOTION TO ADD NEW CLAIM AND DECISION DENYING ENTITLEMENT TO COMPENSATION<sup>1</sup>**

Two issues require adjudication. The first (and easy) one is whether Ms. Jacques has established with preponderate evidence that the hepatitis B vaccine caused her to suffer Sjögren's syndrome. Ms. Jacques admits that she has not.

The second (and more complicated) issue is whether Ms. Jacques can pursue an alternative claim, that the hepatitis B vaccine caused her to suffer small fiber neuropathy. Because she had a full and fair opportunity to raise this claim earlier, her request is denied.

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<sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

## **I. Factual History<sup>2</sup>**

In August 2016, Ms. Jacques was 41 years old and was working as a nursing assistant. During her job, urine from a patient's catheter back splashed into her eye. Exhibit 1 at 12; Exhibit 24 at 74. As part of her treatment, she received the first dose of the hepatitis B vaccine. Exhibit 1 at 51 (August 8, 2016).

She continued to follow-up. In a September 8, 2016 appointment, Ms. Jacques reported she "sometimes feels muscle aches." Exhibit 1 at 35. She received a second dose of the hepatitis B vaccine. Id. at 53.

Over the next few months, she saw a variety of doctors for different complaints. Sometimes Ms. Jacques's complaints included joint pain and muscle pain. See, e.g., Exhibit 7 at 24 (October 4, 2016), Exhibit 7 at 76 (November 30, 2016), Exhibit 3 at 10-12 (January 10, 2017).

In early 2018 (about 18 months after vaccination), Ms. Jacques told a neurologist, Kristine Ziemba, that she developed numbness in her elbow about six months earlier. Exhibit 6 at 13. After additional evaluations, Dr. Ziemba was concerned that Ms. Jacques's symptoms were "possibly related to small fiber / autonomic neuropathy." Exhibit 6 at 32 (April 20, 2018). Ms. Jacques underwent a punch biopsy on April 27, 2018. Id. at 35. Based upon these results, Dr. Ziemba diagnosed Ms. Jacques with small fiber neuropathy on June 20, 2018. Exhibit 6 at 40-41. Lab work from August 2018 showed an elevated ANA, positive anti-GD1a antibodies, and slightly elevated free kappa light chains. Exhibit 6 at 47.

Over the next years, Ms. Jacques sought care from doctors, including her primary care doctor, a neurologist, and a rheumatologist, multiple times. Ms. Jacques agrees that no treating doctor diagnosed her with Sjögren's syndrome. Pet'r's Br., filed Nov. 13, 2024, at 31.

## **II. Procedural History**

### **A. Petition to Petitioner's First Expert Report**

Represented by Robert Krakow, Ms. Jacques started this case by filing her petition on August 2, 2019. The petition alleged that the two hepatitis B vaccinations caused 16 different problems:

The injuries Ms. Jacques suffered as a result of receiving the two hepatitis vaccines include small fiber neuropathy, inflammatory polyarthropathy, inflammatory polyarthritis, bilateral primary myalgia, peripheral neuropathy, arthropathy, paresthesia of her feet, bilateral feet burning at night, weakness of right arm, lumbosacral radiculopathy, cervical radiculopathy, right, urinary

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<sup>2</sup> This summary highlights the most important medical records. But, because the disputed issues are relatively procedural, Ms. Jacques's medical history is abbreviated. For more details, see Pet'r's Br., filed Nov. 13, 2024, at 3-18.

incontinence, numbness and tingling in right arm, leg numbness, right, autonomic neuropathy, and dysautonomia.

Pet. at 1-2.

The petition recounted a series of events, which is basically consistent with the above, and cited medical records. She filed exhibits 1-11 a few days later. This set of exhibits included exhibit 6, which contained Dr. Ziemba's April 20, 2018 record regarding small fiber neuropathy. Exhibit 6 at 32. Over the next year, Ms. Jacques sought more information, such as her employment file. Ms. Jacques narrated events in her life via a declaration, filed as exhibit 17 on March 24, 2020. In this declaration, Ms. Jacques discussed the diagnosis of small fiber neuropathy. Exhibit 17 ¶ 27-28, 31-33.

The Secretary reviewed this material and advised against an award of compensation. Resp't's Rep., filed July 31, 2020. With respect to the litany of problems that the petition alleged the hepatitis B vaccines to have caused, the Secretary maintained that Ms. Jacques "appears to have been diagnosed with small fiber neuropathy." Id. at 15. The rest, however, "appear to be symptoms rather than diagnoses." Id.

A status conference was held. As to how Ms. Jacques planned to put her case together, Mr. Krakow discussed either getting a rheumatologist or a neurologist. See Order, issued Aug. 5, 2020 ("petitioner intends to retain a rheumatologist and/or neurologist"). In conjunction with that order, a proposed set of instructions for experts were issued. After neither party commented, the instructions became final on September 2, 2020. The Instructions directed the experts to address diagnosis. ¶ 4.

Over the next year, Mr. Krakow and Ms. Jacques had difficulties with obtaining more factual records. During this period, Ms. Jacques filed records from the Social Security Administration. Exhibit 30. This material showed that an administrative law judge determined Ms. Jacques was disabled as of June 23, 2018. Id. at 12.

Ms. Jacques added a report from a rheumatologist, Petros Efthimiou. Exhibit 31. In his opinion, Ms. Jacques suffered from Sjögren's syndrome. Id. at 12. Dr. Efthimiou also loosely maintained that the hepatitis B vaccines caused the Sjögren's syndrome.

## **B. Development of Expert Opinions regarding Sjögren's Syndrome**

In response to Dr. Efthimiou, the Secretary presented two experts. One is Robert Fujinami. Exhibit C.<sup>3</sup> The Secretary's other expert is a rheumatologist, Carlos Rose. Exhibit A, filed Oct. 3, 2023. Dr. Rose opined that Ms. Jacques did not suffer from Sjögren's syndrome. Id. at 23.

Ms. Jacques was informed that Dr. Rose and Dr. Fujinami made "strong arguments against the claim that the hepatitis B vaccines harmed petitioner." Order, issued Oct. 4, 2023.

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<sup>3</sup> Dr. Fujinami challenged whether the hepatitis B vaccine can cause Sjögren's syndrome. His opinions do not affect the issues being resolved. Therefore, his opinions and Dr. Efthimiou's responses to his opinions are not summarized in this decision.

She was directed to amend her petition and to be prepared to discuss the case at the next status conference.

In compliance with that order, Ms. Jacques amended her petition. She asserted that the two hepatitis B vaccinations “caused her to develop Sjögren’s syndrome manifesting as a constellation of symptoms that included . . . small fiber neuropathy.” Am. Pet., filed Oct. 18, 2023, at 1. She quoted medical records about small fiber neuropathy. *Id.* ¶¶ 42-46, 48-53.

In the November 1, 2023 status conference, the undersigned discussed the weakness in Ms. Jacques’s evidence, including Dr. Efthimiou’s report. With respect to diagnosis, Mr. Krakow stated he wanted to explore retaining a neurologist. Order, issued Nov. 1, 2023.

Initially, Mr. Krakow stated his law firm lacked financial resources for a supplemental report from Dr. Efthimiou. Pet’r’s Mot. for Enlargement of Time, filed Jan. 5, 2024. But, he anticipated submitting a supplemental report from Dr. Efthimiou soon. As part of this motion, Mr. Krakow stated that he would file a status report about getting a report from a neurologist.

Of the two items, Ms. Jacques did one but not the other. She did not file a status report about getting a neurologist. She did, however, file two reports from Dr. Efthimiou. In response to Dr. Rose, Dr. Efthimiou continued to put forward Sjögren’s syndrome. Exhibit 45. The second report was in response to Dr. Fujinami and addressed causation. As memorialized in an order, in the ensuing status conference, Mr. Krakow stated that he was not retaining a neurologist. Order, issued Feb. 28, 2024.

Another report from Dr. Efthimiou followed, but this report also addressed how the hepatitis B vaccines can cause Sjögren’s syndrome. Exhibit 57. This report completed the submission of expert reports on the theory that the hepatitis B vaccinations caused Ms. Jacques to suffer Sjögren’s syndrome.

### **C. Tentative Finding and Pending Motion**

Upon completion of the reports from experts, the evidence was reviewed. Ms. Jacques was tentatively found not to be entitled to compensation on her claim that the hepatitis B vaccine caused her to suffer Sjögren’s syndrome. A primary, but not exclusive, flaw was that Ms. Jacques did not establish that she suffered from Sjögren’s syndrome. Two points were the basis for this tentative finding: first, that no treating doctor had diagnosed Ms. Jacques with Sjögren’s syndrome, and second, Ms. Jacques has not tested positive for any antibodies that commonly appear in Sjögren’s syndrome. Tentative Finding Denying Entitlement, issued Aug. 29, 2024. Ms. Jacques was allowed an opportunity to explain how she wanted to proceed.

Ms. Jacques discussed her proposed plan in an October 9, 2024 status conference. Ms. Jacques requested an opportunity to assert a claim that the hepatitis B vaccinations caused her to suffer small fiber neuropathy. Ms. Jacques argued that her case is like other recently decided cases in which petitioners were compensated for small fiber neuropathy. The Secretary, however, objected. The Secretary suggested that adding a claim for small fiber neuropathy now would be against the spirit of the statute of limitations, although not a technical violation of the statute of limitations. Due the dispute between the parties, a briefing schedule was established. Order, issued Oct. 10, 2024.

In accordance with the October 10, 2024, Ms. Jacques argued that she should be permitted to claim that the hepatitis B vaccinations caused her to suffer small fiber neuropathy. Pet'r's Br., filed Nov. 13, 2024.<sup>4</sup> The brief is lengthy, approximately 32 pages. Approximately half of the brief is devoted to recounting events in Ms. Jacques's medical history from 2010 to 2018. *Id.* at 2-18. She next extensively discussed two potentially similar cases, Quirino v. Sec'y of Health & Hum. Servs., No. 17-989V, 2023 WL 9229145 (Fed. Cl. Spec. Mstr. Dec. 18, 2023), and Coons v. Sec'y of Health & Hum. Servs., No. 20-1067V, 2024 WL 1741619 (Fed. Cl. Spec. Mstr. Mar. 29, 2024). *Id.* at 19-27. With that background, Ms. Jacques maintained that "the perspective of a specialist in another medical discipline, such as neurology, would appropriately take a different view of the case, consistent with the analysis presented here as well as the Quirino and Coons Decisions." *Id.* at 27. Ms. Jacques asserted that with the assistance of a new expert, she could establish the hepatitis B vaccinations were the cause-in-fact of her small fiber neuropathy. *Id.* at 27-31. On the final substantive page of her brief, Ms. Jacques cited these authorities as supporting her request: 42 U.S.C. § 300aa-12(d)(3)(B), Vaccine Rule 3(b), and DeLozier v. Sec'y of Health & Hum. Servs., 154 Fed. Cl. 392, 394-95 (2021).

The Secretary opposed Ms. Jacques's request in a brief, which is approximately eight pages. Although Ms. Jacques's had discussed her medical history for multiple pages, the Secretary omits any lengthy discussion. Instead, the Secretary emphasized the procedural history, which Ms. Jacques had omitted. Resp't's Br., filed Dec. 13, 2024, at 1-5. "Over the past five years, petitioner was given numerous opportunities to pursue her claim for SFN." *Id.* at 5-6. With respect to Quirino and Coons, the Secretary cited cases about small fiber neuropathy starting back to a decision issued in 2014. *Id.* at 6 n.2. Based upon Vaccine Rule 3(b)(2), the Secretary argued that Ms. Jacques has already received a full and fair opportunity to present her case. As an example of a case in which a petitioner was denied an opportunity to present another expert report, the Secretary cited K.A. v. Sec'y of Health & Hum. Servs., 164 Fed. Cl. 98, 114-15, 128 (2022), *aff'd*, 2024 WL 2012526 (Fed. Cir. 2024).

Ms. Jacques was given an opportunity to reply. In doing so, she was directed to address two topics: (1) "the procedural aspects of the case, . . . explain[ing] why she did not present this claim [the claim for small fiber neuropathy] earlier" and "whether she intends to seek, at an appropriate time, attorneys' fees and costs for pursuing a claim based upon Sjörger's syndrome." Order, issued Dec. 16, 2024.

Ms. Jacques argued that allowing her small fiber neuropathy claim to proceed would be consistent with the purposes of the Vaccine Program, which "is to provide a full and fair opportunity to vaccine injury claimants in the context of Congressional acknowledgement that vaccine injuries happen, albeit rarely." Pet'r's Reply, filed Jan. 17, 2025, at 2. A thrust of Ms. Jacques's reply is that the proper question is "whether the medical evidence sufficiently supports

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<sup>4</sup> Although the title of this document is "Petitioner's Brief in Response to the Tentative Finding Denying Entitlement and in Support of Further Proceedings" (capitalization modified), this document is the equivalent of a motion in that Ms. Jacques is requesting relief from the special master. The difference in nomenclature does not affect the outcome of Ms. Jacques's request.

the petitioner's claim to merit further and transparent adjudication, irrespective of the reason it was not pursued earlier." Id. at 4.

However, this reply did not answer the questions posed in the December 16, 2024 order. Thus, Ms. Jacques was directed to file a supplemental reply. Order, issued Jan. 21, 2025.

Ms. Jacques basically recounted some aspects of her case's procedural history. She maintained that the Dr. Efthimiou's opinion was sound and reliable, affording her reasonable basis for her claim. Pet'r's Supp'l Reply, filed Feb. 24, 2025, at 3. As to why Ms. Jacques did not pursue her claim earlier, Ms. Jacques does not engage with this issue particularly well. It appears that Ms. Jacques's primary explanation is that the theory that vaccines can cause small fiber neuropathy "has gained traction in recent special masters' decisions." Id., citing Quirino and Coons.

As the other question Ms. Jacques was instructed to answer, Ms. Jacques stated that "she will likely pursue attorneys' fees and costs for pursuing her Sjögren's syndrome claim." Id. at 5. However, in Ms. Jacques's view, whether she intends to pursue attorneys' fees and costs for her Sjögren's syndrome claim is not relevant to determining whether she can add a claim for small fiber neuropathy. Instead, according to Ms. Jacques, the question about whether reasonable basis supported the Sjögren's syndrome claim should be deferred until after she files any motion for attorneys' fees and costs. Id. at 5-6.

On this last point, Ms. Jacques's argument is persuasive. Any plan to seek attorneys' fees and costs does not affect the outcome of her request to add a claim that the hepatitis B vaccines caused her to suffer small fiber neuropathy. Thus, that point is not further discussed in the following analysis.

### **III. Analysis**

As stated in the introduction to this decision and order, two issues are pending. The more substantive issue is whether Ms. Jacques may add a claim for small fiber neuropathy. The second issue is whether Ms. Jacques can prevail upon the claim that the hepatitis B vaccines caused her to suffer Sjögren's syndrome.

#### **A. Adding a New Claim**

After the amendment to the original petition, Ms. Jacques has been alleging that the hepatitis B vaccinations "caused her to develop Sjögren's syndrome." Am. Pet., filed October 18, 2023, at 1. The amended petition supersedes the original petition and more closely aligns Ms. Jacques's pleading allegations with her evidence, notably the report from Dr. Efthimiou. More specifically, Dr. Efthimiou opined that the hepatitis B vaccinations caused her to suffer Sjögren's syndrome. Exhibit 31 at 24. By way of contrast, Dr. Efthimiou did not allege that the hepatitis B vaccinations caused her to suffer small fiber neuropathy.

The parties have completed the development of evidence regarding the amended petition's claim about Sjögren's syndrome. As explained in section III.B. below, the evidence does not preponderate in Ms. Jacques's favor on this claim. Faced with a possible dispositive ruling against her, Ms. Jacques is attempting a different tactic. The essence of Ms. Jacques's current request is a request to add a claim to her amended petition, the claim that the hepatitis B

vaccinations caused her to suffer small fiber neuropathy.<sup>5</sup> Both parties rely upon Vaccine Rule 3(b)(2).

Although Vaccine Rule 3(b)(2) directs a special master to afford “each party a full and fair opportunity to present its case,” the rule provides little guidance as to the meaning of “full and fair.” Thus, for guidance, the undersigned looks to Rule 15 of the Rules of the Court of Federal Claims (“RCFC”). See Vaccine Rule 1(c).

RCFC Rule 15, in pertinent part, provides: “a party may amend its pleading only with . . . the court’s leave. The court should freely give leave when justice so requires.” RCFC Rule 15(a)(2). Ample precedent has interpreted this provision.

“Notwithstanding the view that Fed.R.Civ.P. 15(a) is to be construed liberally, courts have not hesitated to deny motions to amend that have been filed after significant delay. Delay alone, even without a demonstration of prejudice, has thus been sufficient grounds to deny amendment of pleadings.” Te-Moak Bands of Western Shoshone Indians of Nevada v. United States, 948 F.2d 1258, 1262 (Fed. Cir. 1991). “It is clear that ‘if the amendment [to a pleading] substantially changes the theory on which the case has been proceeding and is proposed late enough so that the opponent would be required to engage in significant new preparation, the court may deem it prejudicial.’” Cencast Services, L.P. v. United States, 729 F.3d 1352, 1364 (Fed. Cir. 2013) (quoting 6 Wright & Miller, Federal Practice and Procedure § 1487 and ruling that the Court of Federal Claims did not abuse its discretion in denying a party’s motion to amend a complaint).

Awareness of the potential cause of action is relevant to determining whether to allow an amendment. “Critical to a finding of undue delay is that the party seeking to amend had prior access to the relevant information that underlies the proposed, new amendment.” FreeAlliance.com, LLC v. United States, 173 Fed. Cl. 598, 604 (2024).

With that guidance, a review of the opportunities to develop a claim for small fiber neuropathy is worthwhile:

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<sup>5</sup> Although Ms. Jacques has stylized her request as a request to add a new expert, any new expert would be supportive to only the claim regarding small fiber neuropathy. Ms. Jacques does not seek a new expert to support her existing claim regarding Sjögren’s syndrome. Ms. Jacques’s case does not present a situation in which a party’s expert dies, becomes ill, or otherwise refrains from participating in the litigation.

<u>No.</u>	<u>Date</u>	<u>Event</u>	<u>Notes</u>
01	8/2/2019	Petition	Including small fiber neuropathy
02	3/24/2020	Petitioner's Declaration	Discussing diagnosis of small fiber neuropathy
03	7/31/2020	Resp't's Report	Stating petitioner was apparently "diagnosed with small fiber neuropathy"
04	8/5/2020	Order after status conference	Noting Mr. Krakow was considering retaining a rheumatologist and/or a neurologist.
05	8/6/2021	SM Ruling (public version)	<u>E.M. v. Sec'y of Health &amp; Hum. Servs.</u> , No. 14-753V, 2021 WL 3477837 (finding flu vaccine caused small fiber neuropathy)
06	6/5/2023	Dr. Efthimiou's first report	Asserting petitioner suffered from Sjögren's syndrome
07	10/3/2023	Dr. Rose's first report	Disputing assertion that petitioner suffered from Sjögren's syndrome
08	10/18/2023	Amended Petition	Alleging hepatitis B vaccinations caused Sjögren's syndrome manifesting as small fiber neuropathy
09	11/1/2023	Order	Memorializing Mr. Krakow's plan to explore retaining a neurologist
10	1/12/2024	SM Ruling (public version)	<u>Quirino v. Sec'y of Health &amp; Hum. Servs.</u> , No. 17-989V (finding tetanus-diphtheria-acellular pertussis vaccine and/or hepatitis B vaccine caused small fiber neuropathy)
11	2/19/2024	Dr. Efthimiou's response to Dr. Rose	Maintaining an opinion that petitioner suffered from small fiber neuropathy
12	2/28/2024	Order	Memorializing Mr. Krakow's statement that he did not plan to retain a neurologist
13	4/23/2024	SM Ruling (public version)	<u>Coons v. Sec'y of Health &amp; Hum. Servs.</u> , No. 20-1067V (finding tetanus-diphtheria vaccine cause small fiber neuropathy)

These multiple opportunities to obtain a report from an expert distinguish Ms. Jacques's situation from a case on which she relies, DeLozier, 154 Fed. Cl. at 392. In DeLozier, after the Court found that Ms. DeLozier was entitled to compensation and remanded the case for a determination of damages, Ms. DeLozier sought to retain an expert to help with the process of quantifying the compensation to which she was entitled. The special master denied Ms. DeLozier's request for expert assistance. Upon review, the Court determined that the special master's denial prevented Ms. DeLozier from having a full and fair opportunity to present her case. Id. at 395. Ms. DeLozier's expert in damages was not needed until she was found entitled to compensation. Thus, her request to add a new expert did not constitute a shift in her position.

This chronology set forth in the procedural history and chart above demonstrates that both Ms. Jacques and Mr. Krakow were aware that the treating doctors diagnosed her with small fiber neuropathy from the beginning of the case. This awareness means that Ms. Jacques had sufficient information to assert that the hepatitis B vaccines caused her to suffer small fiber neuropathy. Early in the litigation, the Secretary alerted Ms. Jacques and Mr. Krakow that small fiber neuropathy appeared to be an appropriate diagnosis. Resp't's Rep., filed July 31, 2020, at 15. In response, Mr. Krakow stated that he was considering exploring retaining a neurologist. See Order, issued Aug. 5, 2020. Despite being aware that Ms. Jacques had been diagnosed with small fiber neuropathy, Mr. Krakow did not retain a neurologist. Instead, Mr. Krakow chose to pursue a claim through a rheumatologist, who asserted that Ms. Jacques suffered from a condition with which none of her treating doctors had diagnosed her, Sjögren's syndrome.

Ms. Jacques and Mr. Krakow had other opportunities to go down a different path. For example, after Dr. Rose credibly challenged the assertion that Ms. Jacques suffered from Sjögren's syndrome (Exhibit A), Mr. Krakow could have explored getting a neurologist. See Order, issued Nov. 1, 2023. And, at least once, Mr. Krakow affirmatively declined to retain a neurologist. Order, issued Feb. 28, 2024. These constituted opportunities for Ms. Jacques to present her case. See Vaccine Rule 3(b)(2). Yet, despite these chances, Ms. Jacques and Mr. Krakow pushed forward with a claim based upon Sjögren's syndrome until the Tentative Finding explained that this claim was not likely to succeed.

To explain the switch in positions, Mr. Krakow points to Quirino and Coons. However, these cases do not justify a belated addition of a new claim for three reasons. First, whether rulings favorable to a petitioner justify adding a new claim is not clear. As set forth above, the key evidence is that Ms. Jacques was diagnosed with small fiber neuropathy. Ms. Jacques's attempt to base her claim upon the allegation that she suffered from a condition with which none of her treating doctors diagnosed her, Sjögren's syndrome, seems to build an extra challenge in her case. Neither Quirino nor Coons explains why Ms. Jacques started down the path with Sjögren's syndrome in the first place.

Second, Ms. Jacques could have asserted the claim that the hepatitis B vaccinations caused small fiber neuropathy before Quirino and Coons. Favorable precedent is not a requirement for asserting a claim. If petitioners could bring only claims that special masters have accepted in the past, then litigation in the Vaccine Program would grow stale.

Third, even if favorable precedent were somehow required, Ms. Jacques's omits any discussion of an earlier case that credited the theory that a vaccine can cause small fiber neuropathy. A special master issued E.M. roughly two years before Dr. Efthimiou's first report.

To the extent that Ms. Jacques wants to rely upon rulings from special masters, she should have explained why E.M. did not open the door for her to claim small fiber neuropathy.

In short, Ms. Jacques has not justified the delay in raising a new claim. She had sufficient knowledge of the critical fact, her diagnosis of small fiber neuropathy, at least five years before she attempted to develop evidence to support this cause of action.

Notwithstanding the above, Ms. Jacques argues that allowing an adjudication on the merit of her (inchoate) claim that the hepatitis B vaccinations caused her to develop small fiber neuropathy is consistent with the policies underlying the Vaccine Program. See Pet'r's Reply at 3-4. Of course, resolving cases based upon a weighing of the evidence is one goal. However, procedural obstacles can and do prevent a special master from reaching the evidence.

A prominent example of such a procedural limitation is the statute of limitations. 42 U.S.C. § 300aa-16(a)(2). Admittedly, the statute of limitations is a statute, meaning a bill was passed by Congress and signed by the President. However, judicial officers have foregone opportunities to ameliorate the consequences of the statute of limitations. For example, the en banc Federal Circuit determined that the discovery rule did not delay the start of the running of the Vaccine Program's statute of limitations. Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1339 (Fed. Cir. 2011). Similarly, although the same en banc Federal Circuit accepted that equitable tolling could affect the statute of limitations, 654 F.3d at 1341, the Court held that the petitioner, Melissa Cloer, was not entitled to equitable tolling on the facts of her case. Id. at 1344-45. Arguably, it would have been more "fair" if Dr. Cloer's claim would have been adjudicated on the basis of whether evidence supported it. For other examples in which a failure to comply with the statute of limitations and a lack of equitable tolling supported dismissal of a Vaccine Program case, see W.J. v. Sec'y of Health & Hum. Servs., 93 F.4th 1228 (Fed. Cir. 2024), and Falzon v. Sec'y of Health & Hum. Servs., No. 21-1082V, 2023 WL 395879 (Fed. Cl. Jan. 25, 2023), aff'd, No. 2023-1659, 2024 WL 3407439 (Fed. Cir. July 15, 2024).

The foregoing discussion of the statute of limitations is intended to illustrate that although litigation in the Vaccine Program is less formal, litigation in the Vaccine Program has *some* rules. The dictate in Vaccine Rule 3(b)(2) to allow the parties a "full and fair opportunity" to present their cases is not unlimited. See K.A., 164 Fed. Cl. at 118-19 (ruling that the special master did not deprive petitioner of a full and fair opportunity to present his case when the special master denied a request to add a sixth expert report).

For these reasons, Ms. Jacques's request to add the claim that the hepatitis B vaccines caused her to suffer small fiber neuropathy is denied.<sup>6</sup>

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<sup>6</sup> If Ms. Jacques's were permitted to add a claim that the hepatitis B vaccines caused her to suffer small fiber neuropathy and develop a new expert, then the Secretary would probably also be required to obtain a new expert, someone with experience in small fiber neuropathy. The fact that the Secretary will be burdened with expending additional resources to respond to a claim that could have been raised much earlier tends to support a denial of Ms. Jacques's request to add a new claim. However, the prejudice to the Secretary is a secondary, not primary, reason for denying Ms. Jacques's request.

**B. Ms. Jacques's Claim based upon Sjögren's Syndrome**

The foregoing determination that Ms. Jacques cannot add another claim leaves the presently pending claim that the hepatitis B vaccines caused her to suffer Sjögren's syndrome. See Am. Pet., filed Oct. 18, 2023. As set out in the procedural history, Ms. Jacques appears not to dispute the tentative finding that she has not established her claim with preponderant evidence.

A petitioner must establish she suffers from the condition for which she seeks compensation. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). For Ms. Jacques, Dr. Efthimiou proposes Sjögren's syndrome. However, Dr. Rose has persuasively explained why Ms. Jacques does not meet the diagnostic criteria for Sjögren's syndrome. See Exhibit A at 12-24; Exhibit E at 5-12. Without a finding that Ms. Jacques suffers from the disease allegedly caused, a causation-in-fact analysis pursuant to Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), is not required. Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

**IV. Conclusion**

Ms. Jacques filed her petition in 2019, aware that she had been diagnosed with small fiber neuropathy. Yet, she did not attempt to bring a claim based upon this diagnosis until after the case had been pending for approximately five years. Ms. Jacques has not established this delay is justified. Thus, her request to add a new claim to her amended petition is DENIED.

In addition, the evidence does not support a finding on the claim asserted in the October 18, 2023 amended petition. This claim is, therefore, DENIED.

Ms. Jacques is not entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

**IT IS SO ORDERED.**

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