In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

NIBERLEY WALTON,	*	No. 20-791V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	
v.	*	
	*	Filed: July 30, 2025
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner;
Madelyn Weeks, United States Dep't of Justice, Washington, D.C., for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

Petitioner, Niberley Walton, filed a petition for compensation on June 29, 2020, alleging that the tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine she received on December 4, 2018, caused her to suffer from "vaccine-induce neuropathy, including small fiber neuropathy, and fibromyalgia." In the alternative, Ms. Walton alleged that these conditions were significantly aggravated by the vaccine. On July 24, 2025, Ms. Walton filed a motion for a decision dismissing her petition.

[1] 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.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

I. Procedural History

Ms. Walton filed her petition on June 29, 2020, alleging that the Tdap vaccine she received on December 4, 2018 caused or significantly aggravated her small fiber neuropathy and fibromyalgia. She submitted medical records over the next year. Respondent filed his Rule 4(c) Report on November 8, 2021, arguing that Ms. Walton had not put forth a medical theory to support an onset of small fiber neuropathy or fibromyalgia within 24 hours. Resp't's Rep. at 13. Respondent also argued that the records do not show that Ms. Walton's condition worsened as a result of her vaccination, nor that she suffered from small fiber neuropathy or fibromyalgia prior to her vaccination. Id. at 15.

The case then moved to the expert stage. See Order, issued Nov. 9, 2021 (proposing draft instructions). Ms. Walton submitted her report from a rheumatologist, Dr. Axelrod, August 8, 2022. Exhibit 9. Dr. Axelrod opined that Ms. Walton suffered from both small fiber neuropathy and fibromyalgia, but recognized that, as he is not a neurologist, he could not comment further about small fiber neuropathy. Id. at 5.

Respondent filed reports from a neurologist, Dr. Lancaster, and an immunologist, Dr. Schroeder, on January 30, 2023. Dr. Lancaster stated that Ms. Walton "may have a mild degree of small fiber neuropathy," but that it would not account for many of her symptoms. Exhibit A at 16. He saw no evidence that the small fiber neuropathy was caused by the vaccine, and stated that the "very rapid onset and progression of symptoms weighs against a causal link." Id. Dr. Schroeder noted that Ms. Walton's treating doctors generally agreed upon a diagnosis of fibromyalgia, but the small fiber neuropathy diagnosis was "on softer ground due to the borderline results from the skin biopsies." Exhibit C at 7. He emphasized that "there is no evidence that fibromyalgia is an inflammatory/autoimmune disorder." Id. at 13.

A status conference was held on March 21, 2023. The undersigned stated that there was stronger evidence for fibromyalgia than small fiber neuropathy. The undersigned also indicated that respondent had presented a strong case against entitlement, and Ms. Walton had presented no evidence that an increase in cytokines causes harmful effects. See Order, issued Mar. 23, 2023. Ms. Walton was given an opportunity to file a supplemental report from Dr. Axelrod addressing how cytokines cause harmful effects.

Ms. Walton filed a second expert report from Dr. Axelrod on July 21, 2023. Exhibit 36. Dr. Axelrod stated that Ms. Walton "developed Fibromyalgia and perhaps a small fiber neuropathy following Tdap vaccination." Id. at 2. He stated that her symptoms were "consistent with expected adverse events within the first few days" following a Tdap vaccination, and "consistent with the expected increase in cytokines to vaccination." Id. at 4. Respondent's experts disputed that a rise in cytokines can cause fibromyalgia or small fiber neuropathy. Exhibit E at 2-3; Exhibit F at 5.

A November 20, 2023, order highlighted the deficiencies in Ms. Walton's case. The undersigned noted that it was unsettled whether petitioner suffered from any degree of small fiber neuropathy. Even assuming Ms. Walton suffered from fibromyalgia, it is not considered an autoimmune disease, making it difficult to understand how a vaccine might cause the condition. The undersigned stated that Dr. Axelrod asserted a theory involving cytokines, but had not explained it persuasively. Ms. Walton was given a "final opportunity to present a supplemental report from Dr. Axelrod."

Ms. Walton filed her third report from Dr. Axelrod on April 1, 2024. Exhibit 54. Dr. Axelrod explained that there is "evidence for involvement of the immune system in Fibromyalgia," such as effective treatments, evidence of the involvement of mast cells, and "retrospective evidence to suggest that Small Fiber Neuropathy is not a significant contributor to the pathophysiology of Fibromyalgia." Id. at 1-2. He described a study by Goebel in which IgG from humans with fibromyalgia was administered to mice, resulting in both mechanical and cold hypersensitivity, "suggest[ing] that there are targets of the immune system in subjects with Fibromyalgia that are responsible for symptoms of Fibromyalgia." Id. at 2. Although Dr. Axelrod agreed with Dr. Schroeder that fibromyalgia appears to be a stress-related disorder, he noted that stress has been linked to the onset or aggravation of autoimmune diseases, and that stress does not determine the target for an autoimmune response. Id. at 3.

Dr. Axelrod further opined that Ms. Walton "developed Fibromyalgia and perhaps a small fiber neuropathy following Tdap vaccination." Exhibit 54 at 4. He agreed that "the onset of symptoms within 48 hours of the vaccination is too fast for a specific immune response," but posited that her first symptoms were associated with the "expected increase in cytokines," and that a secondary adaptive immune response le to her fibromyalgia and possible small fiber neuropathy. Id. at 6. Dr. Axelrod highlighted LGI1 antibodies as being associated "with a variety of

clinical presentations, including isolated peripheral nerve hyperexcitability," and discussed a potential role of the NMDA receptor in central sensitization. Id. at 6-7.

An Order to Show Cause issued on May 13, 2024. The order advised Ms. Walton that she had not carried her burden of presenting a minimally persuasive case that the Tdap vaccine caused her injury. In particular, she had not established that she suffered from small fiber neuropathy. Furthermore, her more likely injury of fibromyalgia is not considered an autoimmune disease, making it unlikely to have been caused by a vaccine. Although Dr. Axelrod argued that the classification of fibromyalgia continues to change, Ms. Walton had not presented preponderant evidence that fibromyalgia is autoimmune in nature. Ms. Walton was directed to explain why her case should not be dismissed for a failure to present persuasive evidence with an expert report and/or arguments from counsel.

In response, Ms. Walton submitted a report from a neurologist, Dr. Jeret. Exhibit 56. Ms. Walton stated that Dr. Jeret "confirms her diagnosis, including small fiber neuropathy . . . [which] is known within the program to be an autoimmune condition and has been previously linked to vaccinations." Pet'r's Resp. to Order to Show Cause, filed July 19, 2024.

Dr. Jeret explained that symptoms of small fiber neuropathy "vary widely in features and severity," and highlighted how petitioner satisfies the Freeman criteria. Exhibit 56 at 10-11. He contended that "the prevalence of SFN is probably highly underestimated due to lack of a gold standard for diagnosis and lack of awareness among clinicians." Id. at 12. Dr. Jeret also argued that "Recent data has indicated that FM has an immune base," describing it an "an emerging field," and citing the study by Goebel which Dr. Axelrod referenced. Id.

As to timing, Dr. Jeret stated that it is possible for autoimmune reactions to occur within one day, citing examples in Pan (four cases of GBS within one day of DTap) and Agmon-Levin (one case of fibromyalgia within one day of hepatitis B vaccination). Exhibit 56 at 13. He also explained that "it is accepted that patients with one autoimmune process are at higher risk for additional autoimmune processes. Ms. Walton had a history of optic neuritis, which Dr. Jeret described as "typically autoimmune," and HELLP syndrome, which he stated "is thought to be an inflammatory disorder mediated by a complement cascade." Id. Dr. Jeret also mentioned that Ms. Walton's parents both had autoimmune diseases and that these are often hereditary. "To postulate an autoimmune reaction to a vaccine in such an individual who was 'primed' for a[n] autoimmune event is quite reasonable," he concluded. Id.

In response to Dr. Axelrod and Dr. Jeret's reports, respondent submitted supplemental reports from Dr. Lancaster and Dr. Schroder. Addressing Dr. Axelrod's report, Dr. Lancaster disputed the idea that fibromyalgia is an autoimmune disease. Exhibit F (ECF No. 88-1)[2] at 1-3. He described Dr. Axelrod's theories regarding LGI1 and NMDAR antibodies as unsupported by literature and noted that Ms. Walton did not have symptoms associated with these antibodies. Id. at 3. Dr. Lancaster also noted that Dr. Axelrod "discusses homology but does not define any specific mimic substance in the vaccine and does not specify what single antigen in Petitioner's body this triggered an immune response against." Id. He maintained that the onset of Ms. Walton's symptoms was "too fast for an antibody mechanism, and it is also too fast for a specific T cell mediated immune response." Id.

Dr. Lancaster criticized the Goebel paper cited by both Dr. Axelrod and Dr. Jeret. He referenced his previous report, in which he noted "important limitations" to this "single study." Dr. Lancaster explained that animal behaviors cannot be considered the same as fibromyalgia; the changes were modest and it would be an overstatement to say the animals had fibromyalgia; some experiments were done with pooled antibodies from multiple patients, making it unclear how many patients actually were responsible for the effect; and that there is "no definite proof of specific antibody . . . being found in patients with fibromyalgia. Exhibit E at 1-2.

Dr. Lancaster also addressed the Agmon-Levin paper. He characterized the finding that onset ranged from one day to one year as "implausible on both ends, since an autoimmune disease . . . would be unlikely to damage the nervous system to cause chronic pain within 1 day." Exhibit F at 4. Further, he stated that the authors "seem to have a very expansive view of causation in attributing any disease within a year of vaccination to the vaccination. This range is far outside the usual bounds of vaccine-induced autoimmune disorders." Id. In all, he opined that the Agmon-Levin paper "does not provide reliable evidence that vaccination causes either chronic fatigue syndrome of fibromyalgia." Id.

As with Dr. Axelrod's theory, Dr. Lancaster criticized Dr. Jeret's theory for lack of detail about how a vaccine could cause fibromyalgia through an autoimmune mechanism within one day. Id. In his conclusion, he maintained that Ms. Walton was unlikely to have suffered from small fiber neuropathy, and that it

[2] There are two exhibits labeled as Exhibit F. All references to Exhibit F in this order refer to ECF No. 88-1.

would not account for all her symptoms. Furthermore, he stated the very rapid onset and progression of symptoms weighed against vaccine causation; and that Ms. Walton's expert's theories were unlikely to be true. Id. at 5. Specifically, he argued that Dr. Axelrod's theories "invoked autoimmune processes that have not been shown to occur, or autoimmune diseases that Petitioner very likely did not have," and that homology is not a reliable method to predict autoimmune disease post-vaccination. He refuted Dr. Jeret's theories by noting that fibromyalgia is not treated as an autoimmune disease by the medical community. Id.

Dr. Schroder also responded to Ms. Walton's experts' reports. Exhibit G. Expanding upon Dr. Jeret's comment about how reliance on subjective complaints makes diagnosing fibromyalgia and small fiber neuropathy difficult, Dr. Schroder noted that this also makes mechanistic study difficult. Id. at 1-2. Dr. Schroder further argued that the onset of Ms. Walton's symptoms occurred too soon after her Tdap vaccination to be attributable to an adaptive immune response to the vaccine. Id. at 2. He explained the timeline of an adaptive immune response, stating it follows "a predictable pattern" wherein it ultimately takes five to seven days before anti-antigen activity becomes apparent, with a peak response occurring around fourteen days after the antigen activation. Id. at 3. Dr. Schroder disputed that the Tdap vaccine could cause fibromyalgia via molecular mimicry, noting the "widespread and prolonged" exposure to self-antigen molecular mimics. Id. at 4. He further noted that Dr. Axelrod acknowledged the commonality of molecular mimicry despite the infrequency of autoimmune disease. Id. at 5.

Ms. Walton was invited to submit additional expert reports. Order, issued Dec. 6, 2024. In response, Ms. Walton stated that the parties had already exchanged reports, and requested a Rule 5 conference to discuss next steps. Pet'r's Status Rep., filed Feb. 6, 2025.

To provide guidance and discuss outstanding issues, the undersigned issued an order again explaining the deficiencies in Ms. Walton's case. Order, issued April 3, 2025. Ms. Walton was given an opportunity to consider whether it was reasonable to continue to pursue her case.

Ms. Walton filed a status report on May 5, 2025, reporting that she had met with counsel several times to discuss the order and research that she had done. Ms. Walton wanted to seek a second legal opinion, and requested additional time to determine her course of action. On June 6, 2025, Ms. Walton filed a status report

stating that she had "decided to withdraw her case and will be filing a motion to dismiss shortly." Ms. Walton filed her motion to dismiss on July 24, 2025.

II. Analysis

To receive compensation under the National Vaccine Injury Compensation Program ("Program"), a petitioner must prove either 1) that the vaccinee suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations, or 2) that the vaccinee suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, Ms. Walton filed medical records and expert reports in support of his claim. Nevertheless, Ms. Walton wishes to have her claim dismissed and judgment entered against her. Given Ms. Walton's clear intent that a judgment issue in this case, the undersigned will construe this as a motion filed pursuant to 42 U.S.C. § 300aa-21(b) (regarding involuntary dismissal).

To conform to § 12(d)(3), a decision must "include findings of fact and conclusions of law." To conform to section 12(d)(3), a decision must "include findings of fact and conclusions of law." For causation-in-fact cases, the Federal Circuit has defined elements of a petitioner's claim. Petitioners bear a burden to show by a preponderance of the evidence that the vaccination brought about their injury by providing:

> (1) a medical theory causally connecting the vaccination and the injury;
> (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
> (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

As explained in the November 20, 2023; May 13, 2024; and April 3, 2025, orders, it appears more likely that Ms. Walton suffers from fibromyalgia than

small fiber neuropathy. Beyond stating that science and research is evolving, Ms. Walton's experts do not dispute that fibromyalgia is still predominantly regarded as a non-autoimmune disease. Without this showing, Ms. Walton's theory of molecular mimicry cannot adequately explain how a vaccine would cause her condition. Moreover, Ms. Walton's theory of molecular mimicry is too vague to this carry her burden under Althen. As Dr. Lancaster describes, Ms. Walton's theory of molecular mimicry is "unclear" and does not identify which components of the immune system would have interacted with some other host tissue to trigger an autoimmune response. Exhibit F at 3. To prevail on a theory of molecular mimicry, a petitioner must "offer reliable and persuasive medical or scientific evidence of some kind (whether expert testimony or literature) that suggests the vaccine components could interact with the self structures as maintained." Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018); see also Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *15 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020) (finding that the theory of molecular mimicry was unpersuasive even when sequence homology was identified).

Furthermore, even assuming that Ms. Walton does have an autoimmune condition, her experts do not persuasively explain how an autoimmune response may occur within 24 to 48 hours. Special masters have previously found that vaccines do not cause autoimmune conditions question. See, e.g., Henry v. Sec'y of Health & Hum. Servs., No. 17-721V, 2022 WL 2301321, at *35-36 (Fed. Cl. Spec. Mstr. May 2, 2022) (finding 20 hours too quickly because, in part, Dr. Gershwin stated that 24-48 hours is needed for a significant IgM response); O.M.V. v. Sec'y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *47 (Fed. Cl. Spec. Mstr. June 16, 2021) (finding that an innate immune response cannot cause a demyelinating condition in 24 hours), mot. for rev. denied on unrelated ground, 157 Fed. Cl. 376 (2021); Samuels v. Sec'y of Health & Hum. Servs., No. 17-071V, 2020 WL 2954953, at *20-21 (Fed. Cl. Spec. Mstr. May 1, 2020) (finding that petitioner had failed to establish proinflammatory cytokines could cause demyelinating injuries within 24 hours); Parker v. Sec'y of Health & Hum. Servs., No. 14-979V, 2019 WL 3425297 at *28-29 (Fed. Cl. Spec. Mstr. June 24, 2019) (finding 24 hours is an insufficient time for molecular mimicry). Ms. Walton has therefore not met her burden under Althen.

Thus, this case is DISMISSED WITH PREJUDICE for insufficient proof. The Clerk shall enter judgment accordingly. See Vaccine Rule 21(b).

IT IS SO ORDERED.

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