

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 23-1494V

UNPUBLISHED

ANDREA MAE WARREN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 24, 2024

Robert M. Hatch, Bronster Fujichaku Robbins, Honolulu, HI, for Petitioner.

Julia M. Collison, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On August 29, 2023, Andrea Mae Warren filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 through 34² (the “Vaccine Act”). Petitioner alleges that she suffered various injuries due to a human papillomavirus (“HPV”) vaccine she received on May 28, 2008. ECF No. 1 at 2.

Because the petition was untimely filed, and Petitioner has failed to establish a basis for equitable tolling, this case is **DISMISSED**.

Relevant Factual Background

Petitioner stated she received an HPV vaccination on May 28, 2008, when she was twenty-four years old. ECF No. 1. Petitioner has not submitted the administration records to establish this vaccination or even a vaccination history. The oldest medical

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), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “Sec.” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

records submitted by Petitioner is a January 14, 2019 appointment, an almost eleven year gap in Petitioner's medical history. Exhibit 1 at 22.

Petitioner stated that her (unspecified) injuries "progressed in the subsequent years." ECF No. 1 ¶ 5. Petitioner appears to have been diagnosed by her cardiologist with postural orthostatic tachycardia syndrome ("POTS") in June 2020 but has not filed the cardiology records. Exhibit 2 at 31, 39. In September 2020, Petitioner described her POTS symptoms as chronic. ECF No. 1 ¶ 7.

Petitioner alleged the preceding medical history in the petition and repeated the history in her response to the order to show cause. Facially, Petitioner's claim herein was filed over *fifteen* years after her last HPV dose, which was administered in 2008, and several years after she began manifesting symptoms.³ But Petitioner maintains her delay is excusable. Thus, in an affidavit dated November 2023, Petitioner has attested that, at the time this vaccination occurred, no Vaccine Information Statement (VIS) was provided and no information was relayed about the Vaccine Program. ECF No. 11 at 21, ¶ 4. Petitioner only learned that the HPV vaccine might be capable of causing adverse effects in September 2020. *Id.* at 22, ¶ 6.

Relevant Procedural History

Given that the timeliness of the claim was legitimately called into question merely by the face of the actual Petition, while the case was still in the initial "pre-assignment review" (a process utilized by the Office of Special Masters to assess whether a claim's primary evidentiary documentation has been filed), I ordered Petitioner to show cause why the claim had not been filed outside the Act's 36-month statute of limitations. Sec. 16(a)(2); ECF No. 7.

On November 20, 2023, Petitioner filed a response. ECF No. 11. Petitioner did not dispute that the onset of symptoms occurred more than three years before the petition was filed in 2023, but instead argued that the limitations period should be equitably tolled. Petitioner asserted that she had diligently pursued her rights once she realized the connection between her injuries and the HPV vaccine and became aware of the Vaccine Program. Petitioner also made allegations not relevant to a Vaccine Act claim, about the perfidious conduct of the vaccine manufacturer in fraudulently concealing the HPV vaccine's harmful character from the public. ECF No. 11 at 17. Relatedly, Petitioner argued that the failure of a healthcare professional to provide her with a VIS at the time

³ As noted in the order to show cause, ECF No. 7, because Petitioner described her symptoms as "chronic" by September 2020 and that her symptoms had progressed over years, I understand the onset of these symptoms to have occurred years before 2020. Petitioner did not contradict this understanding in her response to the order to show cause and did provide any further detail about the onset of her symptoms. ECF No. 11.

of vaccination can be attributed to the Department of Health and Human Services' failure to systematically ensure that VIS are provided and explained to all vaccine recipients. *Id.* at 3.

On January 10, 2024, Respondent submitted a responsive brief of his own, arguing for dismissal due to untimeliness. ECF No. 13. Respondent maintained that Petitioner in fact had not diligently pursued her rights before filing a vaccine claim in 2023. Respondent also disputed the veracity of contentions about the manufacturer's conduct, and whether it could in any event constitute an extraordinary circumstance that would serve as a basis for tolling of the statute.

On January 24, 2024, Petitioner filed a reply to Respondent's arguments. ECF No. 15. The reply generally reiterates Petitioner's prior arguments.

Legal Standards

The Vaccine Act's statute of limitations is thirty-six months. Sec. 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id.*; *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act's statute of limitations. See *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). However, in keeping with applicable U.S. Supreme Court precedent, equitable tolling of a limitations period is to be permitted "sparingly." *Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 96, (1990). The appropriateness of equitable tolling is ultimately to be determined on a case-by-case basis, without rigid application of any relevant overarching guidelines. *Holland v. Florida*, 560 U.S. 631, 649-50 (2010); accord *Arctic Slope Native Ass'n v. Sebelius*, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

Petitioners must prove two elements to establish equitable tolling: (1) that petitioner diligently pursued her rights, and (2) an extraordinary circumstance prevented her from timely filing the claim. *K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing *Menominee Indian Tribe v. United States*, 577 U.S. 250, 255 (2016)). When first articulating this limited exception to equitable tolling, the Federal Circuit primarily enumerated fraud and duress—but not, for example, *lack of awareness* on a petitioner's part that she might have an actionable claim. *Cloer*, 654 F.3d at 1344-45 (noting that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine").

Analysis

The untimeliness of this filing is acknowledged by Petitioner, so the only question to be resolved is whether equitable tolling should save the claim. But Petitioner has failed to establish both elements of equitable tolling – diligent pursuit and extraordinary circumstances.

A) Diligent pursuit

Petitioner was twenty-four years old when she received an HPV vaccination in 2008. Petitioner argues that she was impeded by the failure of the vaccine administrator to provide her with a VIS or any other information about the Vaccine Program. Petitioner only began to diligently pursue a vaccine claim after she learned that the HPV vaccine had potential adverse effects in September 2020.

These arguments are wholly unpersuasive. It is beyond question that claims asserted in the Vaccine Program are not subject to a “discovery rule,” accruing only when a claimant *learns* he or she might possess a cause of action. Rather, the statute of limitations period is triggered by the onset of Petitioner’s symptoms – whether or not onset was understood to be the start of the claimed injurious illness or condition. *Cloer v. Sec’y of Health & Hum. Servs.*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc). And the failure to be advised of the Vaccine Program or the Act does not support equitable tolling of the statute of limitations period for an otherwise-untimely filed petition. *Speights v. Sec’y of Health & Hum. Servs.*, No. 03-2619V, 2013 WL 5944084, at *13 (Fed. Cl. Spec. Mstr. Oct. 17, 2013). Thus, a petitioner cannot generally shield an untimely claim from dismissal by asserting, even in good faith, that she literally was unaware of her Vaccine Act “rights.”

B) Extraordinary Circumstances

Petitioner’s arguments about the purported fraudulent conduct of the vaccine’s manufacturer, in hiding proof of the vaccine’s dangers, deserve even less consideration. ECF No. 11 at 17. As a threshold matter, these contentions are speculative and not evidentiarily-supported. And regardless of their actual truth, the fact remains that the Government *has approved* the HPV vaccine for administration to minors, rendering it “covered” under the Act. The only issue to be resolved in a Program case is whether (assuming, as here, the claim is not a Table claim) the claim meets the standards for causation – and those standards have nothing to do with a manufacturer’s alleged misconduct in preparation or promotion of the underlying vaccine.

These allegations also are not a basis for tolling under the circumstances. Petitioner simply has not shown that contentions of corporate misconduct not specific to, or directed at, her personally could rise to the level of the kind of “fraud” that might excuse

failing to file a Program claim in a timely manner. Nor has she persuasively established that the vaccine administrator's "failure to warn," or provide a VIS in 2008, is an extraordinary circumstance. Even assuming the factual accuracy of that allegation,⁴ it remains the case (as the Circuit recognized in *Cloer*) that vaccine claims accrue upon onset – and that the failure to be advised of the Vaccine Program does not support equitable tolling. *Cloer*, 654 F.3d at 1340; see also *Speights*, 2013 WL 5944084, at *13. And arguments about governmental agency knowledge of a failure to warn reflect overheated, almost-conspiratorial allegations that do not come close to excusing the claim's untimely nature.

Finally, Petitioner also asserts that the safety of the HPV vaccine is "in dispute [and] the Court should not simply accept the assertions of the Respondent over those of the Petitioner without further proceedings including expert testimony on the subject." No. 15 at 2. But this argument willfully ignores the extent to which I have personally ruled in numerous prior cases that medical science does not preponderantly support the contention that the HPV vaccine can cause POTS or other autonomic issues. See, e.g., *J.S. v. Sec'y of Health & Hum. Servs.*, No. 16-1083V, 2022 WL 20213038, at *20 (Fed. Cl. Spec. Mstr. July 15, 2022), *mot. for review denied*, 164 Fed. Cl. 314 (2023), *appeal docketed*, No. 23-1644 (Fed. Cir. Mar. 22, 2023); *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092, at *31 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), *mot. for review denied*, 154 Fed. Cl. 640 (2021); *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *40, 43 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), *mot. for review denied*, 154 Fed. Cl. 149 (2021); *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113, at *44–45 (Fed. Cl. Spec. Mstr. July 15, 2019). The Act does not require that the same theory rejected so many times before must be relitigated by the Program ad infinitum (especially in the absence of new compelling evidence). Rather, special masters are expressly empowered to rely on their expertise, earned in adjudicating Program cases, in subsequent similar matters. To suggest that they should ignore what they have learned in that process reveals a complete miscomprehension of the Program's underlying goals and purposes.

⁴ Vaccine administration records typically state whether VIS are provided to patients and/or whether patients have been counseled about the vaccine. As noted above, Petitioner has not submitted a vaccine administration record or vaccination history to establish the HPV vaccination. Thus, Petitioner has not submitted any contemporaneous medical records of the vaccination to determine whether a VIS was provided to her. Petitioner's only evidence that no VIS or information about the Vaccine Program was provided is her affidavit dated November 2023, in which she attested about events that occurred over fifteen years earlier. ECF No. 11 at 21, ¶ 4.

Conclusion

Thus, Petitioner has failed to establish equitable tolling. **This case is dismissed for being untimely filed. The Clerk of Court shall enter judgment accordingly.**⁵

IT IS SO ORDERED.

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

⁵ If Petitioner wishes to bring a civil action, she must file a notice of election rejecting the judgment pursuant to § 21(a) “not later than 90 days after the date of the court’s final judgment.”