

I. FACTUAL HISTORY

Kodi Stevens was born in 1990. Exhibit A1.² Ms. Stevens received her hepatitis B vaccine on April 21, 2003. Exhibit A2 at 1-3.³ On April 22, 2003, the day after receiving the Hep B vaccine, Ms. Stevens “experienced complete numbness in both legs and generalized body aches.” Pet. at 1; exhibit A10 (Aff. of JoAnn Stevens) at 1-2. On April 24, 2003, Ms. Steven’s mother telephoned her daughter’s pediatrician about Ms. Stevens’ symptoms, including the numbness and aches, experienced two days before. Exhibit A2 at 8. The phone message in the record is followed by a separate note stating “seems ok now just FYI,” and there is no indication that further action was taken. Id.

The parties did not attribute any significance to medical records created between 2003 and 2010. While there are some records from this time, these records do not affect the timeliness of the petition. See exhibit 2 at 1-112; exhibit 6 at 2-11; exhibit 7 at 1-29.

On September 22, 2010, Ms. Stevens visited Nova Southeastern University Health Clinic for vaginal numbness, shortness of breath, and tingling down her spine upon bending of her neck. Exhibit A3 at 1-4 (NSU clinical records). The tingling down her spine is known as a Lhermitte’s sign. Dorland’s Illustrated Medical Dictionary, 1713 (32d ed. 2012) (defining a Lhermitte’s sign as “the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord.”) According to Ms. Stevens, these symptoms constituted the first objectively recognizable sign of her MS. Am. Pet. at 2. The doctor diagnosed her with pain likely secondary to an ovarian cyst and gave her a course of NSAIDS.⁴ Id. at 3-4.

² Although the usual practice in the Vaccine Program is for the petitioners to label their exhibits with numbers, the exhibits submitted with Ms. Steven’s pro se petition are designated exhibit A1-A10. Petitioner’s remaining exhibits are sequentially numbered starting with exhibit 1.

³ The petition and amended petition assert different dates for the hepatitis B vaccine. The amended petition states that the date of the vaccine was on April 4, 2003, while also stating that it was on April 21, 2003. Am. Pet. at 1. Ms. Steven’s medical records show her vaccine was the latter date, April 21, 2003. Exhibit A2 at 1-3.

⁴ NSAIDs are nonsteroidal anti-inflammatory drugs. Dorland’s at 1293.

On November 11, 2011, Ms. Stevens underwent a brain MRI due to left eye blurriness. Exhibit A4 at 1. The results showed “extensive white matter disease” which was “suggestive of a diagnosis of multiple sclerosis.” Id. There were several lesions indicating “areas of active demyelination.” Id.

Following complaints of generalized muscle weakness and vision loss, Ms. Stevens underwent a spinal MRI to evaluate for MS. Exhibit A4 at 2 (MRI results, dated Nov. 28, 2011). The MRI showed a “lesion on the left side of the spinal cord . . . indicative of active disease.” Id. The results were “compatible with the clinical diagnosis of multiple sclerosis.” Id.

On November 30, 2011, Ms. Stevens was seen by Dr. Paul Ginsburg for a second opinion following her MS diagnosis. Exhibit A5 at 1-3. Dr. Ginsburg stated that “there really is not much doubt that this is multiple sclerosis.” Id. at 3.

After Dr. Ginsburg’s diagnosis, doctors have continued to treat Ms. Stevens for MS. The details of her post-diagnosis history are not relevant to the timeliness of Ms. Steven’s petition.

In addition to these medical records, Ms. Stevens also submitted affidavits from herself and her mother. The affiants chronicle the difficulties Ms. Stevens has endured, pointing to numerous common MS symptoms. See Aff. of Kodi Stevens, filed Dec. 23, 2013; exhibit A10 (Aff. of JoAnn Stevens).⁵

II. PROCEDURAL HISTORY

On September 20, 2013, Ms. Stevens filed her petition pro se with exhibits A1-A10. In her petition, Ms. Stevens alleged that one day after the administration of her Hep B vaccine, she experienced “complete numbness in both legs and generalized body aches.” Pet. at 1. Then, Ms. Stevens stated that on September 22, 2010, she experienced “vaginal numbness, shortness of breath, and tingling down her spine upon flexion of her neck.” Id. at 2.

Before the first status conference, Ms. Stevens’ current counsel became her attorney of record. An initial status conference was held on October 28, 2013. At this status conference, the undersigned reviewed Ms. Stevens’ petition and Ms. Stevens confirmed that her MS symptoms began shortly after her April 21, 2003

⁵ The affidavit of Kodi Stevens was filed on December 23, 2013, but was not assigned an exhibit number.

vaccination. Order, issued Oct. 30, 2013. The Secretary suggested that the statute of limitations bars Ms. Stevens' claim. Id. The parties then discussed the limited availability of equitable tolling and Ms. Stevens was directed to review the decision in Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322 (Fed. Cir. 2011) (en banc), cert. denied, 132 S. Ct. 1908 (2012)).

The next status conference was held on November 13, 2013. During this status conference, Ms. Stevens announced that she would file an amended petition to address the onset of her neurologic problems. Order, issued Nov. 14, 2013. Ms. Stevens argued that the onset of her MS was the Lhermitte's sign in 2010. After the parties discussed the significance of Cloer, the undersigned described typical interpretations of the temporal requirement under the third prong of Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).⁶ The Secretary stated that she reserved the right to challenge the reasonable basis for this case.

On December 23, 2013, Ms. Stevens filed her amended petition and a duplicate set of the records filed with her original petition. Ms. Stevens again alleged that she suffered injuries, including MS and seizures, as a result of the hepatitis B vaccine received on April 21, 2003. Am. Pet., filed Dec. 23, 2013. The only change in the amended petition was the last sentence of paragraph number six regarding her September 22, 2010 symptoms of vaginal numbness, shortness of breath, and tingling down her spine (the Lhermitte's sign). Ms. Stevens asserted that these symptoms "constituted the first event objectively recognizable as a sign of a vaccine related injury by the medical profession at large." Am. Pet. at 2. With her amended petition, Ms. Stevens also filed a detailed affidavit supporting her petition. Aff. of Kodi Stevens, filed Dec. 23, 2013.

⁶ See, e.g., Werderitsh v. Sec'y of Health & Human Servs., No. 99-310V, 2006 WL 1672884, at *26 (Fed. Cl. Spec. Mstr. May, 26, 2006) (discussing the appropriate temporal relationship between the hepatitis B vaccine and the onset of MS as within a few days to four weeks).

The first manifestation of a disease is relevant to the statute of limitations and the third prong of Althen. Some petitioners who received a vaccination more than three years before the filing of the petition must confront a dilemma. If onset of the disease occurred relatively close in time to the vaccination (and years before the petitioner was filed), petitioners could prevail on Althen prong three but have the statute of limitations bar the action. On the other hand, if the onset of the disease occurred relatively far from the vaccination (and within the time permitted by the statute of limitations, then the action would be timely but petitioners could not prevail on Althen prong three.

The Secretary filed her Rule 4 report on June 5, 2014. In her report, the Secretary argued that Ms. Steven's case is barred by the statute of limitations, or in the alternative, that Ms. Stevens failed to present a prima facie case under the Vaccine Act. Resp't's Rep., filed June 5, 2014, at 10.

The parties discussed the Secretary's report in a status conference held on June 11, 2014. Ms. Stevens proposed filing a brief on the statute of limitations issue alone, before proceeding to the develop evidence regarding causation. Order, issued June 13, 2014. The Secretary did not object to this request. *Id.* Ms. Stevens asserted that between vaccination in 2003 and diagnosis in 2011, the facts in her affidavit were accurate; these facts included that she experienced heat intolerance, difficulty urinating, eye blurriness, and difficulty breathing. *Id.* The parties agreed that these symptoms were manifestations of MS; therefore, neither party was required to submit the opinion of a doctor addressing the symptoms of MS. *Id.* The Secretary again raised the statute of limitations problem and repeated her concerns about the lack of reasonable basis in this case.

On August 27, 2014, Ms. Stevens filed her response to the Secretary's Rule 4 report. In her response, Ms. Stevens averred that the symptoms of numbness and tingling she experienced before the Lhermitte's sign, taken alone or separately, could easily be attributed to a host of conditions other than MS. Pet'r's Resp., filed Aug. 27, 2014, at 7-8. She argued that the Lhermitte's sign is the first manifestation of onset and not the symptoms experienced in 2003, before the Lhermitte's sign. *Id.* at 8-9.

On September 22, 2014, the Secretary filed her response to Ms. Steven's opposition to the Secretary's Rule 4 report. In her response, the Secretary argued that the earlier symptoms in 2003 were the first manifestation of onset, pointing out that there can only be one first event that triggers the statute of limitations period. Resp't's Resp., filed Sept. 22, 2014, at 3.

On October 17, 2014, Ms. Stevens filed her sur-reply. *See* Pet'r's Sur-Reply, filed Oct. 17, 2014. Ms. Stevens echoed Judge Newman's dissent in Carson v. Secretary of Health and Human Servs., 727 F.3d 1365, 1370 (Fed. Cir. 2013), and argued that the statute of limitations period cannot be triggered before the cause of action that it limits. *Id.* at 2.

III. ANALYSIS

The Vaccine Act limits the time in which a claim may be filed. The Vaccine Act states that

In the case of ... a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of significant aggravation of such injury.

42 U.S.C. §§ 300aa-16(a)(2).

“[T]he statute of limitations begins to run on a specific statutory date: the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large.” Cloer, 654 F.3d at 1340. The cause of action accrues on the date when the first sign or symptom of injury appears, not when a petitioner knew or reasonably should have known about the injury or its cause. Id. at 1338-39. Furthermore, the Federal Circuit refused to add a discovery rule into the Vaccine Act that would begin statute of limitations accrual at the time the petitioners discovered a vaccine caused an injury. Id. at 1339 (“a discovery rule cannot be read into the Vaccine Act statute of limitations”).

Ms. Stevens stated in her amended petition that the signs of MS began shortly after she received her April 21, 2003 vaccine. Am. Pet. at 2. Yet, Ms. Stevens filed her petition on September 30, 2013, over ten years after her first signs of MS. In light of this sequence, the Secretary asserted that Ms. Stevens’ claim is untimely and moved to dismiss the case. Resp’t’s Rep., filed June 4, 2014, at 3-4.

Ms. Stevens raises two arguments in response to the Secretary’s motion to dismiss. First, Ms. Stevens asserts that the Lhermitte’s sign she experienced in 2010 should be the first symptom of the MS, triggering the statute of limitations, because that was determined to be first symptom in Cloer. Pet’r’s Resp., filed Aug. 27, 2014, at 6-7. Second, Ms. Stevens argues that the tingling, numbness, and generalized body aches in 2003, before the Lhermitte’s sign in 2010, should not trigger the statute of limitations because they were not medically recognizable

symptoms of MS and could have been attributed to other disorders or illnesses. Id. at 7-8.

First, in determining when the cause of action accrues, the critical event is the first symptom or manifestation of the disease for which compensation is sought. See Markovich v. Sec'y of Health and Human Servs., 477 F.3d 1353, 1360 (Fed. Cir. 2007) (holding that the "first symptom or manifestation of onset" of a vaccine injury, for the purposes of 42 U.S.C. § 300aa-16(a)(2), "is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large"); see also Cloer, 654 F.3d at 1335 (holding that the "analysis and conclusion in Markovich is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset."). Although a disease may have many signs or symptoms, "[t]here cannot be two first symptoms or onsets of the same injury." Shalala v. Whitecotton, 514 U.S. 268, 274 (1995).

Here, the parties do not dispute that the numbness in both legs and generalized body aches from 2003 are symptoms of MS. Ms. Stevens has admitted on several occasions that her symptoms following her April 21, 2003 vaccination could be characterized as MS symptoms. See aff. of Kodi Stevens, filed Dec. 23, 2013, at 2; exhibit A10 (Aff. of JoAnn Stevens) at 2; order, issued Oct. 30, 2013; Am. Pet. at 2. Ms. Stevens cannot argue that the 2003 symptoms and the 2010 Lhermitte's sign were both the first signs and symptoms of her MS. See Whitecotton, 514 U.S. at 274. The 2003 symptoms triggered the running of the statute of limitations, which concluded in 2006, nearly seven years before Ms. Stevens filed her action.

Second, Ms. Stevens attempts to escape the consequences of the 2003 manifestation by arguing that the medical community did not recognize, in April 21, 2003, that the numbness in both legs and generalized body aches she experienced were manifestations of MS. The medical community did not link the numbness and generalized body aches to MS until Ms. Stevens' MRIs in November 2011. Thus, in Ms. Stevens' view, the statute of limitations does not begin to run until November 2011.

The Federal Circuit rejected the approach Ms. Stevens advocates in three vaccine cases. See Markovich, 477 F.3d 1353; Cloer, 654 F.3d 1322; Carson, 727 F.3d 1365. Before the en banc Cloer decision, a Federal Circuit panel decided Markovich. In Markovich, the petitioners' infant daughter, Ashlyn, received a series of vaccinations, and later that same day, the petitioners first observed

episodes of rapid eye blinking in their daughter. Markovich, 477 F.3d at 1354. At the time, the petitioners thought the eye-blinking episodes were normal. Id. at 1355. About 50 days later, their daughter was taken to the emergency room because of a grand-mal seizure. Id. at 1354-55. Their daughter continued to have grand-mal seizures regularly after this point. Id. After the Markoviches claimed the vaccinations caused her seizure disorder, their expert pointed to the first eye-blinking episode as a symptom of Ashlyn's seizures. Id. at 1359-60.

The special master found the occurrence of the first symptom or onset of the seizure to be the first eye-blinking episode and dismissed the petition pursuant to 42 U.S.C. § 300aa-16(a)(2). Markovich v. Sec'y of Health & Human Servs., No. 03-2015V, 2005 WL 6117470 (Fed. Cl. Spec. Mstr. July 22, 2005), mot. for rev. denied, 69 Fed. Cl. 327 (2005), aff'd, 477 F.3d 1353 (Fed. Cir. 2007).

At the Federal Circuit, the petitioners argued that the eye-blinking observed the same day of the vaccination which “pre-dated the seizure diagnosis cannot be considered a triggering event because it was an everyday event, which they thought meant only that Ashlyn was tired.” Markovich, 477 F.3d at 1356. The Federal Circuit stated that the eye-blinking episode on the day of the vaccination was “objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset.” Id. at 1360. The Federal Circuit thus affirmed. Id. at 1360-61.

In Cloer, Dr. Cloer experienced Lhermitte's sign a month after receiving a hepatitis B vaccination in 1997 and did not recognize it as a manifestation of MS until after her MS diagnosis several years later. Cloer, 654 F.3d at 1328. The special master found that Dr. Cloer's Lhermitte's sign in the month following her vaccination in 1997 was a manifestation of MS, triggering the accrual of the statute of limitations. Cloer v. Sec'y of Health & Human Servs., No. 05-1002V, 2008 WL 2275574, at *1 (Fed. Cl. Spec. Mstr. May 15, 2008), mot. for rev. denied, 85 Fed. Cl. 141 (2008), aff'd, 654 F.3d 1322 (Fed. Cir. 2011) (en banc). On appeal, the en banc Federal Circuit rejected Dr. Cloer's argument that she had no reason to know of the causal link between the hepatitis B vaccine and MS at the time of the Lhermitte's sign and affirmed the retrospective analysis used in Markovich. Id. at 1344-45.

In Carson, the petitioners alleged that their son's autism was a vaccine-related injury. Carson, 727 F.3d at 1366-67. Their son demonstrated severe language delay at his 18-month checkup, 24-month checkup, and three-year checkup. Id. The petitioners argued that speech delay was “too vague and

common of an occurrence” to be recognized as the first objective manifestation of a vaccine-related injury. Carson, 727 F.3d at 1369. The special master relied upon the medical records and testimony of the petitioners’ medical expert to determine that the first event objectively recognizable as a manifestation of autism was the early symptom of speech delay, which was more than 36 months before the filing of the petition. Therefore, the petition was deemed untimely. Carson v. Sec’y of Health & Human Servs., No. 02-0873V, 2009 WL 2957312, at *5 (Fed. Cl. Spec. Mstr. Aug. 26, 2009), mot. for rev. denied, 97 Fed. Cl. 620 (2010), aff’d, 727 F.3d 1365 (Fed. Cir. 2013).

The Federal Circuit held that “it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism.” Carson, 727 F.3d at 1370. The court also found that there was no abuse of discretion and thus affirmed. Id.

In dissent, Judge Newman stated that the majority’s approach effectively starts the statute of limitations “before the fact or even the likelihood of vaccine-related injury is recognizable by medical professionals.” Carson, 727 F.3d at 1370. Here, Ms. Stevens relies on Judge Newman’s dissent that it cannot “have been the legislative intent that the period of limitations starts to accrue during a period of normal behavior or unresolved symptoms of unknown significance.” Id. However, the dissent does not establish controlling precedent. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1356 n.2 (Fed. Cir. 2010) (declining “to discuss a dissent; it is not controlling law”). Rather, on three occasions, the Federal Circuit has not required a doctor to appreciate the significance of a symptom when the symptom first appeared. Under this method, it is easy to find Ms. Stevens’ numbness and generalized body aches she experienced in 2003 were symptoms of MS and they triggered the accrual of the statute of limitations.

IV. CONCLUSION

Ms. Stevens received a hepatitis B vaccine on April 21, 2003, and started having problems the next day. Ms. Stevens filed her petition on September 20, 2013, more than ten years after the initial symptoms that occurred on April 22, 2003. Ms. Stevens did not file within the 36-month time frame permitted by the statute of limitations. 42 U.S.C. § 300aa-16(a)(2). Thus, the Secretary’s motion to dismiss is GRANTED.

IT IS SO ORDERED.

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