

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

No. 05-920V

**(Filed: March 7, 2013)**

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DEVORA JAMES, parent of  
DANIEL R. JAMES, a minor,

Petitioner,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

\* \* \* \* \*

Devora James, Boston, MA, pro se petitioner.

Linda Renzi, Washington, D.C., for respondent.

**DECISION**<sup>1</sup>

On August 15, 2005, petitioner filed a Short-Form Autism Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program (“the Program”),<sup>2</sup>

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<sup>1</sup> Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

<sup>2</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (“Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

alleging that her son, Daniel, was injured by his receipt of a vaccine or vaccines listed on the Vaccine Injury Table. See § 14. Using the special “Short-Form” petition developed for the Omnibus Autism Proceeding (“OAP”), petitioner alleges that various vaccinations caused Daniel to develop an autism spectrum disorder.

## **I. PROCEDURAL HISTORY**

On November 15, 2012, after reviewing the medical records filed by petitioner (“Pet’r’s Med. Rec.”), respondent moved to dismiss this claim based on the Vaccine Act’s statute of limitations, 42 U.S.C. § 300aa-16(a)(2), which defines the period of time within which a vaccine claim must be filed. Along with the motion to dismiss, respondent filed several medical articles and the testimony of several experts from the OAP describing the types of symptoms that first present in individuals with autism spectrum disorders (“ASD”).<sup>3</sup> Petitioner filed her response to respondent’s motion to dismiss on December 17, 2012.<sup>4</sup>

The parties in this case disagree as to the date of Daniel’s first symptom of injury. Respondent points to Daniel’s loss of language, which is documented in the medical records as occurring around two years of age. Pet’r’s Med. Rec. at 36. During a digitally-recorded status conference held on November 7, 2012, petitioner confirmed that Daniel’s loss of language first appeared during that time, but insisted that at the time, his language loss was not linked to his ASD, which was diagnosed several years later. Daniel turned two years old on December 19, 2001. Because Daniel’s vaccine claim was not filed until August 15, 2005, respondent contends that it was filed outside the 36 months set forth in the statute of limitations.

In response to the motion to dismiss, petitioner reiterates the arguments she made during the November 7, 2012 status conference. Petitioner contends Daniel did not display any adverse symptoms, other than loss of speech, until he was about 4 ½ years old or around June 19, 2004. Petitioner argues that speech delay by itself is not enough to demonstrate the emergence of an ASD and as such, other symptoms—more particular to an ASD—had to occur before Daniel could be considered to have that injury. To support her reasoning, petitioner states that Daniel’s treating pediatrician, Dr. Newberg,

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<sup>3</sup> These exhibits are the only medical literature submitted by either party.

<sup>4</sup> Petitioner did not number the pages of her response. Attached to her response were five pages of the previously filed medical records for Daniel. For consistency, petitioner’s response, which was comprised of only four pages, shall be cited to as Pet’r’s Resp. at \_\_\_\_\_. The medical records petitioner attached to her response shall be cited using their original page numbers.

had advised her that loss of speech was “normal and does occur sometimes.”<sup>5</sup> Pet’r’s Resp. at 2.

In her response, petitioner offers two new arguments that were not urged during the earlier status conference. The first is that Daniel’s loss of speech may be indicative of Childhood Disintegrative Disorder (“CDD”) rather than ASD. Pet’r’s Resp. at 2-3. The second argument is that Daniel’s laboratory test results indicate that Daniel’s vaccinations had an adverse effect on him, by affecting his amino acids. Id. at 3

Review of the filed medical records confirms that there is a timing issue with petitioner’s claim. For the reasons discussed more fully below, the undersigned must now dismiss this case.

## II. DISCUSSION

### A. Applicable Legal Standard

A claim for compensation under the Vaccine Program cannot be considered if not timely filed. The Vaccine Act provides that “no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . .” 42 U.S.C. § 300aa–16(a)(2).

The Federal Circuit has held that the first symptom or manifestation of onset of a vaccine-related injury is “the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.” Markovich v. Sec’y of Health & Human Servs., 477 F.3d 1353, 1360 (Fed. Cir. 2007); see also Cloer v. Sec’y of Health & Human Servs., 603 F.3d 1341, 1345 (Fed. Cir. 2010), vacated, 399 F. App’x 577 (Fed. Cir. 2010) (en banc), aff’d on reh’g, 654 F.3d 1322 (Fed. Cir. 2011) (en banc), cert. denied, 132 S. Ct. 1908 (2012). The Vaccine Act does not contain a discovery rule, either expressed or implied. Cloer, 654 F.3d at 1337. Instead, the “first symptom or manifestation of onset” is a “statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition.” Id. at 1339; see also Markovich, 477 F.3d at 1357. In other words, the onset of Daniel’s injury is not determined by what petitioner knew or did not know.

For the purposes of the Vaccine Act, the “first symptom or manifestation of onset” is the first event objectively recognizable as a sign of a vaccine injury by the

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<sup>5</sup> Petitioner does not provide a citation to the medical records to support her claim that Daniel’s physician assured her that nothing was amiss with Daniel until he reached 4 ½ years of age. The undersigned notes, however, that the records from Daniel’s routine checkups are silent regarding the existence of any abnormalities or developmental problems during this time period. Pet’r’s Med. Rec. at 7-19

medical profession in general.” Markovich, 477 F.3d at 1360 (emphasis added). See also Cloer, 654 F.3d at 1334-35 (stating that “the analysis and conclusion in Markovich is correct.”).

## **B. The Petition Was Untimely Filed**

Petitioner’s argument that she did not notice any other symptoms besides speech regression until Daniel was 4 ½ year old is unavailing. What a particular physician believed or knew at the time does not control; rather, the undersigned must consider what the medical community in general knew or understood about particular symptoms.

Here, the relevant legal question is whether Daniel was displaying symptoms understood by the medical profession at large—even if not by a particular doctor—to constitute the earliest evidence of a vaccine-related injury. Petitioner’s assertion that Daniel’s treating physician believed he was “normal” until he reached 4 ½ years of age is not enough.

Delay in speech is a well-known symptom of ASD. See Exhibit B at 1; Exhibit C at 4<sup>6</sup>; Exhibit D at 1276-78, 1284-85; Exhibit E at 1590 (OAP testimony from Dr. Witnitzer, acknowledging that an ASD does not always manifest as a delay in language skills, and explaining that what is important is a change in the normal development of a child’s language progression); Exhibit F at 3251 (Dr. Michael Llewelyn Rutter testifying during the OAP that although children with autism do not always present with a speech delay, many do, and most problematically, they fail to use language in a communicative way).

It is not uncommon for children with ASDs to experience a regression of some type. See Exhibit C at 4 (observing that “any child with an ASD can show regression, in which existing skills, particularly spoken language and social-emotional reciprocity, are diminished or lost altogether.”). Regression occurs in approximately “10-50% of children with autism, at a mean age of 19 months.” Id.

Daniel’s records indicate that on May 9, 2005, he received a diagnosis of autism from Gary McAbee, D.O., F.A.A.P., a pediatric neurologist, at Cooper Children’s Regional Hospital. Pet’r’s Med. Rec. at 39. Dr. McAbee observed that Daniel was displaying poor neurobehavioral symptoms; in particular, he was non-verbal, had poor socialization skills, had no eye contact, and tended to throw tantrums in new places. Id. Dr. McAbee wrote that “[t]he best diagnosis for Daniel’s neurobehavioral symptoms is autism.” Id.

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<sup>6</sup> Respondent mistakenly numbered the pages in exhibit C as Resp. Ex. B-\_\_\_.

While a lack of speech by itself is not indicative of an ASD, it is frequently the first symptom of an ASD. In this case, Daniel received a diagnosis of autism several years after he began to lose his words. Dr. McAbee, who evaluated Daniel's neurobehavioral symptoms, expressly considered Daniel's lack of speech when he diagnosed Daniel with autism. This particular symptom was observed as early as two years of age, and the medical records indicate that Daniel was still non-verbal on November 21, 2005, at five years and eleven months of age. *Id.* at 36. Evidence of Daniel's loss of speech coupled with the broad recognition by the medical community that speech regression is frequently an early symptom of ASD persuades the undersigned that the first symptom of Daniel's ASD appeared at two years of age when he became non-verbal. None of petitioner's passionate arguments to the contrary can compel a different finding.

Petitioner seems to argue in the alternative that Daniel's speech delay was not due to his autism but instead was caused by CDD. Pet'r's Resp. at 2. This diagnostic distinction does not change the undersigned's determination in this case. CDD is on the spectrum of autistic disorders, and loss of speech is a common presenting symptom of CDD also. See Hazlehurst v. Sec'y of Health & Human Servs., 2009 WL 332306, at \*22, *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); see also Exhibit D at 1276-77; Exhibit E at 1589; Exhibit F at 3255-56.

Petitioner further claims that Daniel's amino acid test results from November 21, 2005, point to the vaccines he received as the cause of his ASD. Pet'r's Resp. at 3. But this argument is not pertinent to the timeliness issue now before the undersigned. The alleged cause of Daniel's injury cannot and need not be considered if the petition was not filed within the time limit prescribed by the statute. Nothing in these lab results speak to the issue of timely filing.<sup>7</sup> Pet'r's Med. Rec. at 41-42.

Petitioner filed her petition on August 15, 2005, more than 43 months after Daniel's first showed symptom of his ASD. Thus, the petition is time-barred by the Vaccine Act's statute of limitations.

### **C. The Doctrine of Equitable Tolling Is Unavailable in this Case**

In her motion to dismiss, respondent acknowledges that equitable tolling is available for claims arising under § 16(a)(2) of the Vaccine Act. Motion to Dismiss at 3 (citing Cloer, 654 F.3d at 1344). But the Court of Appeals for the Federal Circuit has made clear in Cloer that, although available, equitable tolling should be used sparingly.

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<sup>7</sup> Moreover, the amino acid test results provide dubious support for petitioner's vaccine claim. A note in Daniel's records dated November 28, 2005, indicated that the discrepancies found in Daniel's plasma amino acids were most likely due to his dietary intake. Pet'r's Med. Rec. at 38.

654 F.3d at 1345 (citing Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96 (1990)). The Circuit counseled that the doctrine is to be applied only in cases involving deception or in cases where the petition was timely filed but was procedurally defective. Id. To successfully invoke the doctrine of equitable tolling, a petitioner must put forward evidence that she was prevented from diligently pursuing her rights by fraud, duress, or some other extraordinary circumstance. Id. at 1344.

Petitioner does not assert an equitable tolling claim, and there is no evidence in the record of deception, fraud or duress, or any extraordinary circumstance that would support the application of equitable tolling on these facts.

Because none of the grounds mentioned in Cloer are present in this case, equitable tolling is not available to petitioner.

### **III. CONCLUSION**

Although the diagnosis of autism has become pervasive among children over the past ten years, there is yet no evidence on the theories of causation presented to the Office of Special Masters that vaccines play a causal role in the development of the condition. Before the issue of causation can be reached in a case, however, the timeliness of the vaccine claim must be evaluated. The Vaccine Act prohibits the filing of a petition more than 36 months after the appearance of the first sign or symptom of the vaccine-related injury, see 42 U.S.C. § 300aa-16(a)(2), and this petition was filed outside of the permitted time limit.

Mrs. James's careful and devoted attention to her three autistic children is apparent from her remarks during the status conference held on November 7, 2012, and as related in her response to the motion to dismiss. Her frustration with the limitations of the Vaccine Program is also apparent. However, the Vaccine Act places the burden on petitioner to show that a claim was filed timely. Because Mrs. James cannot make this legal showing, her claim must be dismissed for untimeliness. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

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Patricia E. Campbell-Smith  
Chief Special Master