In the United States Court of Federal Claims

No. 02-791V

(Filed June 13, 2003)

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JOHN and ELIZABETH SETNES,	*	
as parents and natural guardians,	*	
on behalf of their minor son	*	
AUSTIN J. SETNES,	*	
	*	National Childhood Vaccine
Petitioners,	*	Injury Act; Autism Spectrum
	*	Disorder; Standard of review;
V.	*	Statute of Limitations, 42 U.S.C.
	*	§ 300aa-16(a)(2).
THE UNITED STATES,	*	
	*	
Respondent.	*	
-	*	
* * * * * * * * * * * * * * * * * * * *	*	

Sheila Ann Bjorklund, Minneapolis, Minnesota, attorney of record for petitioners.

Vincent James Matanoski, Department of Justice, Washington, D.C., with whom was Assistant Attorney General Robert D. McCallum, Jr., for respondent. Helene M. Goldberg, Director, John Lodge Euler, Deputy Director, and Mark W. Rogers, Assistant Director.

OPINION

Futey, Judge.

This vaccine case is before the court on petitioners' motion for review of the special master's dismissal of the Petition For An Award For Compensation as untimely. Austin J. Setnes (AJ), on whose behalf petitioners, John and Elizabeth Setnes, as parents and natural guardians, brought this action, seeks compensation for alleged vaccine related injuries pursuant to the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§ 300aa-1 to -34 (2000). The special master determined that the symptoms of autism spectrum disorder (autism) began to appear by December 11, 1998, and, therefore, the petition filed on July 15, 2002, was not

within the statute of limitations. Petitioners maintain that the special master's determination that symptoms of autism were apparent by December 11, 1998, was arbitrary and capricious because it preceded medical verification by seven months. Petitioners also contend that the issue of equitable tolling, as applied to autism cases, should be re-examined. Respondent asserts that the special master's decision to place the onset of autism prior to December 11, 1998, was supported by the record. Relying on *Brice v. Sec'y of DHHS*, 240 F.3d 1367 (Fed. Cir. 2001), *cert. denied sub nom.*, 70 U.S.L.W. 3360 (U.S. Nov. 26, 2001) (No. 01-341), respondent also avers that the doctrine of equitable tolling is not available in Vaccine Act cases.

Factual Background

AJ was born on June 10, 1997. The pregnancy was relatively uncomplicated and the birth itself was uneventful. For the beginning period of his childhood, AJ's developmental progress was that like any other child his age. AJ's "normal" development was confirmed by his pediatrician and his actions reflected typical childhood behavior.

Petitioners adhered to the vaccination schedule suggested by their pediatrician and AJ, therefore, received all the recommended vaccinations.³ On September 11, 1998, AJ received his fifteen-month vaccinations, which included MMR, DTaP-Hib, Varicella and OPV immunizations.⁴ Following these immunizations, petitioners "began to notice significant changes" in AJ's behavior.⁵

The sequence of events and chronology of changes is most vividly depicted in the affidavit submitted by petitioners as an attachment to their Petition For An Award For Compensation. The affidavit, in pertinent part, reads as follows:

7. After the September 11, 1998 immunizations, [Mrs. Setnes] noted that AJ started making a constant humming noise. He was doing a lot of babbling. Because he was slow to develop words and would no longer respond when we called his name, we were worried that he had a hearing problem. His pediatrician had his hearing checked and it

Elizabeth Setnes Affidavit (Setnes Aff.) ¶ 3.

² *Id.* ¶¶ 3, 6.

³ *Id.* $\P 5$.

⁴ *Id.*

⁵ *Id.*; see also Petition For An Award For Compensation at 2.

was normal. His first words came in December 1998 and were "mama" and "baba."

- 8. Sometime after September 1998, AJ started to have temper tantrums. He would kick and scream and was at times unconsolable. About this time, we noticed that he would run around the kitchen table and would stare at the edge of the table or counter. We also began to notice that he would eat the cardboard boxes that held videotapes.
- 9. By the time AJ was two years old, we noticed that he was no longer the happy, smiling little boy who liked to play with his brother and interact with his parents. He did not follow directions. We could no longer take him places away from home because he would either run away, or would kick and scream and become totally unconsolable. He was no longer playing with his brother but hitting and kicking him. He stopped making eye contact with us. His speech had not continued to develop. He had developed a "vacant" stare, like he was no longer in the same place with the rest of us. His behavior deteriorated and his development became more and more behind. We expressed our concerns to our pediatrician.⁶

On July 16, 1999, AJ's pediatrician noted AJ's lack of speech as well as his developmental delays.⁷ The pediatrician expressed concern that AJ's impediments may be the result of pervasive developmental disorder (PDD).⁸ Specifically, the pediatrician characterized AJ's lack of eye contact as an "abnormal physical finding." The pediatrician also indicated that AJ was experiencing "speech delay" and that AJ exuded "poor social skills." Following a January 7, 2000 evaluation,

⁶ Setnes Aff. ¶¶ 7-9 (internal citations omitted).

Petitioners' Exhibit (Petitioners' Ex.) 6, at 158.

Id.

⁹ *Id.*

¹⁰ *Id.*

doctors for the first time used the terms "probable PDD/autism." AJ was diagnosed with autism on March 3, 2000. 12

On July 15, 2002, petitioners filed a petition for compensation under the Vaccine Act. Subsequently, on August 5, 2002, special master Hastings granted petitioners' request to have the proceedings stayed pursuant to the Omnibus Autism Proceeding. *Setnes v. Sec'y of DHHS*, No. 02-791 (Fed.Cl.Spec.Mastr. Aug. 5, 2002). Respondent filed a motion to dismiss for lack of subject matter jurisdiction on October 15, 2002. Relying on Mrs. Setnes' affidavit, respondent asserted that the onset of symptoms occurred between September 1998 and June 1999. Respondent, therefore, concluded that the petition was filed one month outside the statute of limitations. Petitioners responded on November 4, 2002, and contended that the petition was timely because it was filed within 36 months of the pediatrician's July 16, 1999, notation regarding PDD. In the alternative, petitioners maintained that the doctrine of equitable tolling was available to preserve their claim. The case was transferred to special master Millman on November 14, 2002.

Special master Millman dismissed petitioners' claim on January 31, 2003, for lack of subject matter jurisdiction. *Setnes v. Sec'y of DHHS*, No. 02-791, 2003 WL 431591 (Fed.Cl.Spec.Mastr. Jan. 31, 2003). The special master relied on the conclusions reached by petitioners' expert, Dr. Donald H. Marks, M.D., Ph.D., that AJ's symptoms of autism began to appear by December 11, 1998. The special master, therefore, held that the petition was filed "seven months too late." *Id.* at *1. The special master also held that the United States Court of Appeals for the Federal Circuit's (Federal Circuit) decision in *Brice* precluded the application of equitable tolling to petitioners' claim.

On February 27, 2003, petitioners filed this motion for review. Having been filed within 30 days of the special master's decision, petitioners' motion is timely. **Vaccine Rule** 23.¹³ Further, respondent's response is timely as it was filed within 30 days of petitioners' motion for review. **Vaccine Rule** 25(a). All pertinent documents have been submitted.

Discussion

¹¹ *Id.* at 160.

Petitioners' Ex. 7, at 201 ("Austin's history and examination are most compatible with the diagnosis of autistic spectrum disorder.").

The Vaccine Rules are located in Appendix B of the Rules of the United States Court of Federal Claims.

When deciding a motion for review, the court proceeds in accordance with the rules set forth in the Vaccine Act. The Vaccine Act provides, in pertinent part:

- (2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter -
- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

Prior to delving into the crux of petitioners' argument, the court first addresses the relief that is available and the parameters in which the analysis must be conducted. Petitioners contend that the special master erred in "ostensibly find[ing] no basis upon which . . . [to] impose equitable tolling in this matter." ¹⁴ In this assertion, however, petitioners are mistaken. The Federal Circuit, in *Brice*, held that equitable tolling is not available for claims arising under § 16(a)(2) of the Vaccine Act, which concerns vaccines administered after the Vaccine Act's effective date. Brice, 240 F.3d at 1370-75. The special master was, and the court is, bound by the Federal Circuit's decision. Petitioners would have the court disregard the majority opinion in *Brice* and apply the principles set forth in the dissenting opinion. Although Judge Newman's dissent in Brice raises legitimate concerns, it is the majority opinion and not the dissenting opinion that the special master and the court must apply. In addition, the court will not interject a distinction between Table cases and causation-in-fact cases into the Brice decision where the only distinction the Federal Circuit referenced was between cases arising before and after the effective date of the Vaccine Act. 15 The special master, therefore, correctly denied petitioners' request for equitable tolling.

Petitioners' Motion For Review Of The OSM's Order Of Dismissal (Petitioners' Mot.) at 4.

In this regard, in *Weddel v. Sec'y of DHHS*, 100 F.3d 929 (Fed. Cir. 1996), the Federal Circuit reached the same conclusion as in *Brice* when presented with the issue of whether equitable tolling should apply for claims concerning vaccines administered prior to the effective date of the Vaccine Act.

Petitioners also urge the court to postpone resolution of this case because the United States Congress is currently scrutinizing the statute of limitations for claims under the Vaccine Act and a strong possibility exists that the statute of limitations may be extended to six years. A similar statute of limitations extension argument was raised in *Brice* in 2001. Approximately two years later, the Federal Circuit's rejection of this argument still rings true:

We are told by parties that Congress may be asked to consider an extension of the statute of limitations for post-Act cases because parents of injured children are often not aware of the remedies available under the Act. It is not our role to opine on whether such legislation is desirable or undesirable. That is a proper decision for Congress to make. We determine only that equitable tolling [is] inconsistent with the existing statutory scheme.

Brice, 240 F.3d at 1374. The court's role is, therefore, limited to deciding whether petitioners' claim falls within the "existing statutory scheme," regardless of any statutory changes that may be forthcoming.¹⁶

The court now turns to the special master's finding that the she lacked subject matter jurisdiction over petitioners' claim because it was filed outside the 36-month statute of limitations. Application of the statute of limitations is a question of law, which the court reviews *de novo*. *Goetz v. United States*, 45 Fed. Cl. 340, 341 (1999), *aff'd*, 2001 WL 65708 (Fed. Cir. 2001) (unpublished opinion); see also *Childs v. Sec'y of DHHS*, 33 Fed. Cl. 556, 558 (1995) (citing *Munn v. Sec'y of DHHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) (explaining that legal questions are reviewed under the "not in accordance with law" standard)). The court proceeds with a full understanding that a ""statute of limitations is a condition on the waiver of sovereign immunity by the United States,' and courts should be 'careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended." *Brice*, 240 F.3d at 1370 (quoting *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed. Cir. 2000)). Section 16(a)(2) of the Vaccine Act reads as follows:

Petitioners also assert that no action should be taken in this case because their petition was stayed as a result of special master Hastings granting their request to be considered a part of the Omnibus Autism Proceeding. When presented with a jurisdictional challenge, however, the court "is bound to dismiss [the case] as soon as it is aware of the deficiency." *Dico, Inc. v. United States*, 33 Fed. Cl. 1, 4 (1993); see also *Johns-Manville Corp. v. United States*, 893 F.2d 324, 326 (Fed. Cir. 1989) (quoting *The Mayor v. Cooper*, 73 U.S. (6 Wall.) 247 (1867) ("If there were no jurisdiction, there was no power to do anything but to strike the case from the docket.")).

[I] fa vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation . . . 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 the significant aggravation of such injury

42 U.S.C. § 300aa-16(a)(2). Petitioners assert that the 36-month statute of limitations period should run from July 16, 1999, "when [AJ's] pediatrician, for the first time, found [AJ] was not meeting *medically appropriate* development guidelines." Specifically, petitioners maintain that "because of the unique nature of autism spectrum disorder, there can be no 'manifestation of onset' until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet the criteria for autism spectrum disorder." Respondent contends that the plain language of the statute indicates that the statute of limitations can only begin to run upon "the occurrence of the first symptom" of the injury.

In pertinent part, the Vaccine Act provides that the statute of limitation runs upon the "[1] occurrence of the first symptom or [2] manifestation of onset" of the injury. 42 U.S.C. § 300aa-16(a)(2). Either event triggers the running of the statute of limitations and the court addresses their application to the facts of this case in turn. First, the court may apply the "occurrence of the first symptom" standard. As distinguished from other medical conditions, however, the beginning stage of autism cannot be reduced to a single, identifiable symptom.¹⁹ Many of the initial "symptoms" are subtle and can easily be confused with typical child behavior.²⁰ Where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the "occurrence of the first symptom."

Respondent, however, would make no distinction between the "occurrence of first symptom" and the "manifestation of onset," because according to respondent, the terms "symptom" and "onset" are synonymous. In this regard, respondent argues that the United States Supreme Court (Supreme Court) "implicitly reject[ed] the argument that onset is determined by a constellation of symptoms" in **Shalala v.**

Petitioners' Mot. at 2 (emphasis in original).

¹⁸ *Id.*

Dr. Eric V. Larsson Affidavit (Larsson Aff.) ¶ 3.

²⁰ *Id.*

Whitecotton, 514 U.S. 268, 274 (1995).²¹ Respondent misinterprets the Supreme Court's opinion. The Supreme Court held that "[i]f a symptom or manifestation . . . has occurred before a claimant's vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury's onset. There cannot be two first symptoms or onsets of the same injury." *Whitecotton*, 514 U.S. at 274. The Supreme Court's holding stands for the proposition that a "first symptom" or "manifestation of onset" cannot occur twice. The statement contains no connotation to the affect that an onset cannot constitute more than one symptom.

Respondent's argument also runs contrary to basic principles of statutory construction. A statute is to be construed in a manner that gives meaning and effect to all its terms. *Williams v. Taylor*, 529 U.S. 362, 404 (2000); *W&F Bldg. Maint. Co. v. United States*, 2003 WL 1848652 (Fed. Cl. 2003) (citing *McAbee Constr., Inc. v. United States*, 97 F.3d 1431, 1435 (Fed. Cir. 1996)). Under respondent's interpretation, there would be no discernable difference between "first symptom" and "manifestation of onset." The statute, as respondent asks the court to read it, would require that the petition be filed within 36 months of the "occurrence of the first symptom or manifestation of [the first symptom]." Such a construction renders "manifestation of onset" meaningless and leads to a nonsensical result. *Arizona v. United States*, 216 Ct. Cl. 221, 235 (1978). Accordingly, respondent's argument that "onset" cannot be determined by more than one symptom is rejected.

Having set aside respondent's argument, the court examines the special master's determination that petitioners' petition was untimely because it was filed "seven months too late." *Setnes*, 2003 WL 431591, at *1. Petitioners assert that the special master's finding that the onset of autism was evident by December 11, 1998, was arbitrary and capricious. Petitioners submitted the affidavit of Dr. Eric V. Larsson, Ph.D., who attested to the difficulty of ascertaining the subtle symptoms of autism and that "the characteristics [of autism]... are usually not apparent until *after* the child is two years of age." Petitioners also maintain that AJ's doctors did not associate AJ's behavior with possible autism until July 16, 1999. Respondent, however, contends that petitioners' own expert, Dr. Marks, stated that the symptoms of autism began to appear within the three-month period following AJ's September 11, 1998, vaccinations.

The court again turns to the plain language of the Vaccine Act. "Manifest" is defined as "evident to the senses . . . obvious to the understanding, evident to the mind, not obscure or hidden, and is synonymous with open, clear, visible,

Respondent's Response To Petitioners' Motion For Review Of Special Master's Order Of Dismissal at 8.

Petitioners' Mot. at 3 (citing Larsson Aff. ¶ 3) (emphasis in original).

unmistakable, indubitable, indisputable, evident, and self-evident."²³ The court must, therefore, ascertain when the onset of autism was evident and, in turn, whether petitioners' petition for compensation was timely.

According to Dr. Marks, on whose opinion the special master relied, the symptoms of autism appeared by December 11, 1998. Setnes, 2003 WL 431591, at *1. Dr. Marks' opinion, however, was rendered over two years after AJ's official diagnosis, was the product of a retroactive evaluation and enjoyed the benefit of hindsight. In other words, Dr. Marks had the fully assembled puzzle in front of him, and when taking the puzzle apart, opined that the pieces he was taking apart must have come from the puzzle. Dr. Marks' retroactive diagnosis is plainly inconsistent with AJ's contemporaneous medical evaluations. On July 16, 1999, AJ's pediatrician expressed a "concern about PDD."²⁴ It was not until January 7, 2000, that the terms "probable PDD/autism" were used.²⁵ The fact that AJ's treating physicians did not connect his behavior to autism is indicative of the fact that AJ's behavior was not "recognizable as a sign of a vaccine injury by the medical profession at large" Goetz, 45 Fed. Cl. at 342. To uphold the special master's decision would be an endorsement of the proposition that the "manifestation of onset" in autism cases occurs when a mother observes her child "humming," "babbling," "kicking and screaming" or "eating [videotape] cardboard boxes." The court is not persuaded that this type of behavior clearly or obviously signals the onset of autism. Based on the contemporaneous medical evaluations and notations, AJ's onset of autism became evident between July 16, 1999, and January 7, 2000. The special mater's determination that the onset of autism appeared by December 11, 1998, was therefore, not in accordance with law. Accordingly, petitioners' petition for compensation, filed on July 15, 2002, was timely.

The court is not holding that a medical or psychological diagnosis or verification of the "occurrence of the first symptom or manifestation of onset" begins the running of the statute of limitations. See *Goetz*, 45 Fed. Cl. at 342 (explaining that "[t]he fact on which a Vaccine Injury Table claim is based is the occurrence of an event recognizable as a sign of a vaccine injury by the medical profession at large,

BLACK'S LAW DICTIONARY 867 (5th ed. 1979); see also WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (UNABRIDGED) 1375 (1993) (defining the term as "to show plainly: make palpably evident or certain by showing or displaying.").

Petitioners' Ex. 6, at 158.

²⁵ *Id.* at 160.

²⁶ Setnes Aff. ¶¶ 7-8.

not the diagnosis that actually confirms such an injury in a specific case."). Rather, in a situation such as that before the court, where the symptoms of autism develop "insidiously over time"²⁷ and the child's behavior cannot readily be connected to an injury or disorder, the court may rely on the child's medical or psychological evaluations for guidance in ascertaining when the "manifestation of onset" occurred. At some point between AJ's doctors noting a "concern for PDD" and "probable PDD/autism," the beginning stages of autism became evident. The court reaches this conclusion by relying on the contemporaneous medical reports and not through a post-dated expert evaluation or a lay person's description of her child's behavior.

The court is aware that the Federal Circuit has held that "the statute of limitations . . . begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury." *Brice*, 240 F.3d at 1373; see also *Goetz*, 45 Fed. Cl. at 341-42; Childs, 33 Fed. Cl. at 557 n.2. In each of these cases, however, the symptoms or the injury was clearly apparent. In *Childs*, the child suffered a febrile seizure which this court described as follows: "[The child] became stiff, her eyes deviated to the left, and her left arm shook for a few minutes." Childs, 33 Fed. Cl. at 557. In *Brice*, the child suffered a seizure. *Brice*, 240 F.3d at 1369. In *Goetz*, this court explained that "[petitioners'] detailed description of [the child's] immediate post-vaccination distress leaves no doubt that petitioners were aware that their child had suffered an 'injury' following one or more of the vaccinations" and that "the symptoms that triggered the running of the statute were obvious when they occurred and were never hidden " Goetz, 45 Fed. Cl. at 341, 343. It is one thing to be unaware that an obvious injury or its onset was caused by a vaccination. It is quite another to lack knowledge, through no assignable fault, of the existence of the onset. This is especially true where the treating physician does not associate the behavior as an onset of an injury.

Conclusion

For the above-stated reasons, the court holds that petitioners' Petition For An Award For Compensation was timely. Petitioners' motion for review is hereby GRANTED. The special master's decision is REVERSED and the case is REMANDED for further proceedings consistent with this opinion.

BOHDAN A. FUTEY
Judge

Larsson Aff. ¶ 3.