

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-497V

May 8, 2008

HOWARD McLAUGHLIN and DOMINIANA *
McLAUGHLIN, parents of AARON AGRIPINO *
G. McLAUGHLIN, *

Petitioners, *

v. *

Autism; statute of limitations;
significant aggravation

SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *

Respondent. *

ORDER¹

On June 27, 2007, petitioners filed a petition pro se under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq. (hereinafter, the Vaccine Act), alleging that

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order 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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

various vaccinations caused autism in their son Aaron Agripino G. McLaughlin (hereinafter, “Aaron”). The vaccinations were administered from 1992 through 1998 with the last one administered January 27, 1998.

On January 29, 2008, respondent filed a Motion to Dismiss the petition on the ground that Aaron’s onset of autism was more than 36 months before petitioners filed their petition. The Vaccine Act requires petitioners to file their petitions within 36 months of the first symptom or manifestation of onset of the alleged injury. See §300aa-16(a)(2) of the Vaccine Act. That means that if the first symptom or manifestation of onset of Aaron’s autism occurred before June 26, 2004, petitioners’ petition would be time-barred for their failure to file the petition within 36 months of the onset of Aaron’s autism. Autism begins at its first symptom or manifestation of onset, not when the autism is diagnosed. See Markovich v. Secretary of HHS, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

Respondent notes in the Motion to Dismiss that Aaron was seen on October 1, 1996, eleven years before petitioners filed their petition, for concern about his communication skills. Med. recs. at Ex. 6, p. 6. R Motion at 3. Dr. B. Leong, Aaron’s pediatrician, notes not only no spontaneous use of word phrases but also behavioral problems. Ex. 6, pp. 6, 7. Dr. Leong assessed that Aaron might have pervasive developmental delay (PDD) with attention deficit hyperactivity disorder (ADHD) as well as developmental delay. He recommended occupational therapy (OT). Ex. 6, p. 8. Speech delay is a symptom of autism.

Aaron’s last vaccination was for hepatitis B which was administered on January 27, 1998. Med. recs. at Ex. 5, p. 6.

On March 5, 2008, petitioners filed a Motion for the Federal Claims Court to Deny Health and Human Services Motion to Dismiss, stating that they also were alleging that hepatitis B vaccine significantly aggravated Aaron's pre-existing autism spectrum disorder. P Motion at 8. Petitioners state this significant aggravation manifested in December 2004 when Aaron completely lost the ability to form a single word. *Id.* If the onset of Aaron's significant aggravation was December 2004, their petition would fall within the 36-month statute of limitations.

On April 3, 2008, respondent filed a Reply to Petitioners' "Motion for the Federal Claims Court to Deny Health and Human Services Motion to Dismiss" and Renewed Motion to Dismiss. Respondent notes that there is an almost seven-year gap between the hepatitis B vaccination Aaron received on January 27, 1998 and the onset of his alleged significant aggravation in December 2004. Respondent notes several record references to Aaron's stopping speaking as early as November or December 2002. Med. recs. at Ex. 6, pp. 28, 35. R Reply at 6 and n.5.

On April 25, 2008, petitioners filed a Reply to Respondent's Renewed Motion to Dismiss and Motion to Deny Respondent's Renewed Motion to Dismiss, reiterating that when Aaron completely lost the ability to form a single word in December 2004, this was the time that significant aggravation manifested itself, resulting in a markedly greater disability. P Reply at 4.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence "(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. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

Petitioners discuss Setnes v. Secretary of HHS, 57 Fed. Cl. 175 (2003) in their filings as if its holding supports their view. Petitioners should be aware that the Federal Circuit in the Markovich decision, cited above, discussed Setnes and disagreed with its holding. Since the Setnes decision was not directly before the Federal Circuit in the Markovich case, the Federal Circuit could not reverse the Setnes holding. But the Federal Circuit leaves the U.S. Court of Federal Claims (from which Setnes arose) in no doubt that Setnes was wrongly decided.

In Setnes, a judge on the U.S. Court of Federal Claims opined that the beginning of the running of the statute of limitations (occurring when the first symptom or manifestation of onset of the illness happened) should not apply in autism cases because it takes so long to get a diagnosis of autism and parents should not be expected to file within 36 months of the onset of autism until they get a diagnosis of autism.

However, the Federal Circuit in Markovich stated that the beginning of the running of the statute of limitations occurs when the medical community could objectively recognize the first symptom or manifestation of onset as indicative of a particular condition or illness, not when the parents finally learn what their child has. The Federal Circuit stated:

A significant problem with the rationale of Setnes is that it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence showing a

symptom *and* a manifestation of the injury. However, the Vaccine Act states that the statute of limitations is triggered by the “*first* symptom *or* manifestation of onset.” 42 U.S.C. § 300aa-16(a)(2) (emphasis added). The use of the words “first” and “or” require that the statute of limitations commence with whichever event (*i.e.*, symptom or manifestation of onset) occurs first. The statute does not require that both events occur before the running of the limitations period can occur.

The *Setnes* construction also suggests that a subtle symptom or manifestation of onset of the injury, such as a symptom that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger the running of the statute. Yet the Vaccine Act has consistently been interpreted as including subtle symptoms or manifestations of onset of the injury within the ambit of evidence that triggers the running of the statute. . . . By commencing the running of the limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to identify, with reasonable certainty, the nature of the injury.

477 F.3d at 1358.

Petitioners, herein, recognize that the onset of Aaron’s autism began before June 26, 2004 (which is 36 months before they filed their petition) and that their petition must be dismissed for their failure to file within 36 months of the onset of his autism. However, petitioners assert an alternative claim: that Aaron’s last vaccination on January 27, 1998 significantly aggravated his pre-existing autism spectrum disorder whose first symptom or manifestation of onset was in December 2004 when he stopped speaking (although medical records state he stopped speaking in November or December 2002). If the first symptom or manifestation of onset of Aaron’s significant aggravation occurred in December 2004, petitioners’ filing of their petition on June 27, 2007 would be timely.

Assuming that Aaron’s first symptom or manifestation of onset of significant aggravation ever occurred, and that the course of his symptoms does not in fact merely reflect the course of

autism spectrum disorder, petitioners have the burden of proving their sole remaining allegation that the January 27, 1998 vaccination significantly aggravated his autism spectrum disorder and that the first symptom or manifestation of onset of this significant aggravation occurred in December 2004.

Therefore, the undersigned orders petitioners to file a medical doctor's report answering the question whether Aaron's January 27, 1998 hepatitis B vaccination significantly aggravated his pre-existing autism spectrum disorder and that the first symptom or manifestation of onset of this significant aggravation occurred in December 2004. The medical doctor shall give a basis for his opinion, particularly explaining how a vaccination can significantly aggravate a condition when the first symptom or manifestation of onset of the significant aggravation does not occur until nearly seven years after the vaccination.

Petitioners shall file this medical doctor's report by **July 14, 2008**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master