In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* *		
MARISSA AREVALO, Guardian & Mother of R.M.R., a minor,	*	
	*	No. 15-406V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: December 15, 2016
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Table claim for encephalopathy
	*	
Respondent.	*	
* *		

Peter C. Beard, Holley, Rosen & Beard, Springfield, IL, for petitioner;
Adriana Teitel, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED RULING FINDING ENTITLEMENT TO COMPENSATION[1]

RMR, daughter of petitioner Marissa Arevalo, was born in March 2012. At approximately two months of age, on Thursday, May 10, 2012, RMR received a dose of the diphtheria-tetanus-acellular pertussis (DTaP) vaccine. By Monday, May 14, 2012, medical personnel were documenting seizures consistent with infantile spasms. Doctors have since confirmed the diagnosis of infantile spasms, a horrible condition that prevented RMR's development.

Ms. Arevalo alleges that the DTaP vaccination harmed RMR. The petition asserts two causes of action, one based on the Vaccine Table, and the other an off-

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Table claim. To address the on-Table claim, a hearing was held. In this hearing, Ms. Arevalo produced persuasive evidence that showed RMR suffered an "encephalopathy" as the regulations define that term. Therefore, Ms. Arevalo is entitled to compensation.

Background

Congress created the Vaccine Program to promote recovery for people injured by vaccinations. In doing so, Congress created a table that associates certain vaccines with certain conditions that arise in a certain amount of time. When a petitioner establishes an on-Table injury, there is a presumption that the vaccine caused the injury. The Secretary may rebut this presumption with other evidence. Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995).

The current version of the table is found at 42 C.F.R. § 100.3(a). (For a discussion about the Secretary's authority to modify the Vaccine Table, see Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1312-15 (Fed. Cir. 1999)). For the DTaP, the Vaccine Table lists "encephalopathy" within 0-72 hours. 42 C.F.R. § 100.3(a) ¶ II.B.

Through Qualifications and Aids to Interpretation, the Secretary has further defined "encephalopathy." An "acute encephalopathy" means "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). For children who are less than 18 months of age, including RMR, "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). The definition of the critical phrase "significantly decreased level of consciousness" is found in paragraph D. This provision provides:

> A "significantly decreased level of consciousness" is indicated by at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(i)(A) and (2)(i)(B) of this section for applicable time frames):
>
> > (1) Decreased or absent response to environment (response, if at all, only to loud voice or painful stimuli);

> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2)(i)(D).

The Secretary has also excluded some factors from contributing to an "encephalopathy."

> The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3(b)(2)(i)(E).

Analysis

This regulatory structure means the field of evidence relevant to determining whether RMR suffered an encephalopathy is relatively circumscribed. Evidence is relevant if it tends to show or tends not to show that RMR suffered a "decreased level of consciousness" arising within 72 hours of vaccination and persisting for 24 hours. The factors for a "decreased level of consciousness" include: (1) a decreased response to the environment, (2) decreased eye contact, or (3) an inconsistent response to external stimuli. 42 C.F.R. § 100.3(b)(2)(i)(D).

Conversely, evidence about fussiness, inconsolable crying, etc. is not relevant. 42 C.F.R. § 100(3)(b)(2)(i)(E).[2]

The hearing was held because the parties disputed RMR's health in the 72 hours after the vaccination. The parties, however, agree about RMR's health before the vaccination on May 10, 2012, and after May 15, 2012.

On May 10, 2012, RMR was seen for her two-month well baby visit with her pediatrician, Dr. Ho. Dr. Ho noted no health concerns. Exhibit 4 at 10-11. It is likely that by two months, RMR was able to track an object with her eyes. See Faoro v. Sec'y of Health & Human Servs., No. 10-704V, 2016 WL 675491, at *7 (Fed. Cl. Spec. Mstr. Jan. 29, 2016), mot. for rev. denied, 128 Fed. Cl. 61 (2016); see also Bayless v. Sec'y of Health & Human Servs., No. 08-679V, 2015 WL 638197, at *7 (Fed. Cl. Spec. Mstr. Jan, 15, 2015) (relying upon milestones listed in What to Expect the First Year). At the two-month appointment, RMR received the DTaP vaccination. The DTaP vaccination was given at approximately 3:00 PM. Exhibit 4 at 13-14; Tr. 18, 127.[3] RMR's good health before the vaccination serves as one bookend to the parties' debate.

The other bookend to the debate is that on Monday, May 14, 2012, RMR's parents brought her to the emergency room at Saint Francis Medical Center in Peoria, Illinois. Exhibit 5 at 3. They were concerned that RMR was having seizures. Id.; Tr. 54-56. While in the hospital, RMR's parents gave various accounts of her condition since the vaccination approximately four days earlier. E.g., exhibit 5 at 3, 13-14. Although the histories are not absolutely consistent, the records created on Monday evening tend to show that RMR's seizures started early Sunday morning, perhaps 1:00 or 2:00 AM. Exhibit 4 at 18; exhibit 5 at 16, 21; see also exhibit 10 (Ms. Arevalo's affidavit) at 1-2; Tr. 137-38. A more extensive discussion of seizures is not needed because "Seizures in themselves are not

[2] Also irrelevant is the testimony from RMR's treating pediatric neurologist, Blas Zelaya, that RMR suffered an encephalopathy in his opinion. Tr. 80-81. The Secretary's cross-examination brought out that Dr. Zelaya's definition of "encephalopathy" was broader than the regulatory definition. Tr. 91-92. Thus, although the undersigned appreciates Dr. Zelaya's testimony, the undersigned cannot simply defer to his opinion. See Nordwall v. Sec'y of Health & Human Servs., No. 05-123V, 2008 WL 857661, at *5 (Fed. Cl. Spec. Mstr. Feb. 19, 2008) (distinguishing how the medical community uses the term "encephalopathy" from the regulatory definition), mot. for rev. denied, 83 Fed. Cl. 477 (2008).

[3] The 72-hour window, therefore, closes at approximately 3:00 PM on Sunday.

sufficient to constitute a diagnosis of encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E).

It is sufficient to note that after the seizures, RMR's development essentially halted. See Tr. 41, 141-43. Today, RMR requires a G-tube and a wheelchair. Ms. Arevalo spends almost all her time caring for her. Tr. 16-17, 124-26.

The issue requiring more thorough analysis is RMR's health between 3:00 PM Thursday and 3:00 PM Sunday. In this time, did RMR experience symptoms of a "decreased level of consciousness?"

Here, Ms. Arevalo has produced sufficient evidence to answer this question affirmatively. In the initial consultation with Dr. Zelaya, which occurred relatively late in the evening on Monday, May 15, 2012, after RMR had been admitted to the hospital, Dr. Zelaya obtained the following history from Ms. Arevalo: "The mother has observed that the infant did have good eye tracking except in the last couple of days." Exhibit 5 at 41. Several aspects are significant. As mentioned earlier, it is not surprising for a two-month infant to track objects. Moreover, Ms. Arevalo used the phrase "last couple of days." Because Dr. Zelaya was seeing RMR on Monday, two days places the problem of tracking at some time on Saturday, well before the Sunday 3:00 PM cut off. Ms. Arevalo's observation that her daughter was not tracking with her eyes could have occurred only when RMR was awake on Saturday. This sequence means that the decreased eye tracking must have started before the seizures, which began on Sunday morning. See Tr. 174 (Ms. Arevalo: "I definitely noticed [a decrease in eye tracking] on Saturday. 100 percent").

Dr. Zelaya created his May 15, 2012 record within two days of the decrease in eye tracking, meaning that the account is presumptively accurate. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Ms. Arevalo's additional testimony simply adds detail to information already contained in a medical record. Ms. Arevalo testified that on Saturday afternoon, RMR was "not responding to our little play time with her face." Tr. 135.

One way to demonstrate a "decreased level of consciousness" is to show "decreased or absent eye contact." 42 C.F.R. § 100.3(b)(2)(i)(D)(2). Here, the lack of tracking in a two-month old fulfills this criterion. After Ms. Arevalo establishes that RMR suffered the regulatory definition of an encephalopathy, Ms.

Arevalo is entitled to a presumption that the DTaP vaccine caused the associated injury.[4]

The Vaccine Act affords the Secretary an opportunity to rebut the presumption of causation. 42 U.S.C. § 300aa–13(a)(1)(B); see also 42 C.F.R. § 100.3(b)(2)(iii). To do so, the Secretary must introduce evidence. The Secretary has not done so. See Tr. 90-91 (Dr. Zelaya's testimony that after extensive investigation, no reason for RMR's infantile spasms was found). Therefore, Ms. Arevalo is entitled to compensation.

A separate order for the damages phase of the case will issue shortly.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master

[4] This presumption means there is not a finding that the DTaP vaccine actually caused RMR's infantile spasms. In Congress, the relevant committee "recognize[d] that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognize[d] that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related." H.R. Rept. No. 99-908, pt. 1, p. 18, reprinted in 1986 U.S.C.C.A.N. 6344, 6359.