

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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ANNE ABBOTT,
on behalf of her minor child, R.A.,

Petitioner,

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v.

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 14-907V
Special Master Christian J. Moran

Filed: July 9, 2018

Measles, mumps, and rubella
("MMR") vaccine; encephalitis;
Table claim.

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner;
Jennifer L. Reynaud, United States Dep't of Justice, Washington, DC, for
respondent.

PUBLISHED RULING REGARDING ON-TABLE CLAIM¹

Anne Abbott filed a petition under the National Childhood Vaccine Injury Act ("Act"), 42 U.S.C. §§ 300aa-10 through 34 (2012), on September 26, 2014, on behalf of her minor child, R.A. Ms. Abbott's petition alleged that R.A.'s June 12, 2012 measles, mumps, and rubella ("MMR") vaccine caused her to develop Rasmussen's encephalitis. The petition claimed compensation via both as an on-Table and off-Table cause of action.

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 ruling 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.

For the on-Table claim alone, Ms. Abbott filed a Motion for Decision on the Record Regarding Table Claim. Ms. Abbott's pending motion is based upon the following basic chronology. When R.A. was just under two years old on June 12, 2012, she received an MMR vaccination.² Exhibit 1, ¶ 2; exhibit 4 at 17-18. On June 28, 2012, 16 days later, R.A. became unresponsive at home. R.A. was taken to the hospital where doctors confirmed that she had suffered a seizure and had a temperature of 101.5°F. Exhibit 2 at 66. R.A. was eventually diagnosed with Rasmussen's encephalitis in February 2014. Exhibit 6 at pdf 5245 (internal page 4061).

The Secretary opposed Ms. Abbott's motion, arguing that Ms. Abbott did not satisfy the time range requirement for an on-Table claim. The Vaccine Table associates the measles vaccine with encephalitis that occurs only 5-15 days after vaccination. Because R.A.'s first seizure happened 16 days after vaccination, the Secretary argues that Ms. Abbott cannot prevail on her on-Table claim.

For the reasons explained below, Ms. Abbott has not presented persuasive evidence that R.A. suffered an encephalitis within the time required by the Table. Ms. Abbott, however, might cure this deficiency in her evidence by obtaining a report from an expert. Therefore, although her motion for a decision in her favor is denied, she may continue her pursuit of compensation as an on-Table claim.

I. Facts³

If the assertions in the affidavits are accepted as accurate, Ms. Abbott's on-Table claim hinges on whether various symptoms are manifestations of an encephalitis. Thus, the fact recitation draws mostly from the affidavits and is limited to the relevant time period from vaccination to initial seizure.

² R.A. also received the diphtheria-tetanus-acellular pertussis (DTaP) vaccination at the same appointment, exhibit 4 at 17-18, but Ms. Abbott has not claimed compensation based on the DTaP vaccination in the present motion.

³ For purposes of responding to the pending motion only, the Secretary assumed the accuracy of the facts presented in the text. Resp't's Rep. at 5. The Secretary could make this assumption because the remainder of the Secretary's response argued that even with the affiants' assertions accepted as facts, Ms. Abbott cannot establish that R.A. suffered an on-Table injury within the time set forth in the Table.

R.A.'s June 12, 2012 vaccination was in the middle of her Bible school, June 11-15, 2012, and the Abbotts stated that volunteers at the Bible school observed that R.A. "didn't play much." Exhibit 28 ¶2, exhibit 29 ¶2. For a few days following the vaccination, R.A. had a red, sore area at the injection site, her thigh. Id.

About one week after the vaccination, the Abbotts commented generally that R.A. seemed "off," not as responsive, more fussy, and lethargic. Exhibit 1 ¶4, exhibit 29 ¶2. At R.A.'s birthday party on June 17, 2012, family members commented that R.A. was sluggish and not very active. Exhibit 28 ¶3, exhibit 29 ¶4. The Abbotts were surprised when R.A. fell asleep around 4 P.M., causing them to end the party early, and she essentially slept until the next morning. Id.

Over the next few days, Ms. Abbott stated that R.A. stayed inside because it was extremely hot outside, and generally observed that R.A. was "a little spacey at times and lethargic on and off" and was not talking as much. Exhibit 28 ¶4. After spending the day at her grandparents' house on June 22, 2012, the Abbotts were told that R.A. did not do her "normal" things, did not play, and did not eat much. Exhibit 28 ¶5, exhibit 29 ¶5.

At a wedding reception on June 23, 2012, the Abbotts observed that R.A. did not eat or play much and seemed irritable and tired. Exhibit 28 ¶6, exhibit 29 ¶6. The Abbotts dropped R.A. and her brother off at their grandparents' house around 6 P.M. Id. When picking up R.A. later that evening, Mr. Abbott heard that R.A. had been asleep since she had been dropped off, and Ms. Abbott heard that R.A. had been acting tired and dazed. Id.

On June 27, 2012 (15 days from the MMR vaccination), Mr. Abbott came home from work and played with R.A. outside until he noticed her being sluggish. Exhibit 29 ¶7. Due to the heat outside, Ms. Abbott took R.A.'s temperature and stated initially that "she had a fever." Exhibit 1 ¶4. Later, Mr. Abbott and she stated her temperature was "around 100 degrees." Exhibit 28 ¶7, exhibit 29 ¶7.

After playing outside on another hot day on June 28, 2012, Mr. Abbott brought R.A. inside to take a shower. Exhibit 29 ¶8. Following the shower, Mr. Abbott set R.A. down on a chair, left the room briefly, and came back to find R.A. unresponsive. Id. He then immediately took R.A. to the Wilson Memorial Hospital emergency room where she was found to have a fever of 101.5 and to be in a full tonic clonic seizure. Exhibit 2 at 66.

At the emergency room, Ms. Abbott reported that R.A. had “felt a little bit hot earlier in the day” on June 28, 2012. Exhibit 2 at 66. After her transfer to Dayton Children’s Hospital late that night, Ms. Abbott reported a tactile fever before R.A.’s seizure. Exhibit 5 at 35. Elsewhere in Dayton’s records, there are notes that prior to her seizure R.A. “had not been ill-acting or febrile” and “there has been no fevers, no cold symptoms ... no ill contacts at home.” *Id.* at 40, 44.

II. Procedural History

Ms. Abbott filed the petition on September 26, 2014, and with it her first affidavit. The initial affidavit sets forth a series of assertions that are not corroborated in medical records from June 2012. Exhibit 1. Ms. Abbott later added details to her first affidavit by filing her second affidavit, exhibit 28, and an affidavit from her husband, Matt Abbott, exhibit 29.

After Ms. Abbott had filed R.A.’s medical records and a statement of completion, the Secretary determined that the record was complete and was ordered to file his Rule 4 report. Order, issued Dec. 16, 2014. Before the Rule 4 report was filed, Ms. Abbott filed an expert report from Dr. David Axelrod on January 5, 2015. Exhibit 12. Dr. Axelrod generally opined that the MMR and DTaP vaccinations were the cause-in-fact of R.A.’s seizures.

The Rule 4 report deadline was suspended, and the Secretary was ordered to address three of Ms. Abbott’s assertions that support her Table claim. Order, issued Jan. 9, 2015.⁴ In a status report, the Secretary denied that there was a preponderance of evidence to support any of the three assertions. Over the next few status conferences, the parties agreed to develop the record further, and Ms. Abbott was ordered to file additional affidavits and other evidence. Orders, issued Feb. 5, 2015; Mar. 10, 2015; Apr. 16, 2015. Ms. Abbott and her husband submitted affidavits dated February 20, 2015. Exhibits 28, 29.

⁴ The Secretary was ordered to respond to these assertions:

1. Ms. Abbott claims that [R.A.] suffered a fever on June 27, 2012, which is 15 days after vaccination. Exhibit 1 (affidavit) at ¶4.
2. This fever begins a process that led to [R.A.] having seizures on June 28, 2012.
3. The seizures and [R.A.]’s behavior on June 28, 2012 satisfy the definition of “acute encephalopathy” (setting aside the day of onset).

The parties continued to develop evidence, primarily related to the off-Table claim.⁵ Ms. Abbott filed an expert report from Dr. David Seigler on June 29, 2015. Exhibit 30 (corrected version, court document no. [31]). On October 16, 2015, the Secretary filed expert reports from Dr. Thomas Forsthuber and Dr. John Zemple. Exhibits A, C. Ms. Abbott filed a second expert report from Dr. Seigler on January 4, 2016. Exhibit 47. She later stated that she believed that Dr. Seigler's report was adequately responsive to the Secretary's expert reports. Status Rep., filed Feb. 5, 2016.

On February 9, 2016, an entitlement hearing and a briefing schedule were set. The hearing was later cancelled due to scheduling issues, and Ms. Abbott advised that she would retain a new neurology expert to file another report. Order, issued July 15, 2016. Due to the new expert's schedule, Ms. Abbott did not file an expert report from Dr. Lawrence Steinman until February 15, 2017. Exhibit 51.

On May 8, 2017, the Secretary filed a responsive expert report from Dr. Forsthuber. Exhibit S. On May 16, 2017, the parties were ordered to coordinate on scheduling an entitlement hearing and were also ordered to file briefs regarding Ms. Abbott's Table claim.

On July 12, 2017, Ms. Abbott filed the pending Motion for Decision on the Record Regarding Table Claim and a status report on hearing logistics. In the status report, Ms. Abbott also stated that a favorable ruling on the Motion for Decision would obviate the need for an entitlement hearing on the causation-in-fact claim.

The Secretary filed a response to the Motion for Decision on August 14, 2017. Ms. Abbott then filed a reply. Accordingly, the Ms. Abbott's motion for decision is now ready for adjudication.

III. Analysis

Ms. Abbott's present motion seeks to prove entitlement to compensation under the Program for a "Table injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to R.A.'s MMR vaccination. See 42 U.S.C. § 300aa-

⁵ One aspect of an off-Table claim is determining when a vaccinee experienced the first sign or symptom of the injury for which compensation is claimed. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008). Thus, in the context of presenting causation-in-fact opinions, some experts discussed onset.

13(a)(1)(A). Pending resolution of this motion on the Table claim, Ms. Abbott is reserving her causation-in-fact claim for a possible entitlement hearing.

To establish a Table injury under the Act, a petitioner must prove that (1) that the vaccinee received a vaccine listed on the Table, (2) the vaccinee suffered an injury corresponding to that vaccine, and (3) the vaccinee suffered the injury within the time range listed. 42 C.F.R. § 100.3(a) (2011); Hellebrand v. Sec'y of Dep't of Health & Human Servs., 999 F.2d 1565, 1569-70 (Fed. Cir. 1993).

As noted above, it is not disputed that R.A. received an MMR vaccination on June 12, 2012, which is listed on the Vaccine Table. 42 C.F.R. § 100.3(a)(III) (2011). Thus, for Ms. Abbott to prevail on her Table claim, she must establish the second and third elements listed above: that R.A.'s injury was a Table encephalitis and that R.A. suffered the "first symptom or manifestation of onset" of the Table encephalitis within the applicable time frame. 42 C.F.R. § 100.3(a)(III)(B).

The Qualifications and Aids to Interpretation for the 2011 Table do not contain a definition for "encephalitis." 42 C.F.R. § 100.3(b).⁶ In absence of a regulatory definition, Ms. Abbott offered that "encephalitis" simply means "inflammation in the brain." Pet'r's Mot. at 4. The Secretary maintained that "inflammation in the brain" as a definition of encephalitis was "too broad for program purposes" because that definition does not describe clinical symptoms that Ms. Abbott would have to establish to demonstrate that R.A. actually experienced brain inflammation. Resp't's Resp. at 8-9 (citing Nuttall v. Sec'y of Health & Human Servs., No. 07-0810V, 2015 WL 691272, at *10 (Fed. Cl. Spec. Mstr. Jan. 20, 2015), mot. for rev. denied, 122 Fed. Cl. 821 (2015), aff'd, 640 F. App'x 996, 997 (Fed. Cir. 2016) (per curiam)). Ultimately, the Secretary did not propose a definition for encephalitis.⁷

⁶ Because Ms. Abbott filed her petition on September 26, 2014, the Vaccine Table in effect at that time, the 2011 Table, is the correct Table to use to evaluate her claim. 42 U.S.C. § 300aa-14(c)(4); Revisions to the Vaccine Injury Table, 76 Fed. Reg. 36367-68 (June 22, 2011) (effective July 22, 2011). As Ms. Abbott noted, using the current (2017) Table to evaluate her claim would be legal error. Pet'r's Reply at 4-5.

⁷ The Secretary argued that because R.A.'s particular type of encephalitis is known (Rasmussen's), then Ms. Abbott should be required to demonstrate the initial symptom/onset that is specific to Rasmussen's encephalitis, not the initial symptoms of encephalitis when more generally defined. Resp't's Resp. at 9-10. Ms. Abbott countered that the Secretary's proposed distinction between encephalitis generally and Rasmussen's encephalitis does not matter because the both injuries share the same pattern of onset with the distinguishing trait for Rasmussen's encephalitis being that it leads to more severe outcomes. Pet'r's Reply at 7.

While the term “encephalitis” appears in the 2011 version of the Vaccine Table, the term “encephalitis” first appeared in the initial Vaccine Table that Congress created. See 42 U.S.C. § 300aa-14(a)(II)(B) (1988); National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99–660, 100 Stat 3743, 3764 (1986). “Congress intended this statute to be understood — and to be applied — as it would be by a medical professional.” Abbott v. Sec’y of Health & Human Servs., 27 Fed. Cl. 792, 794 (1993), aff’d on this point, rev’d on other grounds and remanded, 19 F.3d 39 (Fed. Cir. 1994) (Table) (Text in Westlaw, 1994 WL 32656).⁸

A medical professional’s understanding of “encephalitis” can be found in a medical dictionary. See Munn v. Sec’y of Health & Human Servs., 970 F.2d 863, 867 n.5 (1992) (citing the American Heritage Dictionary and Dorland’s Illustrated Medical Dictionary to define the term “sequela”). Here, a medical dictionary defines “encephalitis” as “inflammation of the brain.” Dorland’s Illustrated Medical Dictionary 436 (26d ed. 1981).

This definition matches the definition that Special Master Hastings used in Nuttall. In Nuttall, the petitioners attempted to establish that either a DTaP or an MMR vaccine caused their son to suffer encephalitis under the Vaccine Table. 2015 WL 691272, at *1. The petitioners in Nuttall, like Ms. Abbott here, put forward the definition of “brain inflammation.” The Secretary proposed that the

The Secretary has not provided any authority for why petitioner would have to establish the initial symptom/onset for a sub-set of encephalitis (Rasmussen’s) rather than the initial symptom/onset for “encephalitis,” the injury listed in the Vaccine Table. Without any authority in support, requiring petitioner to establish a more specific initial symptom/onset would add to petitioner’s burden. The undersigned declines to require Ms. Abbott to establish initial symptom/onset specific to Rasmussen’s encephalitis.

⁸ Congress authorized the Secretary to modify the Vaccine Table administratively. See Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1312-15 (Fed. Cir. 1999) (rejecting argument that administrative changes to a statute were unconstitutional). In 2017, the Secretary exercised his authority to define “encephalitis.” Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294, 6302 (Jan. 19, 2017); Delay of Effective Date, 82 Fed. Reg. 11321, (Feb. 22, 2017) (changing effective date of revisions to Mar. 21, 2017). However, the 2017 changes do not establish the definition of encephalitis in Ms. Abbott’s case. See footnote 6, above.

special master adopt a draft of a proposed rule. Id. at *10.⁹ Special Master Hastings accepted “brain inflammation” as a definition of “encephalitis.” Id.¹⁰

Having defined “encephalitis” as “brain inflammation,” Special Master Hastings evaluated opinions from experts as to whether the vaccinee in Nuttall suffered brain inflammation. The key to the experts’ opinions were MRIs because the child’s clinical symptoms were not dispositive. Id. at *11. Ultimately, the special master found that the petitioners did not carry their burden to show an encephalitis happened in their child. Id. at *11-20.

Consequently, the undersigned holds that “inflammation in the brain” is an adequate definition for “encephalitis.” The ensuing question is how do petitioners, such as Ms. Abbott, present preponderant evidence that the vaccinee suffers from inflammation in the brain. An easy way would be to present the results of imaging such as MRIs that can detect inflammation in the brain. However, R.A. did not have any imaging in the relevant time period.

In lieu of direct evidence of brain inflammation, Ms. Abbott is relying upon circumstantial evidence, including a medical article, affidavits, and expert’s reports. To begin, Ms. Abbott cited a medical reference book for the proposition that “phase one [of Rasmussen’s encephalitis] is a ‘prodromal state’ during which seizures are infrequent.” Pet’r’s Mot. at 4 (citing exhibit 15 (Tiziana Granata & Frederick Andermann, Rasmussen encephalitis, in Handbook of Clinical Neurology, Vol. III, Pediatric Neurology Part I (O. Dulac, M. Lasseonde, and H.B. Sarnat, eds., 3rd Series 2013)) at 1); Pet’r’s Reply at 7. While this reference to a “prodromal state” seems to offer Ms. Abbott some support, the authors of this article also report “the onset [of Rasmussen’s encephalitis] is marked, in almost all cases by focal or secondarily generalized seizures.” Exhibit 15 at 1. Testimony from an expert could help explain the connection between “prodromal state” and “onset.”

⁹ Unlike in Nuttall, the Secretary here has not put forward a definition of “encephalitis.” Although the Secretary did eventually propose and adopt a regulatory definition of encephalitis, the parties agree that the 2017 regulatory definition does not define “encephalitis” for Ms. Abbott’s case.

¹⁰ The Secretary’s brief does not cite Nuttall accurately. The Secretary states that defining encephalitis as brain inflammation is “‘too broad for Program purposes.’” Resp’t’s Resp. at 9. However, the phrase “too broad for Program purposes” comes from an unpublished order a different special master issued earlier in Nuttall. The Secretary’s brief fails to note that Special Master Hastings resolved the case based upon the definition of “brain inflammation.”

Ms. Abbott further relies upon assertions contained in affidavits from her husband and herself. See Pet'r's Mot. at 8, citing exhibits 1, 28, and 29. As noted earlier, the Secretary has accepted such assertions for the limited purpose of determining whether these assertions are material.

It appears that the assertions about R.A.'s behavior in the days shortly before her first seizure are material because one expert, Dr. Siegler, seems to accept that within 5-15 days of the MMR vaccination, R.A. was fussy, not responsive, lethargic, and tired. Exhibit 30 at 1-2. From this starting point, Dr. Siegler opines that R.A.'s "symptoms that appeared within 5 to 15 days of her MMR vaccination were the first onset of her symptoms" of Rasmussen's encephalitis. Id. at 2.

Dr. Siegler's analysis, however, does not quite hit the mark, at least for the on-Table claim. As explained above, the critical question is whether preponderant evidence establishes that R.A. had inflammation in the brain by 5-15 days after the MMR vaccination. Dr. Siegler's report, which refers to the "defined requirements of encephalopathy/encephalitis found in the Aids to Interpretation," id. at 1, confuses the issue because the 2011 Aids to Interpretation do not define "encephalitis." Because the present ruling has defined "encephalitis," Ms. Abbott should have an opportunity to present an opinion from Dr. Siegler as to when R.A. first displayed a symptom of brain inflammation.

Similarly, reports from other experts are also not as precise as they could be. Respondent's expert, Dr. Zemple, stated that the "[t]iming of the vaccination and onset of neurological symptoms is also clear.... [R.A.'s] first clear neurological symptom occurred with seizure on June 28, 2012." Exhibit C at 3.¹¹ In light of the Granata article's description of both a "prodromal stage" and "onset" of Rasmussen's encephalitis, Dr. Zemple's characterization of R.A.'s June 28, 2012 seizure as the "first clear neurological symptom" leaves open the question as to "unclear" neurological symptoms. And the question that Dr. Zemple should address is whether the constellation of R.A.'s behaviors reported by the affiants is, more-likely-than-not, a manifestation of brain inflammation.

¹¹ One of petitioner's experts, Dr. Steinman, quoted the above statement from Dr. Zemple's report and agreed with his conclusion about R.A.'s first symptom or onset. Exhibit 51 at 4, 21.

Obtaining further reports from experts about brain inflammation is appropriate. First, this ruling defines “encephalitis” and provides new information for an expert to consider. Second, when the contemporaneously created medical records do not establish that a vaccinee suffered an on-Table injury, the petitioner must present expert testimony. See Paterek v. Sec’y of Health & Human Servs., No. 02-411V, 2008 WL 2485159, at *14 (Fed. Cl. Spec. Mstr. May 22, 2008) (“The cases hold uniformly that if an injured person’s medical records do not disclose a diagnosis that the injured person’s symptoms constitute a Table injury, then the petitioner must submit a medical expert’s opinion interpreting the injured person’s symptoms as a Table injury”), mot. for rev. denied in relevant part and granted in non-relevant part, 84 Fed. Cl. 19, 46 (2008), on remand, 2009 WL 3288295 (Fed. Cl. Spec. Mstr. Jan. 16, 2009), mot. for review granted and decision reversed, 88 Fed. Cl. 178 (2009), rev’d, 527 Fed. App’x 875 (Fed. Cir. 2013); Carter v. Sec’y of Health & Human Servs., No. 04-1500V, 2007 WL 415185, at *12 (Fed. Cl. Spec. Mstr. Jan. 19, 2007) (in resolving the pending on-Table claim, “an expert is needed to interpret the information in the medical records and the statements in the mother's affidavit”).

In presenting opinions from experts about whether the behaviors described in the affidavits are manifestations of brain inflammation, the parties are ordered to direct their experts to assume that the allegations in the affidavits are correct. However, Ms. Abbott still bears the burden of establishing the accuracy of the affidavits. See Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). Thus, Ms. Abbott and the other percipient witnesses are likely to be called to testify at any hearing.

Accordingly, Ms. Abbott’s motion is DENIED. She may seek a ruling in her favor regarding the on-Table claim after the parties submit additional evidence.

A status conference is set, sua sponte, for **Monday, July 30, 2018 at 2:00 P.M. Eastern Time**. During this status conference, a deadline for simultaneous submission of expert reports will be set. Given the length this case has been pending and the narrowness of the issues for the experts to address, the deadline is likely to be within 60 days of the status conference and unlikely to be extended.

IT IS SO ORDERED.

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