In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

AMEENA JAAFAR, on behalf of A.M., Petitioner,	*	No. 15-267V Special Master Christian J. Moran
	*	Filed: August 10, 2018
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Entitlement; bench ruling; diphtheria, tetanus, acellular pertussis ("DTaP") vaccine; tonic seizures; infantile spasms

William J. Melley, Law Offices of William J. Melley, III, Hartford, CT, for petitioner;
Debra A. Filteau Begley & Mollie D. Gorney, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Ms. Jaafar claimed that a diphtheria-tetanus-acellular pertussis (DTaP) vaccination caused her son, A.M., to suffer infantile spasms.[2] After Ms. Jaafar filed A.M.'s medical records, the parties filed a series of reports from Dr. Maurice Kinsbourne (petitioner's expert), Dr. Vera Byers (petitioner's expert), Dr. Stephen McGeady (respondent's expert), and Dr. Max Wiznitzer (respondent's expert).

A hearing was held on August 6-8, 2018. After the parties submitted all their evidence, the undersigned issued a bench decision, finding that Ms. Jaafar had failed to establish that she was entitled to compensation. See Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 704 n.18 (2008) (noting "[e]ven a special master's ruling on entitlement may be delivered from the bench, with no written opinion").

[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.

[2] During rebuttal testimony, petitioner's experts began to elaborate a second theory that A.M. first suffered tonic seizures that later evolved into infantile spasms. Because a factual finding described below rendered this second theory untenable, this decision focuses on the first theory, that the DTaP vaccine directly caused infantile spasms.

The undersigned is issuing this document for two reasons. First, this document will become available to the public pursuant to 42 U.S.C. § 300aa—12(d)(4).

Second, this document provides an abbreviated recitation for the basis of decision. See Hebern v. United States, 54 Fed. Cl. 548 (2002) (example of a judge from the United States Court of Federal Claims formalizing a bench ruling denying a motion for review). As explained in the bench ruling, the undersigned considered all the evidence, including the medical records, expert reports, medical articles, and oral testimony. The undersigned's consideration of this evidence began when the evidence was received, as outlined in the recitation of the case's procedural history. See Vaccine Rule 5 (providing for a framework in which special masters evaluate the evidence, and even make tentative findings and conclusions, prior to issuing a decision).

Facts

Because the parties agreed that medical records created contemporaneously with the events described in the records accurately set forth events in A.M.'s life and because the parties' briefs are generally in agreement, only a succinct recitation of facts is presented here.

A.M. was born in January 2013. Up through his six-month wellness appointment on July 22, 2013, A.M.'s medical history was uneventful. At the appointment, A.M. received the DTaP and four other vaccines. Two hours after the appointment while shopping at Target, Ms. Jaafar reported that A.M.'s body stiffened, his eyes rolled back, and the area around his lips turned blue. On a call that evening, a doctor told Ms. Jaafar to give A.M. Tylenol and to watch for any more seizure-like activity.

Two days later on July 24, 2013, Ms. Jaafar brought A.M. to the emergency room following more seizure-like activity. No fever was reported in association with A.M.'s seizure-like activity. A video EEG during the hospital stay confirmed a diagnosis of infantile spasms.

Genetic testing of A.M. later in 2013 did not reveal any mutations that had a known association with infantile spasms. A.M. did not undergo any further genetic testing. A.M. went through several anti-seizure medications, combinations of medications, and dietary changes to treat his seizure condition.

In 2014, A.M. resumed receiving scheduled vaccinations, including DTaP. In March 2014, at Ms. Jaafar's request, and over the neurologist's advice, A.M.'s anti-seizure medications were decreased and eventually eliminated. Since that time, A.M.'s seizures have not gotten worse, but they have not decreased in their overall frequency or severity. The parties agreed that A.M.'s subsequent medical history does not relate to whether the DTaP vaccine caused A.M.'s infantile spasms.

At the hearing, Ms. Jaafar testified about A.M.'s current condition. She described that A.M.'s physical development has been regular but his intellectual and behavioral development are delayed. A.M. receives various therapies and assistance through an individualized education plan at his school. Ms. Jaafar noted that he does have behavior issues that require redirection which otherwise have resulted in self-harm or aggression toward others. While frustrated by the difficulties that A.M. has, Ms. Jaafar sounded appropriately proud of the progress that A.M. had

made. As a mother who obviously loves her child, she is deserving of sympathy in her care for a disabled child.

Analysis

Ms. Jaafar bears the burden to establish her case on a more-likely-than-not basis. 42 U.S.C. § 300aa-13(a); Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). The elements are set out in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

As explained in more detail in the bench ruling, Ms. Jaafar failed to meet her burden of proof. Her case faltered as a result of resting her claim of causation on experts who were relatively unqualified compared to the respondent's experts. As a result, petitioner's case fell far short of satisfying the three Althen prongs.

Expert Qualifications

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Human Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016). At the pre-hearing conference, the parties agreed that all of the experts were qualified in their respective fields, but they reserved the right to cross-examine the experts on the weight that should be afforded to their testimony. A comparison of the immunologists, Dr. Byers and Dr. McGeady, and the neurologists, Dr. Kinsbourne and Dr. Wiznitzer, both result in a qualifications advantage for the Secretary.

Immunologists

Dr. McGeady has superior qualifications to discuss the immunological mechanism that allegedly triggered A.M.'s infantile spasms. To start, Dr. McGeady is board-certified in pediatric immunology and Dr. Byers is not. While on a reduced schedule now, Dr. McGeady practices medicine by treating patients for immunological issues. By contrast, Dr. Byers stopped her regular practice of medicine in approximately 2002 and now sees patients only in the context of legal cases. Dr. McGeady has been a professor of pediatrics for over 40 years. Dr. Byers currently holds no academic position, although she was an adjunct professor as recently as 2008.

The contrast in qualifications carried over to their respective presentations. Dr. Byers did not answer questions clearly or cite specific exhibits to support her points. As detailed in the bench ruling, Dr. Byers made several statements that strained credulity.[3] Dr. McGeady explained the basis of his opinions in an understandable way.

[3] In regard to the deficiencies of Dr. Byers's reports and preparation for testifying, the undersigned has more fully articulated similar problems with Dr. Byers in a recent decision. See Wood v. Sec'y of Health & Human Servs., No. 15-1568V, 2018 WL 1150730, at *5-8 (Fed. Cl. Spec. Mstr. Feb. 1, 2018).

Neurologists

Although Dr. Kinsbourne has had a long career in neurology and involvement in the Vaccine Program, the most recent phase of his career has had a shallower connection to pediatric neurology clinical care. Dr. Kinsbourne has not regularly treated patients for over 20 years and his most recent academic position starting in 1995 was as a professor of psychology. As for presentation, Dr. Kinsbourne struggled to make fine distinctions or to distinguish the relevance of some medical literature over others.

In contrast, Dr. Wiznitzer is in the midst of a clinical pediatric neurology practice in which he has recently treated patients with infantile spasms. He also has been certified to read EEG's and reviewed A.M.'s actual EEG's during the litigation. Dr. Wiznitzer answered questions directly and provided citations to support his statements.

Diagnosis

In Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the Althen test." Citing Broekelschen, the Federal Circuit has also explained that "In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

The parties agree that infantile spasms was the correct diagnosis at the time of A.M.'s first hospital stay on July 24-26, 2013. However, during the testimony of Dr. Kinsbourne and Dr. Byers, a disagreement between the parties became more pronounced over what A.M. experienced two hours after he received the DTaP vaccination on July 22, 2013. The petitioner's expert reports and pre-hearing briefs contain faint references to A.M. first experiencing tonic seizures that then developed into infantile spasms. When petitioner's experts began to elaborate on this sketch of a theory, respondent objected on the basis that the theory had not be adequately disclosed in advance of the hearing. Rather than determining whether the petitioner's tonic seizure theory was adequately disclosed, the undersigned will address the evidence relating to the diagnosis for A.M. at two hours following the DTaP vaccination.

A weight of the evidence supports a finding that A.M.'s behavior in Target was a manifestation of infantile spasms. Several factors contribute to this finding. The undersigned relies on Dr. Wiznitzer's opinion that A.M. first experienced infantile spasms based on the strength of his qualifications described above. While Dr. Kinsbourne emphasized that A.M. cried out and stiffened his limbs to support a diagnosis of tonic seizures, he did not counter Dr. Wiznitzer's explanation that infantile spasms can have a tonic component. Further, as described by Ms. Jaafar, the duration of A.M.'s tonic symptoms were brief, a few seconds, rather than the longer period of time in typical full tonic seizures, 30-60 seconds. Based on Dr. Wiznitzer's definitions of tonic seizures and infantile spasms, Ms. Jaafar's description of A.M.'s actions two hours after the DTaP vaccination fits the definition of infantile spasms. Finally, neither Ms. Jaafar nor her experts identified any record from a treating doctor diagnosing A.M. with tonic seizures. Thus, the undersigned finds that the evidence preponderates in finding that the episode

two hours following the DTaP vaccination was, as Dr. Wiznitzer explained, a manifestation of infantile spasms.

Althen Prong Three

The easiest way to explain why Ms. Jaafar failed to meet her burden is to begin with the timing prong. Timing contains two parts: (1) what the expected time interval between the vaccination and injury for which inference of causation is and (2) whether the onset of the vaccinee's injury fell within that expectation.

It is straight forward to establish the onset of A.M.'s injury because the parties do not dispute Ms. Jaafar's testimony about what happened to A.M. two hours after his DTaP vaccination. In accordance with the ruling on diagnosis above, A.M. suffered an infantile spasm two hours after his DTaP vaccination.

As for the expected time interval, Ms. Jaafar is advancing a theory that the innate immune system had developed a memory from earlier vaccinations that facilitated a significant enough release of cytokines to cause infantile spasms in A.M. within two hours. Based on the medical textbooks submitted into evidence, which both immunologists accept as authorities, even the "trained" innate immune system takes at least four hours to generate a response. Dr. Byers never clearly identified any medical literature that supported the idea that innate immune system memory, versus the standard innate immune system, would have a response time less than four hours. The literature did support the idea, accepted by both immunologists, that, in some situations, a "memory" aspect to the innate immune system could provoke a more robust response that the standard innate immune system. But, Dr. Byers did not establish that this more robust response was a quicker response.

Thus, the undersigned finds that Ms. Jaafar has failed to establish the Althen timing prong. Although an absence of preponderant evidence on one Althen prong defeats Ms. Jaafar's case, the undersigned will address the other prongs for a complete evaluation of Ms. Jaafar's case.

Althen Prong One

Althen prong one requires the petitioner to present a theory explaining how the relevant vaccine can cause the relevant illness. Due to the ruling on diagnosis above, only the theory that the DTaP vaccination directly caused infantile spasms will be considered. The theory that the DTaP vaccination can cause tonic seizures that can turn into infantile spasms does not fit the facts of this case, and, therefore, is no longer viable.

Ms. Jaafar had initially presented a molecular mimicry theory via Dr. Shafrir, but after he stepped away from the case Dr. Kinsbourne and Dr. Byers pursued a two-hit theory. The experts posited that the first hit was that A.M. possessed an underlying susceptibility (unknown in this case) that was then triggered by the second hit, the DTaP vaccination, to release cytokines that caused the infantile spasms. This theory was not persuasive.

The critical aspect of the theory is the second hit, whether vaccines can trigger infantile spasms. Given that an underlying susceptibility, such as a genetic mutation, is unknown in this

case, Ms. Jaafar's theory is not bolstered by the establishment of a first hit. Moreover, Dr. Kinsbourne admitted during testimony that having an underlying susceptibility would not be absolutely necessary for cytokines to trigger infantile spasms.

Dr. Byers's opinion that a DTaP vaccination can cause the release of cytokines that can then trigger infantile spasms is unsupported. Although epidemiological evidence is not a required for Ms. Jaafar to prevail, the parties presented epidemiological studies. No epidemiological evidence supports a causal connection between the DTaP vaccine and infantile spasms.

To support her theory that the DTaP vaccine can cause infantile spasms, Dr. Byers relies on medical literature that investigated the connection between the DTaP vaccine and seizures generally, but not infantile spasms specifically. The neurologists acknowledged that infantile spasms differ from other seizure types. When asked to explain how she could extend a theory based on animal models for seizures to a human being suffering from infantile spasms, Dr. Byers said that she could not. This concession significantly undermined the petitioner's case.

As for the mechanism of cytokines, Dr. Byers opined that the DTaP vaccination would lead to cytokines and cytokines can lead to seizures. Although Dr. McGeady agreed that vaccines cause the production of cytokines, he opined that physiologic amounts of cytokines do not cause seizures. On this point, the weightier evidence supports a finding that seizures cause increases in cytokines, not the other way around.

Overall, the undersigned finds Dr. Byers's cytokine theory to be conclusory and not persuasively supported. Thus, Ms. Jaafar has failed to establish a medical theory that a DTaP vaccination causes a release of cytokines that triggers infantile spasms.

Althen Prong Two

Ms. Jaafar failed to establish a logical sequence of cause and effect causally connecting the DTaP vaccine to A.M.'s infantile spasms. As admitted by Dr. Byers on the stand, there is no clinical evidence to support Ms. Jaafar's theory other than the infantile spasms themselves.

Several pieces of clinical evidence suggests that A.M. did not react the way Dr. Byers's cytokine-driven theory would predict. Dr. McGeady contended persuasively that if cytokines did cause the infantile spasms, then he would expect a fever to accompany the infantile spasms. However, the parties agree that the medical records do not show that A.M. had a fever in connection with any of his infantile spams. Similarly, if A.M.'s infantile spasms were the result of an immune reaction, Dr. McGeady stated that using ACTH, an anti-seizure medication that targets an immune mechanism, would be effective. But, when doctors tried ACTH on A.M., it did not alter his infantile spasms.

In considering whether petitioners have met their burden on prong two, the Federal Circuit directed special masters to consider the views of treating doctors. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, Dr. Byers recognized that none of A.M.'s treating doctors linked his vaccines to his infantile spasms. Moreover, A.M.'s treating doctors advised that he resume receiving his vaccinations. A.M. did not experience a

worsening of seizure activity following a subsequent DTaP vaccination, indicating that his case does not fulfill the challenge-rechallenge paradigm. See Capizzano, 440 F.3d at 1325-26.

Thus, the undersigned finds that Ms. Jaafar has not established a logical sequence of cause and effect causally connecting the DTaP vaccine to A.M.'s infantile spasms.

* * *

In summary, for the reasons noted above and further elucidated in the bench ruling, the undersigned finds that Ms. Jaafar has not met her burden of proof under the Vaccine Act. The evidence does not support, by a preponderance of the evidence, that A.M.'s DTaP vaccination caused his infantile spasms.

The undersigned further directs the Clerk's Office to enter judgment based upon the decision in this case if a motion for review is not filed. When the time for filing a motion for review (see Vaccine Rule 23) begins to run is for an appellate tribunal to decide.

IT IS SO ORDERED.

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