

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

LIZETTE STILLABOWER, *
individually and as legal *
representative of her minor *
daughter, A.H., *

Petitioner, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

No. 17-265V
Special Master Christian J. Moran

Filed: June 27, 2019

Entitlement, HPV, Evans syndrome

Sean Greenwood, Houston, TX, for petitioner;
Alexis B. Babcock, United States Dep't of Justice, Washington, DC, for
respondent.

DECISION GRANTING RESPONDENT'S MOTION FOR RULING ON THE RECORD AND DENYING ENTITLEMENT¹

On behalf of her daughter, A.H., Ms. Lizette Stillabower alleged that the third dose of the human papillomavirus (HPV) vaccine caused A.H. to suffer a condition known as Evans syndrome. Ms. Stillabower and A.H. testified at a

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 (<https://www.uscfc.uscourts.gov/aggregator/sources/7>). This posting means that the decision will be available to anyone with the internet. 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.

hearing. Following the hearing, the undersigned issued tentative findings of fact, and Ms. Stillabower obtained a report from an immunologist, Eric Gershwin.

The Secretary has challenged the sufficiency of Dr. Gershwin's report by filing a motion for ruling on the record to which Ms. Stillabower has interposed an objection. For the reasons explained below, Dr. Gershwin's report does not advance Ms. Stillabower's case. Therefore, the Secretary's motion is GRANTED.

Procedural History

Ms. Stillabower filed her petition on February 23, 2017, and shortly thereafter filed medical records. The first set of materials includes, as exhibit 3, a letter from a doctor who treated A.H., Dr. Mehta. The Secretary reviewed this material and concluded that Ms. Stillabower had not established that she was entitled to compensation. Resp't's Rep., filed June 28, 2017. In his report, the Secretary noted that Ms. Stillabower averred facts about A.H. that were not supported in medical records created contemporaneously with the events alleged in the affidavit.

In response and in anticipation of a hearing, Ms. Stillabower filed additional information including affidavits, Facebook posts, and school records. The fact hearing was held on February 13, 2018, in Houston, Texas.

The undersigned issued an order tentatively finding facts on March 6, 2018.² The findings of fact generally found the medical records created in the spring and summer of 2014 probative and the later-given oral testimony not probative.

After a status conference, Ms. Stillabower proposed obtaining a report from an expert. To assist in this process, the undersigned proposed a set of instructions for expert witnesses on June 22, 2018. These instructions became final on July 9, 2018.

Ms. Stillabower filed a report from Dr. Gershwin on August 22, 2018, which was initially labeled as exhibit 21. Dr. Gershwin's August 22, 2018 report cited

² The facts were found only tentatively because Ms. Stillabower had been afforded the opportunity to obtain records from A.H.'s school nurse. It was possible that the nurse's notes could corroborate some of the oral testimony. However, the notes did not support the testimony given in Houston. See exhibit 20.

more than 300 medical articles. Regardless of the number of citations, Dr. Gershwin's report appeared deficient in that Dr. Gershwin accepted assertions from Ms. Stillabower's affidavit that were not accepted in the order tentatively finding facts. In addition, Dr. Gershwin did not adequately address the timing in A.H.'s case. Order, issued Sept. 6, 2018.

Ms. Stillabower then filed a motion to strike Dr. Gershwin's August 22, 2018 report and filed a second report from him on December 6, 2018. This December 6, 2018 report is also labeled as exhibit 21 and all references in this decision to exhibit 21 are to the December 6, 2018 report. In a December 19, 2018 status conference, the Secretary maintained that Dr. Gershwin's report remained insufficient.

The Secretary filed the pending motion for a ruling on the record that Ms. Stillabower is not entitled to compensation on February 22, 2019. Ms. Stillabower responded on March 25, 2019. The motion is ready for adjudication.

Facts³

A.H. was born in 2002. In the first 12 years, she experienced no health concerns relevant here. She began receiving the HPV vaccine when she was 11. The first and second doses of the HPV vaccine were given to her on August 23, 2013 and December 3, 2013, respectively. Exhibit 2 at 1. A.H. received the allegedly causal third dose of the HPV vaccine on March 12, 2014.

The tentative findings of fact filled gaps in the medical records between the vaccination on March 12, 2014 and the hospitalization on July 5, 2014. In this period, A.H. continued to maintain her normal activity level. She attended school and played with her friends. She was not excessively fatigued.

In very early July, Ms. Stillabower noticed that A.H.'s skin tone had become yellower and her eyes were also yellow. This discovery prompted Ms. Stillabower to bring her daughter for medical attention at a local emergency room. Doctors

³ This decision sets forth the most relevant facts only and is consistent with the length of Dr. Gershwin's recitation of facts. While the Secretary presents more facts, see Resp't's Mot. at 3-10, A.H.'s course with Evans syndrome sheds little light on the causation of her Evans syndrome. Thus, while A.H.'s more recent treatment records have been reviewed, they are not discussed in this decision.

diagnosed A.H. first with autoimmune hemolytic anemia and then Evans syndrome. Exhibit 4 at 154-59, 224.

Evans syndrome is a condition in which a person has both immune thrombocytopenia and autoimmune hemolytic anemia. Exhibit 32 (Alice Norton and Irene Roberts, Management of Evans syndrome, 132 Br. J. Haematol. 125 (2006)). “Although Evans syndrome appears to be a disorder of immune regulation, the exact pathophysiology is unknown.” Id. at 126.

Dr. Gershwin opines that the third dose of the HPV vaccine caused A.H.’s Evans syndrome. In the pending motion, the Secretary challenges his opinion.

Standards for Adjudication

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)); see also D’Tiole v. Sec’y of Health & Human Servs., 726 F. App’x 809, 812 (Fed. Cir. 2018). Here, Ms. Stillabower has not interposed any objection to the procedural device of a ruling on the record.

In ruling on the record, special masters use the same standards for adjudication. Petitioners must establish their cases by a preponderance of evidence. 42 U.S.C. § 300aa-13(a); Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

For off-Table cases, like this one, the elements are: “(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. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Special masters are fact finders that use their accumulated expertise to judge the individual merits of claims. See Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Munn v. Sec’y of Health & Human Servs., 970 F.2d 863, 871 (Fed. Cir. 1992).

Analysis

Ms. Stillabower has failed to establish any Althen prong. Each is evaluated in order of its importance, beginning with the most important, timing.

Timing

The third prong of Althen requires “a showing of a proximate temporal relationship between vaccination and injury.” 418 F.3d at 1278. As part of their case-in-chief, petitioners bear the burden of establishing that the onset of their child's disease occurred within an acceptable time. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). This formulation implies that the third prong from Althen actually contains two parts. First, there must be a showing that a range of time is “acceptable” to infer causation. Second, there must be a showing that the vaccinee's disease arose in this acceptable time. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542–43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd per curiam, 503 F. App'x 952 (Fed. Cir. 2013). Here, consistent with this precedent, the parties' experts were instructed to provide opinions about the acceptable temporal interval. Instructions ¶ 6.a.

Dr. Gershwin did not set forth any proposed range. Exhibit 21 at 9-10. He states the interval from vaccination to the appearance of jaundice is “consistent from a temporal perspective.” Id. at 9. However, this statement is too vague to be persuasive. If an expert could satisfy the timing prong by simply saying the timing is “consistent,” then this element would be toothless. See Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 142 (2010).

In addition, Dr. Gershwin seems to assume that A.H. suffered problems based upon affidavits created during this litigation years after the events allegedly occurred. Exhibit 21 at 9-10. However, the undersigned did not find that the affidavits established on a more-likely-than-not basis the timeline asserted in the affidavits. Tentative Findings of Fact. Dr. Gershwin's assumption of a sequence not established by preponderant evidence makes his opinion not creditable. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

The medical records are not clear about when A.H.'s began to suffer from Evans syndrome. (The date of diagnosis is not the same as the date of onset.) Thus, an opinion from the retained expert was critical to fill this gap. However, Dr. Gershwin did not present a clear opinion as to when A.H.'s Evans syndrome began. See exhibit 21 at 9-10. To the extent that Dr. Gershwin seems to accept an affiant's assertion that the affiant observed A.H. having yellow skin on June 9, 2014 (exhibit 21 at 10), even June 9, 2014 seems distant from the March 12, 2014 vaccination. The interval is nearly three months (89 days), which widely exceeds the amount of time often recognized as consistent with a reaction mediated through

the adaptive immune system. See, e.g., Gramza v. Sec’y of Health & Human Servs., No. 15-247V, 2018 WL 1581674, at *17 (Fed. Cl. Spec. Mstr. Feb. 5, 2018) (finding that a medically appropriate interval for the HPV vaccine to cause immune thrombocytopenic purpura to be “four to six weeks”), mot. for rev. denied, 139 Fed. Cl. 309, 334 (2018).

Theory

To link the HPV vaccine with Evans syndrome, Dr. Gershwin proposes molecular mimicry. Exhibit 21 at 6. However, he offers nothing to substantiate the theory. For example, he does not show any homology between components of the HPV vaccine and body parts attacked in Evans syndrome. This omission is significant because according to an expert for the petitioners in a different case, “it was unlikely for the hepatitis B vaccine, having only a single antigen, to have sufficient similarity with both cell lines to result in molecular mimicry.” Bucci v. Sec’y of Health & Human Servs., No. 11-513V, 2019 WL 1891809, at *27 (Fed. Cl. Spec. Mstr. Mar. 27, 2019). Dr. Gershwin’s opinion regarding molecular mimicry in this context is not persuasive. Caves v. Sec’y of Health & Human Servs., 100 Fed. Cl. 119, 135 (2011) (“Without any empirical evidence that the theory actually applies to the influenza vaccine and TM, the first prong of Althen would be rendered meaningless”), aff’d without opinion, 463 F. App’x 932 (Fed. Cir. 2012); see also M.S.B. by Bast v. Sec’y of Health & Human Servs., 117 Fed. Cl. 104, 123 (2014) (requiring submission of persuasive theory), appeal dismissed, 579 F. App’x 1001 (Fed. Cir. 2014); Taylor v. Sec’y of Health & Human Servs., 108 Fed. Cl. 807, 819 (2013) (same).⁴

Logical Sequence of Cause and Effect

Given that Ms. Stillabower has not presented a persuasive theory causally connecting HPV vaccination and Evans syndrome (Althen prong one) and given that she has not established an appropriate temporal interval (Althen prong three),

⁴ Although this decision’s examination of Dr. Gershwin’s invocation of molecular mimicry is relatively short, two other decisions more extensively evaluated a potential causal relationship between vaccination and Evans syndrome and found that the evidence did not support a causal relationship. See Berenji v. Sec’y of Health & Human Servs., No. 14-699V, 2019 WL 2572596, *13-15 (Fed. Cl. Spec. Mstr. May 29, 2019) (discussing a different theory offered by Dr. Gershwin); Bucci, 2019 WL 1891809.

as a matter of logic, she cannot establish a logical sequence of cause and effect (Althen prong two). Nevertheless, this prong is also briefly addressed.

In determining whether petitioners have established that a vaccine did cause a particular injury, the Federal Circuit has directed special masters to consider any statements from treating doctors. Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, Ms. Stillabower has advanced a letter from a treating doctor, Dr. Mehta. See Pet’r’s Resp. at 7 n.5, 9. Dr. Mehta recognized a temporal sequence in that the HPV vaccination preceded the onset of A.H.’s jaundice, marking an obvious manifestation of her Evans syndrome. However, Dr. Mehta did not opine that the HPV vaccination caused the Evans syndrome. Exhibit 3. A tentative statement from a treating doctor does not weigh heavily in support of causation. See Paterek v. Sec’y of Health & Human Servs., 527 F. App’x 875, 883 (Fed. Cir. 2013) (holding that special master did not err in refraining from crediting the testimony of a treating doctor that causation was “not impossible”).

Conclusion

Ms. Stillabower demonstrated her concern for A.H. during the hearing in Houston, and A.H. communicated how Evans syndrome has affected her. In responding to this illness, they merit sympathy. However, special masters cannot decide cases based upon sympathy and, in this case, Dr. Gershwin’s report contains gaps that he has not filled. Thus, Ms. Stillabower has not established that she is entitled to compensation.

The Clerk’s Office is instructed to enter judgment in accord with this decision.

IT IS SO ORDERED.

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