

In the United States Court of Federal Claims

No. 03-2876V

(Filed Under Seal: February 10, 2017)

(Reissued: February 27, 2017)¹

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EILISE MORIARTY, a minor, by her
parents and natural guardians, MARIE
LOUISE MORIARTY and STEPHEN
MORIARTY,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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* National Childhood Vaccine Injury
* Act; Review of Special Master's
* Remand Decision Denying Relief;
* MMR Vaccination; Application of
* Althen Test; Assessment of Expert
* Testimony.

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Petitioners.

Alexis B. Babcock, with whom were *Benjamin C. Mizer*, Principal Deputy Assistant
Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Catharine E. Reeves*, Acting
Deputy Director, and *Gabrielle M. Fielding*, Assistant Director, Torts Branch, Civil
Division, U.S. Department of Justice, Washington, D.C., for Respondent.

OPINION AND ORDER ON REMAND

WHEELER, Judge.

This vaccine case once again is before the Court, on a motion for review of the
special master's opinion issued after remand from the U.S. Court of Appeals for the Federal
Circuit. Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs., 844 F.3d 1322 (Fed.
Cir. 2016) (hereinafter "Federal Circuit remand"). The Federal Circuit vacated this Court's

¹ Pursuant to Rule 18(b) of the Court's Vaccine Rules, this opinion and order was initially filed under seal. As required
under the Rules, each party was afforded 14 days from the date of issue, until February 24, 2017, to object to the
public disclosure of any information furnished by that party. Neither party submitted any proposed redactions.

affirmance of the special master’s original denial of compensation,² and remanded it “to allow the special master to consider the entire record including the relevant medical and scientific evidence” Id. at 1333. The special master has now issued his opinion after remand, again denying compensation to Petitioners. Moriarty v. Sec’y of Health & Human Servs., No. 03-2876V, 2016 WL 5390172 (Fed. Cl. Spec. Mstr. Aug. 23, 2016) (hereinafter “Moriarty II”). Petitioners have again filed a motion for review with this Court. The Court has carefully reviewed the parties’ briefs and the entire record. The Court heard oral argument on December 20, 2016.

At issue in this case is the three-prong Althen test, established by the Federal Circuit in 2005, and well known to the vaccine bar. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). The three-prong test that must be met is as follows: (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 proximate temporal relationship between vaccination and injury. Id. at 1278. The Althen test provides the factors that a petitioner must satisfy by a preponderance of the evidence to prevail in an off-table vaccine case such as this one. See 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A).

In this case, prongs one and three are established, leaving only prong two in question. For the reasons explained below, the Court concludes that the special master’s remand decision denying relief to Petitioners must be vacated. In light of the Federal Circuit’s remand instructions, the special master as a matter of law set the bar too high for prong two, imposing an unreasonable, if not impossible, burden of proof on Petitioners. The Court finds in favor of Petitioners on liability, and remands the case to the special master for a determination of damages.

Factual Background³

Eilise Moriarty was born in 1996, and faced developmental challenges at a young age, receiving treatment beginning at age two. At age three she was diagnosed with hypotonia and developmental delays, which included delayed language development. In the fall of 2000, she began a special education preschool program. A progress report in October 2000 showed that she was making improvements in her fine motor and speech skills. Eilise’s school required her to have vaccinations before returning to class in January 2001. On January 2, 2001, Eilise received the measles, mumps, and rubella (MMR) vaccine at issue in this case. Five days later she suffered a seizure at home, as reported by her older brother.

² Moriarty v. Sec’y of Health and Human Servs., 120 Fed. Cl. 102 (2015), affirming Moriarty v. Sec’y of Health and Human Servs., No. 03-2876V, 2014 WL 4387582 (Fed. Cl. Spec. Mstr. Aug. 15, 2014), (hereinafter “Moriarty I”).

³ All facts are drawn from Moriarty II, and are presented in greater detail in previous decisions. The facts are not in dispute.

Over the next six months, Eilise continued to have seizures and frequent hospitalizations. When she was admitted to the hospital on March 26, 2001, Eilise's mother reported that she had experienced more than 20 episodes of seizures in the prior three days, and that she would fall to the floor during each one. Eilise continued to suffer seizures until her parents brought her to Johns Hopkins Hospital in June 2001 to begin a ketogenic diet in the hope of controlling the seizures. This diet was very successful: Eilise was reportedly seizure-free almost from the beginning of the diet, and was eventually able to stop taking all seizure medications. In January 2002, in a follow-up visit to Johns Hopkins, the treating physician noted that Eilise was still seizure-free and still on the ketogenic diet, and recommended occupational, physical, and speech therapy. During her treatment at Johns Hopkins, Eilise was diagnosed with "static encephalopathy of unknown etiology" and "intractable atonic seizures, resolved with ketogenic diet."

After Eilise's seizures ended, she continued to receive treatment for deficits in language, attention, memory, and other skills. In August 2004, an independent educational evaluation noted that Eilise had a "medically acknowledged MMR reaction." Subsequent reports of treating health professionals at Georgetown University Hospital and George Washington University Speech and Hearing Center noted a history of seizures attributed to an adverse reaction to her MMR vaccination. At the time of the special master's evidentiary hearing in 2013, Eilise was seventeen years old and reading at a fifth grade level, with math and handwriting skills at a third grade level. She was being home-schooled and attending physical therapy and special education sessions. Petitioners seek compensation for damages allegedly caused by the MMR vaccination, including a seizure disorder, encephalopathy, and a decline in cognitive and motor functions.

Standard of Review

This Court has jurisdiction to review decisions of the special masters in accordance with 42 U.S.C. § 300aa-12(e)(1)-(2). Under those provisions, this Court will only set aside findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). With respect to findings of fact, the special masters have broad discretion to weigh evidence and make factual determinations. However, with respect to questions of law, the legal rulings made by a special master in connection with a vaccine claim are reviewed de novo, under a "not in accordance with the law" standard. Following this distinction, "[t]he allocation of the burdens of proof under the Vaccine Act is a legal issue subject to de novo review." Heinzelman v. Sec'y of Health & Human Servs., 98 Fed. Cl. 808, 812 (2011); see also Whitney v. Sec'y of Health & Human Servs., 122 Fed. Cl. 297, 304-305 (2015); Federal Circuit remand at 1327.

Discussion

Petitioners filed this action fourteen years ago, and the relevant facts began occurring in 2000, seventeen years ago. Eilise Moriarty received the MMR vaccine in question when she was four years old, and she is now in her early 20's. The case has been assigned at different intervals to four special masters, and is now before this Court for the second time. Cases arising under the Vaccine Act are not meant to be handled in this manner. See 42 U.S.C. § 300aa-12(g), setting time restrictions of 240 to 420 days, not including suspension or remand periods, to complete a vaccine case.

The age of the case is the crux of the problem. As a practical matter, treating physicians in 2001 did not have available to them the sophisticated medical technology of today, and were not as adept at assessing vaccine injury causation as they are in 2017. This is particularly true in trying to determine whether an MMR vaccine caused an autoimmune encephalopathy, as in Eilise's case. See Resp.'s Supp. Brief, Dkt. No. 102 at 3 (stating that there are no diagnostic criteria for autoimmune encephalopathy, and that diagnosis is only "recently recognized.") The absence of solid diagnostic evidence from 2001 should not serve as a basis for denial of relief in 2017.

The evidence that we do have before us is sufficient to establish causation. The record shows that knowledgeable health professionals pointed to the MMR vaccine as the cause of Eilise's autoimmune encephalopathy, and none of them even questioned this conclusion. The Federal Circuit observed in this regard: "[w]hile her petition was stayed, Eilise underwent examinations by a clinical psychologist, an occupational therapist, and a speech and language pathology clinician, all of whom noted in the background sections of their reports that Eilise's seizures were attributable to her second MMR vaccination." Federal Circuit remand at 1325. If any of these professionals had questioned the plausibility of this causal connection, they surely would have said so in the report, or declined to make note of it. Candidly assessed, this Court could not point to any other cause of Eilise's injury except the vaccine.

At the Federal Circuit, the Court found that the special master had erred in failing to consider the entire record, notably the second written report of Petitioner's expert, Dr. Yuval Shafir, which contained important causation information. That report, found at Docket No. 40, Exhibit 37 of the Court's record, cited and included a study referred to as the Weibel article,⁴ which the Federal Circuit found "squarely addresses" the issue here and suggests that autoimmune encephalopathy such as that allegedly suffered by Eilise can be caused by administration of an MMR vaccine. In Moriarty I, the special master specifically noted that he did not consider written evidence such as the Weibel article

⁴ Robert E. Weibel, Vito Caserta, David E. Benor, & Geoffrey Evans, "Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated With Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program," 101(3) PEDIATRICS 383-87 (1998).

because it was not explained by Petitioners' expert during oral examination. The Federal Circuit found that this was error.

The Federal Circuit determined that the Weibel article provided a persuasive medical theory to explain Eilise's injury. Referring to this article, the Federal Circuit stated that it "teaches the very point that the special master faulted the Moriartys for failing to present evidence to establish – that the MMR vaccine can cause autoimmune epileptic encephalopathy." Federal Circuit remand, at 1329. The Federal Circuit pointed to the expected outcome:

As the special master noted, much of the evidence relevant to proving *Althen* prong one in this case is relevant to proving *Althen* prong two. Thus, the special master's error in not considering relevant evidence with respect to *Althen* prong one affects his analysis with respect to *Althen* prong two as well. Moreover, there is "no reason why evidence used to satisfy one of the [*Althen*] prongs cannot overlap to satisfy another prong." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). And, in certain cases, a petitioner can prove a logical sequence of cause and effect between a vaccination and the injury (*Althen* prong two) with a physician's opinion to that effect where the petitioner has proved that the vaccination can cause the injury (*Althen* prong one) and that the vaccination and injury have a close temporal proximity (*Althen* prong three). *While we believe that this is one such case*, we hesitate to determine that in the first instance. We therefore vacate the decision below and remand to allow the special master to consider the entire record including the relevant medical and scientific evidence, such as Dr. Shafrir's second report and the articles cited therein.

Id. at 1333 (emphasis added).

In his remand decision, the special master conducted an extensive review of all of the evidence in the record including the Weibel article, as instructed by the Federal Circuit. He reversed his finding in Moriarty I that prong one had not been proven, and found that Petitioners had in fact met their burden of proof to establish possible causation. However, with respect to prong two, requiring a showing that the MMR vaccination had actually caused Eilise's injury, the special master found again that Petitioners had failed to meet their burden of proof. While he noted the Federal Circuit's emphasis in its remand opinion on proof of prong two where prongs one and three have already been established, he declined to rely on the testimony and evidence offered by Petitioners' expert to show that the MMR vaccine caused Eilise's injury. Rather, he pointed to the reports of the physicians

treating Eilise at the time of her seizures, which showed no mention of or tests for a possible reaction to vaccination. He concluded that there was insufficient proof of causation, because Petitioners were unable to “present any affirmative evidence that Eilise was antibody positive.” Moriarty II at *30. Even though health professionals treating Eilise in years following the end of her seizures noted that her problems were attributed to the MMR vaccination, the special master dismissed their views as either unreliable or based only on reports from Eilise’s mother. Id., at *32-35.

In their motion for review, Petitioners argue that the special master has discounted the discussion of Eilise’s injury in the Federal Circuit remand, which states that the Weibel article “unmistakably talks about Eilise’s injury. It suggests that the measles vaccine can cause encephalopathy, and it reports that the clinical features of this encephalopathy include seizures” Federal Circuit remand at 1330. Petitioners argue that this is a clear discussion of prong two, Eilise’s specific clinical picture, and taken with proof of prongs one and three, should be sufficient to meet Petitioners’ burden to prove causation. They also argue that the special master cannot infer an absence of autoimmune reaction in Eilise’s case merely from a lack of testing for an immunologic basis sixteen years ago, when the science of diagnosing autoimmunity was not as well developed as it is today.

In summary, instead of following the Federal Circuit’s direction, the special master prepared a 60-page, single-spaced decision finding that Petitioners had failed to satisfy prong two of the Althen test. Indeed, the special master explained away or dismissed virtually every argument offered in Petitioner’s favor. In performing this analysis, the special master imposed too great of a burden on Petitioners that could not reasonably or possibly be met. Even if this case could be regarded as a “close call,” the Federal Circuit has held that “close calls regarding causation are resolved in favor of injured claimants.” Althen, at 1280, citing Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Application of this principle results in Petitioners’ recovery.

Conclusion

Based upon the foregoing, the Court vacates the special master’s remand decision, and finds that Petitioners shall prevail on liability. The Court remands again to the special master to determine damages. Pursuant to RCFC App. B, Rule 28(b), the remand period shall not exceed 90 days.

IT IS SO ORDERED.

s/Thomas C. Wheeler
THOMAS C. WHEELER
Judge