In the United States Court of Federal Claims

No. 06-846
(Filed: June 1, 2011)[1]

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SHARON E. RAYBUCK and RANDALL L. RAYBUCK, as Parents and Natural Guardians of MALACHI M. RAYBUCK,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

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Ronald L. Rosenfield, Cleveland, Ohio, for petitioners.

Glenn A. MacLeod, United States Department of Justice, Civil Division, Washington, D.C., for respondent.

OPINION

BRUGGINK, *Judge*.

Petitioners Sharon E. and Randall L. Raybuck seek review of a decision entered by the special master denying compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2006). Petitioners allege that the trivalent influenza vaccination

[1] In accord with the Rules of the Court of Federal Claims, App. B, Rule 18(b), this opinion was initially filed under seal on May 12, 2011. The parties were afforded fourteen days in which to propose redactions. Neither party proposed any redactions.

administered to their son, Malachi, caused a severe rash, prompting his doctors to change his seizure medicine, which led to a worsening of his epilepsy and resulted in seizures that caused brain damage.

The parties agree that it was reasonable under the circumstances for Malachi's physicians to change his medication. Thus, the question before the special master was whether the vaccination caused the rash and thus triggered the events that culminated in Malachi's injury. The special master, after considering the parties' submissions and hearing testimony from their medical experts, concluded that the Raybucks failed to establish that the vaccine either caused or significantly aggravated Malachi's condition. Accordingly, the special master denied petitioners' petition for compensation.

The Raybucks concede there is no conclusive proof supporting their argument that the vaccination caused the rash but contend that they submitted sufficient evidence to establish their theory of causation. They allege that the special master erroneously rejected their proffered medical theory and wrongly discounted the evidence and testimony purporting to causally connect the vaccination and the injury. The matter has been briefed and we deem oral argument to be unnecessary. For the reasons set forth below, petitioners' motion for review is denied.

BACKGROUND[2]

Malachi Raybuck was born on September 27, 2001. He suffered his first seizure at around the age of five months and was hospitalized twice in 2002 for seizures. Despite treatment with several different medicines, his seizures persisted throughout 2002, resulting in some developmental delays. At 13 months old, Malachi was diagnosed with a generalized seizure disorder. Malachi continued to suffer from seizures into 2003, particularly when he had an infection, but enjoyed a reprieve for about five months in the summer and fall of 2003. In November of that year, Malachi visited a children's clinic as a result of sickness and an episode of seizures.

On December 12, 2003, Malachi received his first trivalent influenza vaccination. Ten days later, his parents brought him to his doctor, complaining

[2] The facts are drawn from the parties' joint stipulation of uncontested facts and the special master's decision and, unless otherwise noted, are undisputed.

of a generalized, severe rash.[3] His doctor suspected that the rash was a hypersensitivity reaction to his seizure medication, Dilantin, and proposed changing Malachi's medication to Klonapin, another anti-convulsant drug. On December 24, 2003, the Raybucks took Malachi to the emergency room for a severe, widespread, red rash and swollen hands. His seizure medication had not yet been changed, and doctors feared he was suffering from a potentially life-threatening drug reaction. They immediately discontinued Dilantin and started Klonapin.

Two days later, on December 26, 2003, Malachi was admitted to a children's hospital because of worsening seizures. Notes on a chest x-ray taken at that time mention possible viral or airway disease. Malachi was hospitalized for nearly two months, during which time he suffered encephalopathy leading to developmental regression. While in the hospital, he also had periodic fevers and another rash. Malachi's doctors resumed use of Dilantin in 2005 with no adverse effects.

PROCEDURAL HISTORY

The Raybucks filed a claim under the Vaccine Act in December of 2006. In 2010, after conducting a hearing on entitlement, the special master issued a written opinion denying the Raybucks' claim.[4] In reaching her conclusion, the special master heard the testimony of three expert witnesses, considered the written report of a fourth expert, and reviewed several dozen medical and scientific journal articles, ultimately concluding that "[t]he preponderance of the evidence under each of the *Althen* [*v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005)] prongs does not support the conclusion that Malachi's rash was caused by his flu vaccination." *Raybuck* at *3.

The Raybucks posited an extended claim of causation: that the vaccination caused the rash, resulting in the change in Malachi's medication, which allowed the seizures that resulted in brain damage. The parties concede that the alteration of Malachi's medicine was reasonable, though mistaken.

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[3] The parties dispute when exactly the rash developed. Petitioners allege it began two or three days after the vaccination. The government, based on a contemporaneous records, argues it began a week after the vaccination.

[4] *Raybuck v. Sec'y of HHS*, No. 06-846V, 2010 WL 4860778 (Nov. 9, 2010) (hereinafter "*Raybuck*").

Accordingly, the issue before the special master was limited to the first step in the causal chain, namely whether the vaccination caused the rash.

In her published decision, the special master summarized the credentials and testimony of Dr. Michael Rieder, the expert witness on whom the Raybucks chiefly relied.[5] Dr. Rieder, an expert in immunopharmacology,[6] stated that the precise cause of Malachi's rash was uncertain, but that there were three possibilities: a virus, a drug reaction, or the flu vaccine. He testified that based on a differential diagnosis—basically the process of elimination—he believed the rash was caused by a vaccine reaction.

Of the three possible causes, Dr. Rieder ruled out a viral rash based on the absence of prodromal[7] symptoms of a viral infection and because of the physical characteristics of the rash, including its spread to Malachi's palms. Nor did he believe the chest x-ray was an indication of viral infection. Dr. Rieder also ruled out a drug reaction as the cause of the rash, a point the government does not contest, because there was no evidence that the medicine concentration in Malachi's blood was any different than its usual level.[8] Thus, while conceding that he could not pinpoint an exact causal relationship, Dr. Rieder testified that a vaccine reaction was the most likely cause of Malachi's rash. He agreed, however, that none of Malachi's treating physicians had suspected or diagnosed a vaccine-induced reaction and that the rash could be consistent with a viral rash. He further admitted that in most cases, both viral- and vaccine-induced rashes are of limited severity and duration, whereas Malachi's rash worsened over several days and lasted more than two weeks.

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[5] Petitioners also submitted the written report of Dr. Amy S. Paller, who did not testify. At the hearing on entitlement, the petitioners did not rely on the theory propounded in her report.

[6] Immunopharmacology involves studying the effects of drugs on the immune system. Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/medical/immunopharmacology.

[7] Prodromal symptoms are the early signs "indicating the onset of a disease or morbid state." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1513.

[8] In his written report, Dr. Rieder suggested that an interaction between the vaccine and Dilantin could have resulted in an elevated level of the anti-convulsant medication and caused the rash. At the hearing before the special master, Dr. Rieder abandoned this theory for lack of evidence.

The special master also summarized the 11 articles submitted with Dr. Rieder's report. Some relate to his subsequently discarded theory that the vaccination caused a drug interaction with Dilantin. *See* note 8. Others related to drug reactions in people with immune system deficiencies—a condition from which Malachi does not suffer. Another discussed instances of erythema multiforme, a rash-like skin disorder, reported after diphtheria-pertussis-tetanus vaccinations. The special master also summarized two articles submitted during the hearing and relied upon by Dr. Rieder that examine data from the Vaccine Adverse Event Reporting System ("VAERS"). Both of these articles note VAERS reports that a rash may be among the adverse events experienced by some children after receipt of the flu vaccine.

The special master's decision also summarized the testimony presented by the government arguing that a viral infection, not the vaccination, was the most likely cause for Malachi's rash. The government relied on two expert witnesses: Dr. Christine McCusker, a pediatric immunologist, and Dr. Gerald Raymond, a neurologist and clinical geneticist with a background in pediatrics.

Dr. McCusker agreed with the Raybucks' expert that there were three possible causes for Malachi's rash, but argued that the most likely cause was a virus. She identified several reasons for this view: Malachi's prior history of rash associated with viral infections, the commonality of viral rashes in children, and Malachi's x-ray suggesting viral infection or airway disease. Dr. McCusker noted that, although there are many viruses that could cause the rash described in Malachi's case, she could not identify a particular virus as causative and merely used that word as a generic term.

In addition, Dr. McCusker discussed the difference between vaccine- and viral-induced rashes, stating that the former typically occur soon after vaccination, last one to two days, and are localized. In contrast, a viral rash may last from several days to several weeks and may be more widespread. She attributed these differences to the fact that a vaccine contains a killed virus and thus has a less potent effect on the immune system than a live virus does. In addition, she noted that many viruses are asymptomatic or that a rash may appear before or independent of other viral symptoms. Dr. McCusker acknowledged that 14% of VAERS reports identified a rash as a possible result of the flu vaccine but found these reports of limited value for proving causation due to the nature and limitations of VAERS.

The government also presented the testimony of Dr. Gerald Raymond, who likewise testified that he believed a virus, not the flu vaccine, had caused

Malachi's rash. He identified several factors in support of this belief, including the widespread and red appearance of Malachi's rash, the chest x-ray, the exacerbation of his seizures, and his encephalopathy.

The special master summarized many of the 32 articles submitted with the government's experts' reports, including articles discussing administration of the flu vaccine to individuals with immune deficiencies, skin reactions to anti-convulsant medication, interactions between the flu vaccine and anti-convulsant medication, and the effect of changing anti-convulsant medications.

The special master carefully and thoroughly laid out the applicable law before evaluating the parties' contentions.[9] She concluded first that the Raybucks had failed to establish a biologically plausible theory explaining how a flu vaccine could cause the type of injury alleged. Specifically, she noted that while a "sufficiently rigorous differential diagnosis can support a finding of causation under the Vaccine Act . . . Dr. Rieder's opinion is not sufficient to establish that Malachi's vaccination could likely have caused a rash of this type." *Raybuck* at *18. She based this conclusion on the fact that, in her view, Dr. McCusker had presented convincing and unrebutted testimony refuting each of the factors upon which Dr. Rieder's diagnosis relied. In making this assessment, the special master found the views of Dr. McCusker, who is a specialist in pediatric immunology, more persuasive than Dr. Rieder's. The special master also discounted the petitioners' reliance on VAERS reports, noting that they are not regarded as strongly probative on causation issues.

Similarly, the special master found that the Raybucks failed to prove a logical sequence of cause and effect showing that Malachi's vaccination caused the rash that led to his eventual injury. She noted that no treating physician had suggested that the rash was related to the flu vaccination and that the evidence made it unlikely that the vaccine had caused a rash with the characteristics of Malachi's.

Finally, the special master considered the temporal association between the vaccination and the rash, noting that it was appropriate as to onset but not as to duration. In the absence of a plausible medical theory, a logical cause-

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[9] The special master noted that the petitioners had not explicitly stated if their claim was for direct vaccine causation or for significant aggravation of a pre-existing condition. She concluded that this distinction was irrelevant because, in either case, the three-pronged *Althen* test applies and petitioners fail to satisfy that test.

and-effect relationship, and an appropriate temporal relationship, the special master concluded that the Raybucks had failed to present a *prima facie* case of vaccine causation and dismissed their case.

DISCUSSION

This court has jurisdiction to review the special master's decision. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). Several outcomes are available to us on review. We may sustain the decision, remand to the special master, or set aside the decision and issue our own findings of fact and conclusions of law. *Id.* § 300aa-12(e)(2). We review the decision for findings and conclusions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 300aa-12(e)(2)(B). This standard of review applies differently to different aspects of the special master's decision: findings of fact are reviewed under the deferential "arbitrary and capricious" standard, legal conclusions under the "not in accordance with law" standard, and discretionary rulings for an "abuse of discretion." *Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In their memorandum in support of the motion for review, the Raybucks allege two errors. First, they argue that the special master erred in ruling that petitioners failed to establish a plausible medical theory of vaccine causation. *See* Ptrs' Mem. in Supp. of Mot. for Rev. (hereinafter "Ptrs' Mem.") at 5. Second, they allege that the special master erred by discounting their expert witness' opinion that based on a differential diagnosis the vaccine was the most likely cause of Malachi's condition. *See* Ptrs' Mem. at 12. Having reviewed the special master's findings and conclusions, we cannot say they were arbitrary, capricious, or not in accordance with law.

I. Overview of the Vaccine Act

The Vaccine Act provides two routes for a petitioner to obtain compensation. Under the easier of the routes, known as a "table injury," the claimant need only show he received a vaccination listed on the Vaccine Injury Table and suffered one of the listed corresponding injuries within the prescribed time after the vaccination. *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1319 (Fed. Cir. 2006)). Upon this showing, the vaccine is presumed to have caused the injury. *Id.*

The other route, which is used in this case, is called an "off-table" injury and does not carry with it the presumption of causation. Instead, the petitioner must prove that the vaccination caused or significantly aggravated an illness, disease, disability or condition.[10] *See* 42 U.S.C. § 300aa-11(c). In *Althen v. Sec'y of HHS*, the Federal Circuit set out a three-prong test for establishing causation in an off-table claim:

> Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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.

418 F.3d 1274, 1278 (2005); *see Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1338 (Fed. Cir. 2010). The first prong asks whether the vaccine in question *can* cause the injury alleged. *Pafford*, 451 F.3d at 1356. The second prong applies the medical theory and asks whether the vaccine *did* cause the petitioner's injury. *Id.* The third prong asks whether symptoms occurred within a time frame that is neither too late nor too soon after the allegedly causal vaccination. *See De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). These three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355.

II. Petitioners' Allegations of Error

Petitioners first allege that the special master erred in ruling that they failed to establish a plausible medical theory of vaccine causation. It is petitioners' burden to prove by a preponderance of the evidence that the vaccine caused the injury alleged, including "a reputable medical or scientific explanation that pertains specifically to [their] case." *Moberly v. Sec'y of HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). Here, petitioners' arguments turn on whether the special master properly evaluated their reliance on a differential

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[10] The claimant must also show that the allegedly injurious vaccine is listed on the Vaccine Injury Table, was received while within the United States, and that the effects of that injury lasted more than six months or resulted in surgery or death. 42 U.S.C. § 300aa-11(c). Litigation rarely concerns these requirements.

diagnosis to determine the most likely cause of Malachi's rash.[11] After review, we cannot conclude that the special master's ruling was arbitrary, capricious, or not in accordance with law.

Both parties' experts concede that the flu vaccine is among the possible causes for Malachi's rash, but they differ as to whether the vaccine actually did cause the rash. Dr. Rieder, the Raybucks' principal expert, admitted that he could not definitively prove causation, but explained the reasons behind his opinion that the vaccination was the most likely cause. These included the appearance of the rash, the absence of other viral symptoms, the temporal association with the vaccination, and VAERS data. The special master, however, found that the government's expert testimony persuasively "refuted each of the factors relied upon by Dr. Rieder." *Raybuck* at *18. Specifically, she was convinced by Dr. McCusker's detailed explanation that a vaccine-induced rash would differ from Malachi's rash in its onset, severity, and duration. Dr. McCusker further explained that because some viruses are asymptomatic or manifest only as a rash—a point conceded by Dr. Rieder—the absence of prodromal symptoms was not conclusive in determining the rash's origin. The special master also noted that the VAERS reports, on which Dr. Rieder partially relied, "are not regarded as strongly probative on the causation issue." *Raybuck* at *18-19 (citing *Analla v. Sec'y of HHS*, 70 Fed. Cl. 552, 558 (2006)).

We cannot say that the special master erred in her evaluation of the testimony and weighing of the evidence. Special masters have broad discretion in determining the credibility and persuasiveness of witnesses and in ascribing weight to that testimony. *Bradley v. Sec'y of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993); *Stapleford v. Sec'y of HHS*, 89 Fed. Cl. 456, 462 (2009); *see Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("[C]onsiderable deference must be accorded to the credibility determinations

[11] The special master and the parties discuss the differential diagnosis in the context of *Althen's* first prong, which requires a medical or biological theory explaining that the vaccine *can* cause the injury alleged. As the special master noted, however, Dr. Rieder "did not actually endorse any biological theory to explain the alleged vaccine injury." *Raybuck* at *17. We think that the analysis of the differential diagnosis is better suited for *Althen's* second prong, which inquires whether there is a logical sequence showing that the vaccine *did* cause the injury. Regardless of how the issue is framed, however, we cannot say the special master was wrong in her conclusion that the differential analysis was not sufficiently robust to support petitioners' claim.

of special masters."). It is not the role of the reviewing court "to reweigh the factual evidence . . . or the credibility of the witnesses," *Munn v. Sec'y of HHS*, 970 F.2d 863, 871 (1992), and we cannot say that the special master's findings were arbitrary and capricious. "'If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" *Masias v. Sec'y of HHS*, 634 F.3d 1283, 1287-88 (Fed. Cir. 2011) (quoting *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

The Raybucks' second numbered objection to the special master's ruling is similar to the first, namely that the special master erroneously discounted petitioners' reliance on a differential diagnosis and ignored their expert's qualifications. Specifically, petitioners allege that the special master wrongly cited to the Federal Circuit's holding in *Moberly* as support for her determination that a differential diagnosis was insufficient proof of causation. In that case, the Federal Circuit confronted an issue similar to the one here: a vaccine conceded to be capable of causing the injury alleged, an absence of any definitive cause for the injury, and a temporal association between the vaccination and the onset of symptoms. The court concluded that this was not enough to prove causation. "'[N]either a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" *Moberly*, 592 F.3d at 1323 (quoting *Althen*, 418 F.3d at 1278). Thus, we cannot say that the special master erred by concluding that Dr. Rieder's elimination of other possible causes of the rash was not sufficient to prove causation.

Nor do we agree with the Raybucks' argument that the special master ignored or discounted Dr. Rieder's qualifications. The special master was clearly aware of his qualifications, which she detailed in her opinion. *See Raybuck* at *5. She also noted that Dr. Rieder was "in every respect a reliable witness" and that his testimony was "clear, candid, and informed." *Id.* at *8 n.12. The special master explained her reasoning in giving more weight to Dr. McCusker, namely that she was a specialist in pediatric immunology. *Id.* at *18.[12] As we have already noted, it is within the special master's discretion to determine the weight to afford the conflicting testimony presented to her, and it was not an error for her to do so.

[12] The special master similarly gave less weight to the government's second witness because he was a neurologist, not an immunologist. *See Raybuck* at *12 n.15.

Finally, although the Raybucks do not explicitly dispute the special master's finding on *Althen's* third prong—the appropriate temporal relationship between the vaccination and the onset of disease—we address it briefly and conclude that the special master was not arbitrary or capricious in concluding that petitioners failed to establish this factor. The special master determined that the time frame for a vaccine-induced rash was, in this case, appropriate as to the onset but not as to its duration.[13] In their testimony, both parties' experts agreed that a vaccine-induced rash would occur very soon after the vaccination. Dr. McCusker persuasively argued, however, and the Raybucks' expert acknowledged, that Malachi's rash, which persisted for more than two weeks, lasted longer than would be expected. Although Malachi's rash developed soon after the vaccination, *Althen's* third prong looks for more than simply a rapid symptom. *See De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (2008) ("[W]e see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked."). Accordingly, we cannot say the special master's ruling was error.

CONCLUSION

Petitioner has failed to demonstrate that the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Accordingly, we sustain the decision of the special master, and deny petitioners' motion for review. The Clerk is directed to enter judgment accordingly.

s/Eric G. Bruggink
Eric G. Bruggink
Judge

[13] The parties dispute the timing of the rash's development. In her discussion of *Althen's* third prong, however, the special master adopted the timing alleged by petitioners. Even so, she concluded that the temporal relationship did not support a finding of vaccine causation.