United States Court of Appeals for the Federal Circuit

CYNTHIA LALONDE, parent of,
M.L., a minor,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2013-5088

Appeal from the United States Court of Federal Claims in No. 06-VV-0435, Judge Margaret M. Sweeney.

Decided: March 28, 2014

CURTIS R. WEBB, Law Office of Curtis R. Webb, of Twin Falls, Idaho, argued for petitioner-appellant.

LINDA S. RENZI, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were STUART F. DELERY, Assistant Attorney General, RUPA BHATTACHARYYA, Director, VINCENT J. MATANOSKI, Deputy Director, and VORIS E. JOHNSON, JR., Assistant Director.

Before NEWMAN, PROST, and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

PROST, *Circuit Judge*.

This case, brought under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, as amended (the "Vaccine Act"), presents the question whether petitioner Cynthia LaLonde, on behalf of her son M.L., has proven by a preponderance of the evidence that M.L.'s diphtheria-tetanus-acellular pertussis ("DTaP") vaccination caused a focal brain injury. The special master found that although M.L.'s DTaP vaccination likely caused his initial anaphylactic reaction, Ms. LaLonde failed to establish under any reliable medical theory that M.L.'s anaphylaxis caused a focal brain injury. *See LaLonde v. Sec'y of Health & Human Servs.,* No. 06-435V, 2012 WL 5351164 (Fed. Cl. Spec. Mstr. Sept. 28, 2012). After a careful consideration of the record, the U.S. Court of Federal Claims upheld that finding. *See LaLonde v. Sec'y of Health & Human Servs.,* 110 Fed. Cl. 184 (2013). We affirm.

I. BACKGROUND

The relevant facts are primarily those found by the special master in his detailed September 28, 2012 decision. *See LaLonde,* 2012 WL 5351164, at *3-6. M.L. was born on September 24, 2003. At his fifteen-month well-child visit, his pediatrician noted that M.L. was walking and generally developing normally but did not "want to talk." On April 14, 2005, M.L. received several immunizations, including the DTaP vaccination. About five hours later, M.L. allegedly began experiencing an abnormally high fever and some swelling. The next day M.L. was admitted to the hospital with a diagnosis of "vaccine adverse reaction with secondary fever, angiodema, and anaphylactoid reaction." J.A. 20. He was discharged on

April 16, 2005. However, the following morning M.L.'s mother called an ambulance because M.L. was exhibiting signs of hypothermia and seizure-like episodes.

In the weeks and months following the administration of the DTaP vaccination, M.L.'s vocabulary allegedly decreased, worrying his parents and his doctors. An MRI of M.L.'s brain with and without contrast was normal, revealing a deep bilateral middle ear infection but no brain damage. Nonetheless, M.L. continued to exhibit several "seizure-like" activities, but after a few months he was weaned off anti-epileptic medication. After observing M.L.'s developmental delays and repetitive behaviors, a pediatric neurologist placed M.L. in the autism spectrum disorder category.

II. PROCEDURAL HISTORY

Ms. LaLonde filed a petition under the Vaccine Act on June 1, 2006, seeking compensation for M.L.'s alleged injuries. The case was assigned to a special master, who heard expert testimony from Dr. Marcel Kinsbourne for Ms. LaLonde. Dr. Kinsbourne testified that M.L. experienced a two-phase anaphylactic reaction that included a delayed second state. He pointed to medical literature that supports the existence of late-phase anaphylactic reactions and offered three possible mechanisms of injury that have been shown in medical literature to result from an anaphylactic reaction. However, Dr. Kinsbourne was unable to point to anywhere in the literature that describes the sequence of events that are presented in this case. Dr. Kinsbourne also admitted that he lacked any reliable medical evidence supporting the notion that anaphylactic shock can cause focal brain injuries.

After reviewing the evidence in the case, the special master saw what he called a "major gap" in Ms. LaLonde's case. *LaLonde,* 2012 WL 5351164, at *1. He alerted Ms. LaLonde to this fact and allowed her to submit new evidence, updated medical records, and a revised

expert report. *Id.* at *2. Nonetheless, after re-reviewing the entire record, the special master found two decisive defects in Ms. LaLonde's case: (1) Dr. Kinsbourne's opinions were based on information provided by Ms. LaLonde and not on medical information found in the record; and (2) the record indicated—and all experts agreed—that M.L.'s initial reaction to the immunizations resolved, and Dr. Kinsbourne's theory that there was a secondary, delayed anaphylactic reaction was unsupported by the record. *Id.* at *3.

On review, the Court of Federal Claims concluded that the special master abused his discretion by discrediting Dr. Kinsbourne's opinions that were based on statements made by Ms. LaLonde, even if some of her statements were in conflict with the medical records. *LaLonde*, 110 Fed. Cl. at 204. Nonetheless, the Court of Federal Claims concluded that this abuse of discretion was "harmless." *Id.* It explained that the special master "quite properly required [Ms. LaLonde] to carry her burden to bring forward a reliable medical or scientific explanation," and she failed to do so. *Id.* at 201. Her expert, Dr. Kinsbourne, testified that he had never seen an anaphylactic reaction lead to a focal brain injury, he did not find any support for a link in the medical literature, and he had an incomplete understanding of how the reaction could evolve into a focal brain injury. *Id.*

We have jurisdiction to review the final judgment of the Court of Federal Claims under 42 U.S.C. § 300aa-12(f).

III. THE VACCINE ACT

In 1986, Congress passed the Vaccine Act to establish a program administered by the Secretary of Health and Human Services to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1; *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). The Vaccine Act created the National Vaccine

Injury Compensation Program, through which claimants could petition to receive compensation for vaccine-related injuries or death. *See* 42 U.S.C. § 300aa-10(a).

To receive compensation, a claimant must show, by a preponderance of the evidence, that the vaccinated person received a covered vaccine and either: (1) suffered an injury, condition, or a significant aggravation of a pre-existing injury or condition listed on the Table within the requisite time frame, in which case causation is presumed (a "Table injury"); or (2) suffered an injury or condition or suffered the significant aggravation of a pre-existing injury or condition not on the Table, in which case causation must be proven (a "non-Table injury"). *See* 42 U.S.C. §§ 300aa-11(c)(1)(C), 300aa-14; 42 C.F.R. § 100.3 (2011). To prove actual causation in a non-Table injury case, the petitioner must

> show by preponderant evidence that the vaccination brought about [the] 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 the vaccination and the injury.

Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (quoting *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). If the petitioner satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen,* 418 F.3d at 1278 (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994)) (alteration in original). The petitioner is not required to prove the case to a level of scientific certainty. Rather, the burden of showing something by a preponderance of the

evidence, the most common standard in the civil law, simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence. *Moberly,* 592 F.3d at 1322 n.2 (quoting C*oncrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)).

IV. STANDARD OF REVIEW

In Vaccine Act cases, we review a ruling by the Court of Federal Claims de novo, applying the same standard that it applies in reviewing the decision of the special master. *Moberly*, 592 F.3d at 1321 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1360 (Fed. Cir. 2000)). We review factual findings under the arbitrary and capricious standard, and we review legal rulings to determine whether they are "not in accordance with law." *Id.* (citing *Munn v. Sec'y of Health & Human Servs.,* 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

V. DISCUSSION

On appeal, Ms. LaLonde argues that the special master made a legal error when he denied her claim for compensation. Relying on *Knudsen v. Secretary of Health and Human Services,* 35 F.3d 543 (Fed. Cir. 1994), she claims that the special master used an incorrect legal standard when he required Ms. LaLonde to prove the mechanism through which the initial anaphylactic reaction caused M.L. to later suffer focal brain injuries. She argues that although Dr. Kinsbourne had proposed three potential mechanisms, the special master discredited him due to his failure to specify which caused M.L.'s injury.

Additionally, Ms. LaLonde acknowledges that under our case law, a temporal relationship alone between a vaccination and injury would not logically support a causal relationship. *Moberly*, 592 F.3d at 1323. But she

argues that "[t]here is a very significant difference between inferring causation from a proximate temporal relationship between an *anaphylactic reaction* and an injury [which is what she requests that we do], and inferring causation from a proximate temporal relationship between a *vaccination* and an injury," which the law states is not enough to receive relief under the Vaccine Act. Pet'r's Reply Br. 10 (emphasis added). Ms. LaLonde claims that such a temporal association is a logical sequence of cause and effect; she asserts that the proximate temporal association between an anaphylactic reaction and a dramatic regression in speech skills suggests that the anaphylactic reaction caused the regression in speech skills.

Finally, Ms. LaLonde reminds the court that the purpose of the Vaccine Act's preponderance of the evidence standard is to "allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen,* 418 F.3d at 1280. Ms. LaLonde also requests a remand and a new hearing so that she may present new evidence that has come to light in the six years since this case began.

We have considered all of Ms. LaLonde's arguments, and while we are certainly sympathetic to her and her son, M.L., we nonetheless conclude that Ms. LaLonde has failed to meet her burden to receive her requested relief. As Ms. LaLonde correctly states in her opening brief, "to require identification and proof of a specific biologic mechanism [in Vaccine Act cases] would be inconsistent with the purpose and nature of the vaccine compensation program." Pet'r's Br. 18 (quoting *Knudsen,* 35 F.3d at 549). However, in the past we have made clear that simply identifying a "plausible" theory of causation is insufficient for a petitioner to meet her burden of proof. *Moberly*, 592 F.3d at 1322. Instead, the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not

caused the condition alleged. *See id.* ("[P]roof of a 'plausible' or 'possible' causal link . . . is not the statutory standard."); *see also* 42 U.S.C. § 300aa-13(a)(1).

Ms. LaLonde's expert, Dr. Kinsbourne, hypothesized that M.L. suffered a two-stage anaphylactic reaction—the first phase occurring before his hospital admission on April 15, 2005 and the second phase occurring when his mother called for an ambulance on April 17, 2005. Although Dr. Kinsbourne submitted medical literature describing a two-phase anaphylactic reaction, this literature does not support his testimony that M.L. had a reaction similar to the type the literature described with regard to either the timing of a two-phase event or the type of injury Ms. LaLonde alleges. Moreover, Dr. Kinsbourne acknowledged that he had never before seen the sequence he posited as having occurred here, and that it was "beyond rare." J.A. 91. And when asked to provide support for his theory that an anaphylactic reaction could cause a focal brain injury, Dr. Kinsbourne testified he did not know whether his theory was generally accepted or even discussed in the medical community. J.A. 90-91. He further testified that he had never seen an anaphylactic reaction lead to a focal brain injury, could not find support for it in the medical literature, and possessed an incomplete understanding of how the injury could evolve into a focal brain injury. *Id.*

Thus, contrary to Ms. LaLonde's argument, the special master did not require Dr. Kinsbourne to provide proof of his proposed mechanism, but instead merely required that he support his testimony with a reputable or scientific explanation that pertained specifically to M.L.'s case. *See Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012) (requiring petitioner to show both the medical plausibility of her theory of causation and that the injury was consistent with that theory). And the special master did not err in finding that Dr. Kinsbourne failed to do so.

In *Moberly*, we concluded that "the only . . . evidence in the record providing any support for [petitioner's] theory of causation was the testimony of Dr. Kinsbourne, which the special master had found to be 'contradictory and confusing' and 'shockingly poor.'" 592 F.3d at 1321. Similarly, in that case, Dr. Kinsbourne testified that his proposed mechanism had never been tested in any peer-reviewed study. *Id.* at 1324. In affirming the finding that Dr. Kinsbourne's testimony was insufficient, we noted that he "undercut his own position by conceding not only that [his proposed theory] had never been tested, but also that there was no evidence suggesting that it applied to [the petitioner's] case." *Id.* at 1325. Likewise, here Dr. Kinsbourne has proposed three mechanisms, but none are supported in any peer-reviewed study. And there is no evidence beyond Dr. Kinsbourne's testimony suggesting that any of the three proffered mechanisms applied to M.L.'s case.

Furthermore, as the finder of fact, the special master was responsible for assessing the reliability of Dr. Kinsbourne's testimony by looking for reliable medical or scientific support. *See Moberly*, 592 F.3d at 1324-25. In doing so, the special master was "entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to [him] and, if appropriate, as to the credibility of the persons presenting the evidence." *Id.* at 1326. Regarding Dr. Kinsbourne's testimony, the special master stated that he found it "necessary to address the credibility of petitioner's expert," and noted that the "testimony in this case was as poor as any the undersigned has experienced in twenty years." *LaLonde*, 2012 WL 5351164, at *17.

Additionally, it was not the government's burden to provide an alternative explanation. *See, e.g.*, *Althen*, 418 F.3d at 1278 (stating that only *after* the petitioner satisfies her burden by preponderant evidence does the burden shift to the government to show that the injury was in

fact caused by factors unrelated to the vaccine); 42 U.S.C. § 300aa-13. Nonetheless, the government's expert witness, Dr. John MacDonald, not only contradicted Dr. Kinsbourne's testimony by stating that he did not believe that M.L. had a focal brain injury as a result of an anaphylactic reaction but also pointed to the evidence in the record supporting his theory that M.L.'s speech delay was caused by a deep bilateral middle ear infection. J.A. 145, 277, 297.

In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard. The level of specificity of such support may vary from circumstance to circumstance. But the special master here could properly find insufficient the reliance by Ms. LaLonde's expert on a theory that is unsupported by the literature to explain a sequence he had never seen before. Given that conclusion, the basis for Ms. LaLonde's petition reduces to a temporal relationship between the administration of the DTaP vaccine and M.L.'s focal brain injuries. As we have stated before, a temporal correlation alone is not enough to demonstrate causation. *Moberly*, 592 F.3d at 1323.

VI. CONCLUSION

In this case, as in *Moberly*, the special master and the Court of Federal Claims applied the correct legal standard and found, based in part on the unconvincing nature of Dr. Kinsbourne's testimony, that the petitioner failed to prove causation by a preponderance of the evidence. That judgment has not been shown to be legally or factually erroneous. We therefore affirm the judgment of the Court of Federal Claims.

AFFIRMED

COSTS

Each party shall bear their own costs.

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Appeal from the United States Court of Federal Claims in No. 06-VV-0435, Judge Margaret M. Sweeney.

NEWMAN, *Circuit Judge*, dissenting.

On April 14, 2005 Petitioner LaLonde's son M.L. had an 18-month well-child visit with his pediatrician, at which he received immunizations for varicella, DTaP (diphtheria, tetanus-a, and pertussis), HiB (Haemophilus influenza type B), and PCV7 (pneumococcal conjugate vaccine). Within five hours after the vaccinations his temperature was 104.8 degrees, accompanied by facial swelling and vomiting. The next morning his pediatrician sent him by ambulance to the hospital, where M.L. received the diagnosis of "vaccine adverse reaction with secondary fever, angioedema, and anaphylactoid reaction." The emergency doctor recorded that M.L. exhibited tongue and lip swelling, facial redness, was unable to

swallow, was drooling and was short of breath. He was discharged a day later, but the next day was returned to the hospital where he experienced multiple seizure-like episodes. He remained in the hospital for four days, as various specialists tested body and brain. Two weeks later, M.L.'s primary pediatrician referred M.L. to a University Hospital Neurologist after his mother reported that he would not speak. All of the contemporaneous records refer to the events as a reaction to his vaccine.

M.L.'s medical history is not disputed, that from his birth to his 18-month well-child appointment, he appeared to be a normal healthy child with an age-appropriate vocabulary, and was reduced to mostly unintelligible sounds following his vaccination. The record consistently describes "seizure disorder and language regression" following his vaccine administration. M.L. thereafter was seen by multiple neurologists, a developmental specialist, and a speech therapist, whose reports are in the record. A treating physician wrote in September 2005:

> Since the day of the shots, (M.L.) has lost the ability to speak as he had previously. Up to that time he had a normal vocabulary for his age and was attempting to put words together such as "I want." Since then, however, he is mostly able to utter only unintelligent sounds and occasionally will utter a recognizable word.

In January of 2006 a pediatric neurologist wrote that "[i]t is puzzling that apparently his development was age appropriate up until 18 months when he had his routine immunization resulting in severe allergic reaction."

The record on this appeal does not state M.L.'s present situation, but does refer to a drastic regression in his development. M.L.'s medical history in the record, the contemporaneous statements of his treating physicians and the petitioner's expert's opinion establish a more-

likely-than-not causal relationship between M.L.'s vaccination and his resultant injuries. In the proceedings before the Special Master and the Court of Federal Claims, the only doctor who eliminated the vaccine as a causative agent of the observed injuries was the government's expert, Dr. McDonald. However, even Dr. McDonald agreed that M.L. had an adverse reaction to the vaccine.

Vaccine injury is rare, and the path of causation is not well understood. Recognizing the uncertainties of immunization science, the Vaccine Act establishes that when injury occurs a claimant is not required to prove causation as a matter of medical certainty. Thus the Vaccine Act requires that, for non-Table injuries, liability must be shown by a preponderance of the evidence, and that reasonable doubt is resolved in favor of the claimant. This standard is premised on the appreciation that a scientific causal relationship between a vaccine and a particular injury may be hard to prove. The court explained in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1280 (Fed. Cir. 2005) that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *See also Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) ("requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in *Althen*.").

Contrary to my colleagues' ruling today, the requirement for specific cause-effect studies published in peer-reviewed scientific journals, whatever the nature and weight of the other evidence, "contravenes section 300aa–13(a)(1)'s allowance of medical opinion as proof." *Id.* As in *Althen*, the mechanism of M.L.'s injury remains "a

sequence hitherto unproven in medicine." 418 F.3d at 1280. Medical certainty is not the standard for a Vaccine Act claim: "[t]he determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994). Precedent also confirms that a claimant may satisfy the Vaccine Act burden with circumstantial evidence, *Althen*, 418 F.3d at 1279–80.

The Vaccine Act also provides that even if there was a preexisting weakness, the resultant injury is compensable when it is aggravated by the vaccine. *See* 42 U.S.C. §300aa-11(c)(1)(C)(ii)(I) (compensation is available if a vaccination "significantly aggravated[] any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in" the Vaccine Injury Table); *Locase v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1379 (Fed. Cir. 2012).

Petitioner's expert witness Dr. Kinsbourne, Professor of Pediatric Neurology at Duke University, posited three possible mechanisms for how the DTaP vaccine could have resulted in M.L.'s injuries. He explained that the mechanism of anaphylaxis includes impairment of blood flow through blood vessels and impairment of oxygenation, which mechanisms are consistent with damage of the cerebral circulation. Dr. Kinsbourne discussed M.L.'s reaction to the vaccine, identified the mechanisms that are frequently part of such reaction, and explained how those mechanisms could have caused M.L.'s injury. He explained how the impairment of oxygenation and blood flow can affect speech. He wrote in his expert report that M.L. was impaired in expressive language and that he only recently began to eat solid foods and had yet to regain his potty-training. He stated that he relied on the medical literature for aspects of M.L.'s case with which he did not have personal experience. He acknowledged that

he had not previously seen speech impairment as a reaction to the DTaP vaccine, and that he had found no publication of scientific/medical study of this aspect. He gave his expert opinion that it was more likely than not that M.L.'s injuries were caused by the vaccine.

The Court of Federal Claims, affirming the Special Master, adopted the opinion of the government's expert, Dr. MacDonald, that M.L.'s speech disability was caused by a "deep bilateral middle ear infection." The record does not show that M.L. had an ear infection at or about the time of his vaccinations, and MRIs on April 26, 2005 and November 25, 2005 were described as normal, with the exception of pan-sinusitis seen in the November MRI. A physician's report on December 27, 2005 stated that M.L. had fluid behind both ears, and suggested that this was leading to conductive hearing loss; this physician also wrote that he has seen nerve deafness resulting from a vaccination. To support his theory, Dr. McDonald referred to a notation in M.L.'s 15-month checkup that M.L. did not "want to talk." Dr. McDonald dismissed the records of M.L.'s physicians with respect to M.L.'s situation before and after the vaccinations and expressed skepticism regarding their treatment plans.

The Special Master found Dr. MacDonald more "credible" than Dr. Kinsbourne, and challenged Dr. Kinsbourne's credibility in part because he relied on an unsigned narrative of events provided by M.L.'s mother, Mrs. LaLonde. Although my colleagues observe that the Court of Federal Claims dismissed the Special Master's credibility determination as erroneous, for Mrs. LaLonde's narrative also appeared in a signed and sworn affidavit that the court found to be both reliable and consistent with M.L.'s medical records, nonetheless my colleagues rule that the petitioner did not submit "trustworthy" and "sufficient" testimony. My colleagues also discard this court's admonition that contemporaneous written statements of treating physicians are "particularly probative."

Capizzano, 440 F.3d at 1326. This court has often observed the difficulties associated with providing scientific proof of vaccine injury causation; thus the court has stressed the standards of reasonableness and likelihood, objectively applied to the particular circumstances. *See Knudsen*, 35 F.3d at 548–49 ("[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."). The court's holding today contravenes not only precedent, but also the purpose of the Vaccine Act.

As a further consideration in this case, Petitioner LaLonde had requested remand in order to provide additional evidence. The record does not describe the proffered evidence, but since the denial of compensation was based on an evidentiary requirement that departed from precedent, minimal fairness required inquiry into the additional evidence. Instead, this too was denied.

I respectfully dissent.