

# United States Court of Appeals for the Federal Circuit

04-5146

MARGARET ALTHEN,

Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellant.

Kevin P. Conway, Conway, Homer & Chin-Caplan, P.C., of Boston, Massachusetts, argued for petitioner-appellee. On the brief was Ronald C. Homer.

Anne Murphy, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellant. On the brief were Peter D. Keisler, Assistant Attorney General, and Barbara C. Biddle and William G. Cole, Attorneys. Of counsel was Elizabeth H. Saindon, Attorney, Office of the General Counsel, United States Department of Health and Human Services, of Rockville, Maryland.

Appealed from: United States Court of Federal Claims

Judge Susan G. Braden

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DECIDED: July 29, 2005

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Before MAYER, CLEVENGER, and SCHALL, Circuit Judges.

MAYER, Circuit Judge.

The Secretary of Health and Human Services (“government”) appeals the judgment of the United States Court of Federal Claims reversing the special master’s denial of Margaret Althen’s claim under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to -34 (“Vaccine Act”), for loss of vision caused by a tetanus toxoid (“TT”) vaccination. Althen v. Sec’y of Health & Human Servs., 58 Fed. Cl. 270 (2003) (“Althen II”). Because Althen met the statutory burden for establishing causation by a preponderance of the evidence, we affirm.

## Background

On March 28, 1997, Margaret Althen, aged 49, received TT and hepatitis A vaccinations. Notwithstanding prior diagnoses of hypothyroidism and Duane’s

Syndrome,<sup>1</sup> Althen enjoyed good health. On April 15, 1997, she sought medical treatment for an incessant headache, painful eye movements, and blurred vision in her right eye, which progressed in four days to a complete loss of sight in that eye. An ophthalmologist initially diagnosed Althen's condition as right optic neuritis, inflammation of the optic nerve, which was confirmed by an April 21, 1997, magnetic resonance image. After subsequent complaints of vision impairment in her right eye and numbness in her right hand, she was diagnosed with significant right optic neuritis on May 23, 1997. On June 4, 1997, Althen was admitted to the hospital after suffering from fever, confusion and neck stiffness. After several days of testing, she was discharged with a diagnosis of acute disseminated encephalomyelitis ("ADEM"),<sup>2</sup> right optic neuritis and congenital Duane's syndrome.

Althen was again admitted to the hospital on July 2, 1997, because of dizziness and gait instability. On July 8, 1997, she was discharged after being diagnosed as possibly suffering from encephalitis<sup>3</sup> or ADEM. By June 4, 1998, her physician concluded that she had developed ADEM. On July 27, 1998, and January 7, 1999, Althen experienced optic neuritis in her left eye. On August 6, 2000, she suffered a

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<sup>1</sup> Duane's Syndrome is a hereditary eye movement disorder which limits the ability to move the eye outward toward the ear (abduction) and, in most cases, the ability to move the eye inward toward the nose (adduction). Dorland's Medical Dictionary 1816 (30th ed. 2003) (Dorland's). This ailment caused Althen to experience double vision when looking to the left.

<sup>2</sup> ADEM is a demyelinating disease affecting the nerve fibers in the nervous system which "occurs most commonly following an acute viral infection . . . but may occur without a recognizable antecedent. . . . It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Clinical manifestations include fever, headache, vomiting, and drowsiness progressing to lethargy and coma; tremor, seizures, and paralysis may also occur[.]" Dorland's at 610.

<sup>3</sup> Encephalitis is inflammation of the brain. Dorland's at 608.

brain seizure. A brain biopsy showed evidence of inflammation in the central nervous system, and she was diagnosed with vasculitis with secondary tissue destruction and demyelination consistent with primary angiitis.<sup>4</sup>

Althen initiated her Vaccine Act claim on March 31, 2000. A special master of the Court of Federal Claims held an evidentiary hearing on June 14, 2002, and in a June 3, 2003, decision denied compensation upon determining that the TT vaccination did not cause Althen's illness. Despite the testimony of Dr. Derek R. Smith, a board-certified neurologist with a subspecialty in neuroimmunology, that the TT shot caused her injury and that the onset of her optic neuritis occurred within a medically-accepted time period for causal connection, the special master found that because Althen did not provide peer-reviewed literature that demonstrated "a suspected or potential association' between the tetanus toxoid vaccine and the alleged injuries" as required by Stevens v. Secretary of Health and Human Services, No. 99-594V, 2001 WL 387418 (Fed. Cl. Sp. Mstr. Mar. 20, 2001), she did not prove causation-in-fact. Althen v. Sec'y of Health & Human Servs, No. 00-170V, 2003 WL 21439669, at \*14 (Fed. Cl. Sp. Mstr. June 3, 2003) ("Althen I") (emphasis in original).

Althen sought review of the decision by the Court of Federal Claims, arguing that the special master erred as a matter of law by imposing the Stevens test to heighten her evidentiary burden. After concluding that the Stevens test was not in accordance with law and the special master's reliance on it was in error, the court reversed, holding that Althen had proven causation in fact under the preponderant evidence standard set forth

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<sup>4</sup> Vasculitis is an inflammation of the blood or lymph vessels. Dorland's at 2009. Angiitis is isolated vasculitis of the central nervous system. Id. at 82. Althen's illness is generally referred to as a central nervous system demyelinating disorder.

in the Vaccine Act. The court remanded to the special master for an award of compensation to Althen. The government appeals, and we have jurisdiction under 42 U.S.C. § 300aa-12(f).

### Discussion

Under the Vaccine Act, the Court of Federal Claims reviews the special master's decision to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B). Because we review the trial court's legal determination that the special master acted in a manner not in accordance with law de novo, we effectively review the special master's decision under the same standard. See Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1524 (Fed. Cir. 1991). While we owe no deference to either the special master or the trial court on questions of law, Whitcotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1106 (Fed. Cir. 1996), we review the trial court's factual findings for clear error, Hines, 940 F.2d at 1523.

The Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I). Althen sought redress for her illness under the Vaccine Act's compensatory provision for off-Table injury. She must prove by a preponderance of the evidence that the TT vaccination caused her malady. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); Hines, 940 F.2d at 1525; see also 42 U.S.C.

§ 300aa-13(a)(1). To meet the preponderance standard, she must “show a medical theory causally connecting the vaccination and the injury.” Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]” the logical sequence being supported by “reputable medical or scientific explanation[.]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]” Grant, 956 F.2d at 1148. Althen may recover if she shows “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, Althen’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. If Althen 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.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

The government urges us to reinstate the special master’s initial ruling under the arbitrary or capricious standard of review. It posits that the trial court’s finding of

causation, based upon its acceptance of Dr. Smith's theory of causation over that of the government's witnesses whose testimony the special master found more credible, was an improper reweighing of the evidence. While the government is correct that the trial court and this court review the special master's factual findings under the arbitrary and capricious standard, the trial court based its reversal on a conclusion that the decision was not in accordance with law. See Althen II, 58 Fed. Cl. at 279. That was, of course, a legal conclusion based appropriately on de novo review. Thus, the true issues presented here are whether the special master's finding that Althen had not established by a preponderance of the evidence a causal connection between her illness and her TT vaccination is in accordance with law; and if not, whether the Court of Federal Claims erred as a matter of law by finding causation under the proper standard.

I.

The disputed Stevens test requires that a claimant provide proof of: (1) medical plausibility; (2) confirmation of medical plausibility from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes. Stevens, 2001 WL 387418, at \*23-26. The special master found that Althen's evidence satisfied prong one, but that, because she did not provide peer-reviewed literature linking the TT vaccine to her injuries, she did not satisfy prong two. Althen I, 2003 WL 21439669, at \*14. He found that "[w]ithout some objective confirmation that the vaccine administered is potentially associated with the injury alleged, petitioner's causal claims are mere speculation and thus insufficient." Id. at \*12. The government argues that although the Stevens test

contravenes law the special master's application of prong two did not impermissibly alter Althen's burden of proof.<sup>5</sup>

We see no "objective confirmation" requirement in the Vaccine Act's preponderant evidence standard. The statute's language is clear; section 300aa-13(a)(1) instructs that a petitioner must prove causation in fact by a "preponderance of the evidence," substantiated by medical records or medical opinion, as to each factor contained in section 300aa-11(c)(1).<sup>6</sup> In turn, section 300aa-11(c)(1)(C)(ii)(I) requires a claimant to provide evidence showing that she "sustained, or had 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 subparagraph (A)[.]"<sup>7</sup> This court

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<sup>5</sup> The government opposed the special master's use of the Stevens test, both in its brief and at oral argument where it asserted that application of the test is not always consistent with the statute because, in some cases, prong two sets the evidentiary barrier too low.

<sup>6</sup> Section 300aa-13(a)(1) states, in relevant part:

(a) General rule.

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1) [42 U.S.C. § 300aa-11(c)(1)], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

42 U.S.C. § 300aa-13(a)(1) (2000) (emphases added).

<sup>7</sup> Tetanus toxoid vaccine is referred to in the Vaccine Injury Table, subparagraph (A).



has interpreted the “preponderance of the evidence” standard referred to in the Vaccine Act as one of proof by a simple preponderance, of “more probable than not” causation. See Hellebrand v. Sec’y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993) (defining “preponderance” in the context of a Table injury case). The government’s suggestion that prong two of Stevens does not impermissibly raise Althen’s burden, ignores the legal and practical effect of that test: by requiring medical literature, it contravenes section 300aa-13(a)(1)’s allowance of medical opinion as proof. This prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants. See Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) (explaining that “to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program”). While this case involves the possible link between TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine, 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.

The government’s postulate that the “heavy lifting” referred to in Lampe v. Secretary of Health and Human Services, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting Hodges v. Secretary of Health & Human Services, 9 F.3d 958, 961 (Fed. Cir. 1993)), signifies this court’s desire to raise the preponderance standard in vaccine cases to that of direct proof similarly fails. Hodges described the difference between causation in the Table- and off-Table contexts:

Bring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting -- causation is conclusively presumed. Failing that, the heavy lifting must be done by the petitioner, and it is heavy indeed. Given the statutory burden of persuasion placed upon the petitioner, 42 U.S.C. § 300aa-13(a)(1) . . . it is not surprising that petitioners have a difficult time proving [off-Table cases].

9 F.3d at 961. This observation was merely a recognition that, as later stated in Grant, 956 F.2d at 1147, “[t]he Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation.” By comparison, in off-Table injury cases, it is the preponderance standard, as opposed to operation of law, that does the “heavy lifting” of establishing causation. While it may be true that proof of causation by preponderant evidence is not as “easy” as proof of causation by operation of law, neither Hodges nor Lampe instructs that the preponderance standard itself is to be made more onerous in vaccine cases. Nor is it to be made more difficult merely because our cases have referred to it as “heavy lifting.”

The special master’s role is to apply the law. Questions of law regarding the interpretation or implementation of the Vaccine Act are matters for the courts. See La Buy v. Howes Leather Co., 352 U.S. 249, 256 (1957) (“The use of masters is to aid judges in the performance of specific judicial duties, as they may arise in the progress of a cause, and not to displace the court.”) (quotation marks and citation omitted). While La Buy described the special master’s role in the Article III courts as set out in Federal Rule of Civil Procedure 53(b), the special master’s role in the Article I Court of Federal Claims is similarly limited by the Vaccine Act. See Knudsen, 35 F.3d at 549 (“The sole issues for the special master are . . . whether it has been shown by a preponderance of the evidence that a vaccine caused [an] injury or that the . . . injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor

unrelated to the vaccine caused the . . . injury.”) (emphasis added) (citing 42 U.S.C. § 300aa-13(a)(1), (b)(1) (2000)); see also Hodges, 9 F.3d at 961 (“Congress assigned to a group of specialists, the Special Masters . . . , the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims.”) To require Althen to provide medical documentation would contravene the plain language of the statute.

We hold today that the special master’s application of the Stevens test was contrary to law. The special master’s role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard to be used in causation-in-fact cases. Moreover, given our holding that prong two of the Stevens test contravenes the plain language of the statute, prong three of the test (requiring an injury recognized by the medical plausibility evidence and literature) cannot fare any better. If the Vaccine Act does not require Althen to provide medical documentation of plausibility, then it cannot require her to demonstrate that her specific injury is recognized by said medical documentation of plausibility. The remainder of the Stevens test—requiring that the claimant provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes—is merely a recitation of this court’s well-established precedent.

## II.

The next question is whether the trial court erred by finding that the TT vaccination caused Althen’s illness. The government argues that, even if we refuse to uphold the special master’s initial decision, the trial court nonetheless was wrong to

make its own factual findings rather than remanding for a re-evaluation of the evidence under the proper legal test. We disagree.

As a preliminary matter, because the special master's decision was not in accordance with law, the trial court was permitted to review the evidence anew and come to its own conclusion. 42 U.S.C. § 300aa-12(e)(2)(B);<sup>8</sup> Saunders v. Sec'y of Health & Human Servs., 25 F.3d 1031, 1033 (Fed. Cir. 1994). So long as the record contained sufficient evidence upon which to base predicate findings of fact and the ultimate conclusion of causation, which it did, the trial court was not required to remand. The court did not, as the government asserts, controvert a special master's finding regarding alternate causation; no such finding was made. See Althen I, 2003 WL 21439669, at \*14 n.44 ("Whether the hepatitis A vaccine played a role in Mrs. Althen's onset of a demyelinating disorder remains an open question which the court need not address given petitioner's failure to satisfy Prong Two of Stevens."). The court did not err in finding no alternative causation; the government's witnessing doctors provided no evidence rebutting Dr. Smith's testimony of the lack of a known causal relationship between the hepatitis A vaccination and central nervous system demyelinating disorder. See 42 U.S.C. §§ 300aa-13(a)(1)(B), -13(a)(2) (2000) (outlining the government's

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<sup>8</sup> Section 300aa-12(e)(2)(B) states, in relevant part:

(2) Upon the filing of a motion [to review the special master's decision], the [United States Court of Federal Claims] shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter--

...

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law.[.]

42 U.S.C. § 300aa-12(e)(2)(B) (emphasis added).

burden of proving that “factors unrelated[,]” e.g., the hepatitis A vaccination, were “principally responsible” for causing Althen’s injury).

Althen established by a preponderance of the evidence that the TT vaccination caused her central nervous system demyelinating disorder. Her proffered evidence, which the trial court accepted as more convincing, provided the requisite showings of a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a proximate temporal relationship between the TT vaccination and her injury. There is no error in the court’s conclusion that the government failed to prove that factors unrelated to the vaccine were principally responsible for Althen’s ailment.

#### Conclusion

Accordingly, the judgment of the United States Court of Federal Claims is affirmed.

AFFIRMED