

# United States Court of Appeals for the Federal Circuit

2008-5013

ADELA QUINTANA DE BAZAN,

Petitioner-Appellee,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellant.

Peter G. Lomhoff, of Oakland, California, argued for petitioner-appellee.

Heather L. Pearlman, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellant. With her on the brief were Jeffrey S. Bucholtz, Acting Assistant Attorney General, Timothy P. Garren, Director, Vincent J. Matanoski, Acting Deputy Director, and Gabrielle M. Fielding, Assistant Director.

Appealed from: United States Court of Federal Claims

Judge Charles F. Lettow

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Appeal from the United States Court of Federal Claims in case no. 03-VV-620, Judge Charles F. Lettow.

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DECIDED: August 28, 2008

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Before MICHEL, Chief Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

MICHEL, Chief Judge.

Respondent-Appellant Secretary of Health and Human Services appeals from the final judgment of the United States Court of Federal Claims awarding compensation to Petitioner-Appellee Adela Quintana de Bazan under the Vaccine Injury Compensation Program ("Vaccine Program") established by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act").

Because we hold that the Court of Federal Claims erred as a matter of law in reversing the special master's original entitlement ruling, we reverse.

## I. BACKGROUND

The basic facts are undisputed. At about 11:00 am on April 19, 2000, Bazan received a tetanus typhoid-diphtheria ("Td") vaccine. Within approximately eleven hours, Bazan began experiencing symptoms, such as soreness and numbness, associated with the onset of acute disseminated encephalomyelitis ("ADEM").<sup>1</sup> These symptoms grew progressively worse over the next week until by May 2, 2000, she could not walk without assistance, and she sought emergency medical attention. She was admitted to a hospital on May 8, 2000, and was thereafter diagnosed with ADEM. Currently, Bazan is a quadriplegic.

Bazan filed a petition under the Vaccine Program on March 19, 2003. The special master held two evidentiary hearings at which expert testimony and other evidence was submitted. On February 7, 2006, the special master issued his decision denying Bazan's petition, holding that she had failed to prove a requisite element of her prima facie case—that her injuries occurred within a "medically appropriate time frame" in relation to the administration of the vaccine. Crediting the testimony of the government's expert, Dr. Subramaniam Sriram, the special master found that the eleven hours between the administration of the Td vaccine and the onset of the first stages of Bazan's ADEM was too little time to be medically appropriate to link them, i.e., that it would have taken longer for ADEM to appear if it had been triggered by the vaccine.

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<sup>1</sup> ADEM is an autoimmune disorder in which the body's immune system, in response to some triggering event, attacks and destroys the myelin sheathing around the neurons of the central nervous system ("CNS"). Myelin sheathing allows neurons to transmit signals at very fast speeds. If neurons become demyelinated, such as through ADEM, they transmit signals much more slowly and, in severe cases, they are unable to transmit signals at all. As a result, the brain's ability to communicate with the body is significantly impaired or eradicated.

On a motion for review, the Court of Federal Claims held that the special master had erred by improperly failing to shift the burden to the government. The court held that the finding that the eleven-hour onset of ADEM was not within a medically appropriate timeframe to attribute to the vaccine was tantamount to finding that Bazan had failed to prove that no other cause could have caused her injuries. Holding that the statute and case law place the burden on the government to prove alternative causation, the court reviewed the evidence and concluded that Bazan had established a prima facie case. The court thus reversed and remanded to the special master to afford the government the opportunity to prove alternative causation.

On remand, the government submitted no further evidence; thus, the special master held that Bazan is entitled to compensation. The Court of Federal Claims affirmed the special master's remand decision. After further proceedings concerning damages, final judgment was entered for Bazan and damages were awarded. The government then timely filed this appeal. We have jurisdiction under 28 U.S.C. § 1295(a)(3).

## II. DISCUSSION

### A.

Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master 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); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005). We review legal determinations of the Court of Federal Claims de novo. Althen, 418 F.3d at 1278. To the extent that the Court of Federal Claims adopts factual findings made by the special

master, we accord them the same deference as the Court of Federal Claims and review them under the arbitrary and capricious standard as provided in the statute. Munn v. Sec'y of the Dep't of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992). When the Court of Federal Claims makes its own factual findings either in the first instance or when it has found the special master's findings arbitrary and capricious, we review those findings for clear error. Id. at 871-72; see also Althen, 418 F.3d at 1278.

B.

As part of her burden of proof, the petitioner must establish that her injuries were caused by a vaccine listed on the Vaccine Injury Table ("Table"). See 42 U.S.C. § 300aa-11(c)(1)(C). The petitioner may meet this burden as to causation in either of two ways. First, causation is presumed if the petitioner can demonstrate by a preponderance of the evidence that her injury meets the criteria in the Table. Grant v. Sec'y of the Dep't of Health & Human Servs., 956 F.2d 1144, 1146-47 (Fed. Cir. 1992). The Table lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury. 42 U.S.C. § 300aa-14. Congress has thus determined that if a petitioner can establish that she received a listed vaccine and experienced such symptoms or injuries within the specified timeframes, she has met her prima facie burden to prove that the vaccine caused her injuries.

If, as here, the petitioner has suffered an injury that is not listed on the Table, or if the petitioner suffered an injury listed on the Table but not within the specified timeframe, she is not afforded a presumption of causation and thus must prove causation-in-fact. Grant, 956 F.2d at 1147-48. We have held that causation-in-fact in the Vaccine Act context is the same as "legal cause" in the general torts context.

Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."<sup>2</sup> See Restatement (Second) of Torts § 431(a).

We observed in Shyface that the "substantial factor" standard requires a greater showing than "but for" causation. 165 F.3d at 1352. The Restatement addresses "but for" causation by stating that "the actor's negligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent." Restatement (Second) of Torts § 432(1). Therefore, "but for" causation requires that the harm be attributable to the vaccine to some non-negligible degree. But, as we explained in Shyface, a merely non-negligible contribution to the harm is insufficient because the vaccine must have been a substantial factor in bringing about the harm. Shyface, 165 F.3d at 1352. However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor. Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (citing Shyface, 165 F.3d at 1352). Applying these principles to the Vaccine Act context, we have held that the petitioner, to meet her burden as to causation-in-fact, must establish by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen,

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<sup>2</sup> The Restatement also provides for an exception when there is a "rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm." Restatement (Second) of Torts § 431(b). However, this part of the tort law causation rule is not implicated here.

418 F.3d at 1278. It is undisputed here that Bazan has met the first two prongs of the Althen test.

With regard to the "proximate temporal relationship" prong, the present case presents an unusual situation in that the basis for the special master's finding that Bazan had failed to prove a proximate temporal relationship was that the onset of her ADEM was too early to be attributable to the vaccine. Usually, a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause. See, e.g., Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006) ("If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame."). But we 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. Thus, the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact. See id.; see also Althen, 418 F.3d at 1281 (equating "proximate temporal relationship" with "medically-acceptable temporal relationship").

Once the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact, the burden shifts to the government to prove "[by] a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the

petition." See 42 U.S.C. § 300aa-13(a)(1)(B); Walther, 485 F.3d at 1150. If the government fails to meet this burden, the petitioner is entitled to compensation. So long as the petitioner has satisfied all three prongs of the Althen test, she bears no burden to rule out possible alternative causes.<sup>3</sup> Walther, 485 F.3d at 1149-50.

### C.

We turn now to the facts of this case. Bazan presented evidence primarily in the form of the testimony of her treating neurologist, Dr. Susan Hansen. Dr. Hansen relied on a number of scientific studies and articles. The government countered with the testimony of their own expert, Dr. Sriram, and his supporting documentary evidence. The special master noted the extensive credentials of both experts.<sup>4</sup> Dr. Hansen opined that ADEM caused by a Td vaccination could manifest as soon as eleven hours after the administration of the vaccine. She relied on several ADEM case studies, but the special master found that these studies did not evidence any instances where ADEM onset occurred as soon as eleven hours after vaccination. The Court of Federal Claims later agreed on review. Dr. Hansen also relied on case studies involving demyelinating disorders of the peripheral nervous system ("PNS"). The special master

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<sup>3</sup> As we explained in Walther, we have held that a petitioner may instead rule out possible alternative causes to prove causation-in-fact when evidence as to the Althen requirements is insufficient. Walther, 485 F.3d at 1149-50; see Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1357-59 (Fed. Cir. 2006) (holding that the petitioner's failure to eliminate other potential causes was fatal to the petition when she had not provided evidence of a proximate temporal relationship between the vaccine and her injury).

<sup>4</sup> The government argues that the Court of Federal Claims erred by discounting the special master's consideration of the medical evidence without an analysis under Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). However, Daubert is inapposite here because the special master did not exclude any expert evidence under Daubert. Rather, the special master admitted and weighed both parties' evidence but simply decided that the government's evidence was more persuasive.

found, however, that the myelin of the PNS is different from that of the CNS and thus the timeframes of PNS disorders are not probative of timeframes in CNS disorders like ADEM.

The special master's findings as to Dr. Hansen's evidence were largely based on the testimony of Dr. Sriram, which the special master credited as more probative and reliable than that of Dr. Hansen. Dr. Sriram testified that, based on animal studies of ADEM, ten to fourteen days are required for ADEM to manifest after vaccination. He explained that, under the medical theory of causation involved here, the immune system would not produce sufficient levels of cytokines (the molecules responsible for the myelin destruction) in the CNS until ten to fourteen days had passed. Crediting this testimony, the special master concluded that Bazan had not proven by a preponderance that eleven hours is a medically acceptable timeframe within which ADEM could manifest after her vaccination, and that Bazan had failed to prove the "proximate temporal relationship" element of her prima facie case as a result.

The Court of Federal Claims held that by accepting the government's evidence, which indicated that Bazan's symptoms arose too early to attribute to the vaccine, the special master erred by effectively requiring Bazan to eliminate alternative causes. The court reasoned that finding that her injuries occurred too soon for the vaccine to be the cause was tantamount to finding that her injuries were the result of an alternative cause. Citing our precedents, the court held that any proof relating to alternative causation is part of the government's rebuttal case under § 300aa-13(a)(1)(B) and not the petitioner's case-in-chief. However, the court misunderstood our precedents.

It is certainly true that a finding that the administration of a vaccine was not a cause-in-fact of an injury necessarily implies that some other cause resulted in the injury, assuming the injury itself is proven. Nevertheless, it is clearly the petitioner's burden to prove that the vaccine was a cause-in-fact of her injuries, including proving a proximate temporal relationship. Althen, 418 F.3d at 1278. Thus, in enforcing that burden, the special master was not imposing an additional burden to eliminate alternative causes.

Bazan argues that the gravamen of the holding of the Court of Federal Claims is that the special master must ignore any government evidence that tends to show that the temporal relationship between the vaccination and the onset of the petitioner's injuries was not medically appropriate when evaluating whether the petitioner met her burden as to causation. But this holding has no support in the statute or case law. The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief. Bazan has identified no statute, regulation, or precedent that indicates that the special master is required to only consider the petitioner's evidence as to whether the vaccine was a cause-in-fact.

Further, the petitioner's case-in-chief concerns the medical evidence relating to the possible role the vaccine had in causing her injury. The government's burden, in contrast, concerns "factors unrelated to the administration of the vaccine described in the petition." See 42 U.S.C. § 300aa-13(a)(1)(B). While a failure of proof that the vaccine was the cause of the petitioner's injury suggests that some other cause was responsible, that is not equivalent to having proven by preponderant evidence that a

particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor). This latter showing is the government's burden once the petitioner has met her burden. In other words, successfully proving the elements of the Althen test establishes that the medical evidence indicating that the vaccine may have caused the petitioner's injury is strong enough to infer causation-in-fact absent proof that some other factor was the actual cause. The government then must provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury. Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994).

Here, the government's evidence did not concern any factors unrelated to the vaccine. Rather, Dr. Sriram's testimony bore directly on whether the medical evidence supported concluding that the vaccine could be the cause-in-fact, which is clearly part of the petitioner's case-in-chief. Therefore, the special master's reliance on the government's evidence was lawful, and we discern no other error in the special master's evaluation of this evidence, the petitioner's evidence, or in his determination that Dr. Sriram's testimony was more credible and probative than that of Dr. Hansen.

#### CONCLUSION

For the reasons provided above, the judgment of the Court of Federal Claims is

REVERSED.