

# **United States Court of Appeals for the Federal Circuit**

05-5049

ROSE CAPIZZANO,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

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

Vincent J. Matanoski, Attorney, United States Department of Justice, of Washington, DC, argued for respondent-appellee. On the brief were Peter D. Keisler, Assistant Attorney General, United States Department of Justice, of Washington, DC and Ann K. Donohue, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC.

Appealed from: United States Court of Federal Claims

Senior Judge James F. Merow

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DECIDED: March 9, 2006

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Before SCHALL, GAJARSA, and PROST, Circuit Judges.

SCHALL, Circuit Judge.

Rose Capizzano appeals the final decision of the United States Court of Federal Claims that sustained the decision of the chief special master denying her petition for compensation under the Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (“Vaccine Act” or “Act”). Capizzano v. Sec'y of Health & Human Servs., 63 Fed. Cl. 227 (2004) (“Capizzano II”). The chief special master ruled that Ms. Capizzano failed to establish that the rheumatoid arthritis (sometimes “RA”) from which she suffers was caused by an injection of hepatitis B vaccine that she received. Capizzano v. Sec'y of

Health & Human Servs., No. 00-759, 2004 U.S. Claims LEXIS 149, at \*2-3, 95 (Fed. Cl. Spec. Mstr. June 8, 2004) (“Capizzano I”). Because we conclude that the Court of Federal Claims’ decision is inconsistent with Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005) (“Althen III”), we vacate the decision and remand the case to the Court of Federal Claims for further proceedings relating to causation.

## BACKGROUND

### I.

We begin with a brief overview of the Vaccine Act. Subchapter XIX of Chapter 6A, Title 42, United States Code, enacted in 1986, established the National Vaccine Program within the Department of Health and Human Services. The program was established “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.” 42 U.S.C. § 300aa-1. Subchapter XIX also established the National Vaccine Injury Compensation Program, “under which compensation may be paid for a vaccine-related injury or death.” Id. § 300aa-10(a). The Program is administered by the Secretary of Health and Human Services. Id. An individual seeking compensation under the Program must establish by a preponderance of the evidence that the injury or death at issue was caused by a vaccine. Id. §§ 300aa-11(c)(1), -13(a)(1).

The Vaccine Act provides for the establishment of causation in one of two ways. See Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 865 (Fed. Cir. 1992). First, a petitioner may demonstrate (i) that the injury suffered is one listed in the Vaccine Injury Table (“Table injury”), see 42 U.S.C. § 300aa-14(a); (ii) that the injury occurred

within the time provided within the Table; and (iii) that the injury meets the requirements of section 300aa-14(a). Munn, 970 F.2d at 865. In such a case, causation is presumed. Id.<sup>1</sup> Second, where the complained-of injury is not listed in the Vaccine Injury Table (“off-Table injury”), the petitioner may prove causation in fact. See 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I). In such a case, the petitioner must prove by a preponderance of the evidence that the vaccine at issue caused the injury. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); Munn, 970 F.2d at 865.

A petition seeking compensation under the Vaccine Act is filed in the Court of Federal Claims. 42 U.S.C. § 300aa-11(a)(1). After a petition is filed, the Clerk of the Court forwards it to the chief special master for assignment to a special master.<sup>2</sup> Id. The special master to whom the petition is assigned “issue[s] a decision on such petition with respect to whether compensation is to be provided under the [Vaccine Act] Program and the amount of such compensation.” Id. § 300aa-12(d)(3)(A). The statute requires that the special master’s decision be issued expeditiously and that it include “findings of fact and conclusions of law.” Id.

The Vaccine Act provides that the Court of Federal Claims has jurisdiction to review the record of the proceedings before the special master and that, following such review, the court may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,

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<sup>1</sup> In such a case, the petitioner is entitled to compensation, as long as “there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine . . . .” 42 U.S.C. § 300aa-13(a)(1)(B).

<sup>2</sup> See 42 U.S.C. § 300aa-12(c)-(d) for the provisions of the Vaccine Act relating to special masters.

- (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, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2). The findings of fact and conclusions of law of the Court of Federal Claims can then be reviewed in the Federal Circuit. Id. § 300aa-12(f).

## II.

The facts of this case are largely undisputed. Ms. Capizzano received her second of three hepatitis B vaccine injections on May 3, 1998. Capizzano II, 63 Fed. Cl. at 229. Within hours, she developed a rash on her abdomen. Id. Several days later, her ailments increased to include stiff and painful joints. Id. Ms. Capizzano continues to suffer from this permanent condition, taking daily medication to keep the pain, swelling, and stiffness under control. Id. The government concedes that “[t]here is no dispute that Ms. Capizzano is diagnosed with RA.” Because several vaccine recipients had developed a worsening of already debilitating symptoms upon receiving an additional dose of hepatitis B vaccine after being injured by a prior dose, Ms. Capizzano’s physician decided that she should not receive a third hepatitis B vaccination.

## III.

On December 15, 2000, Ms. Capizzano filed a petition in the Court of Federal Claims under the Vaccine Act seeking compensation for an off-Table injury. In due course, the petition was forwarded to the chief special master, who assigned the case to himself. Before turning to the proceedings before the chief special master, however, it is important to note the legal backdrop against which this case was litigated because

that backdrop influenced both the chief special master's decision and the decision of the Court of Federal Claims.

On March 23, 2001, the chief special master rendered his decision in Stevens v. Secretary of Health & Human Services, No. 99-594V, 2001 U.S. Claims LEXIS 67 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). In Stevens, the chief special master formulated a five-prong analytical framework for determining whether a petitioner had met his or her burden of establishing causation-in-fact in an off-Table injury case. Id. at \*158. The Stevens test required a claimant to prove the existence of the following five criteria by a preponderance of the evidence:

- (1) that it is medically plausible for a component of the vaccine to cause the injury alleged,
- (2) that the association between the vaccine and the alleged injury is reported by peer-reviewed medical literature,
- (3) that the vaccinee suffered an injury which is medically accepted as a possible reaction to the vaccine,
- (4) that the injury occurred within a medically accepted time period, and
- (5) that alternate causes were considered but otherwise eliminated.

Id. at \*158.

On September 30, 2003, the Court of Federal Claims issued its decision in Althen v. Secretary of Health & Human Services, 58 Fed. Cl. 270 (2003) ("Althen II"), reversing the chief special master's decision in Althen v. Secretary of Health & Human Services, No. 00-170V, 2003 U.S. Claims LEXIS 163 (Fed. Cl. Spec. Mstr. June 3, 2003) ("Althen I"). In Althen I, the chief special master held that the petitioner, Margaret Althen, was not entitled to compensation for her off-Table injury because she had failed to establish the second prong of the five-prong Stevens test. Id. at \*52. Specifically, the special master found that Ms. Althen had failed to prove that the medical community

was seeing, reporting, and discussing a potential relationship between the vaccine she had received (hepatitis B vaccine) and her injury (rheumatoid arthritis). Id. In Althen II, the Court of Federal Claims reversed the chief special master's decision in Althen I because it concluded that the Stevens framework was contrary to the Vaccine Act and Federal Circuit precedent. 58 Fed. Cl. at 281-83. Accordingly, the court held that Ms. Althen was entitled to compensation for her off-Table injury. Id. at 287. The government timely appealed the court's decision to this court. As indicated below in Part II of the DISCUSSION section of this opinion, after briefing before us in Ms. Capizzano's case was completed, we decided Althen III, in which we affirmed Althen II's rejection of the Stevens framework.

We return now to Ms. Capizzano's case. On June 11 and 12, 2003, the chief special master held a hearing. At that hearing, Ms. Capizzano presented (i) her affidavit concerning the timing and severity of her symptoms, (ii) her medical records, (iii) the diagnoses of four treating physicians, (iv) VAERS data,<sup>3</sup> and (v) the expert testimony of Dr. David Bell concerning a mechanism by which a hepatitis B vaccine could cause rheumatoid arthritis. Capizzano I, 2004 U.S. Claims LEXIS 149, at \*2-3, 60-61, 88 n.42. For its part, the government presented the testimony of Dr. Burton Zweiman, Dr. Paul A. Phillips, and Dr. Lawrence Moulton. The government's experts presented testimony challenging Dr. Bell's proposed mechanism by which rheumatoid arthritis is asserted to be caused by hepatitis B vaccination.<sup>4</sup> Capizzano II, 63 Fed. Cl. at 228. After post-trial

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<sup>3</sup> VAERS is the Vaccine Adverse Event Reporting System, a database maintained by the Centers for Disease Control.

<sup>4</sup> The chief special master rejected the testimony of Dr. Bell, Ms. Capizzano's expert, finding that the government's experts were more persuasive and "effectively rebutted" the contention that there exists a causal connection between the

briefing, the chief special master rendered his decision in the case on June 8, 2004, after the decision of the Court of Federal Claims in Althen II. As noted above, the chief special master ruled that Ms. Capizzano had failed to establish that the rheumatoid arthritis from which she suffered was caused by the hepatitis B vaccination she received. Id. at \*94-95.

In his opinion, the chief special master divided his analysis into two parts. First, he addressed the question, “Can the hepatitis B vaccine cause RA?” Capizzano I, 2004 U.S. Claims LEXIS 149, at \*49-59. After a thorough analysis, the chief special master found that scientific and medical evidence shows that hepatitis B vaccine can cause RA. Id. at \*58-59. In so deciding, the chief special master relied on evidence of “rechallenge” in other injectees. A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine. The chief special master stated that this evidence of rechallenge constituted “such strong proof of causality that it is unnecessary to determine the mechanism of cause—it is understood to be occurring.” Id. at \*58.

The chief special master next addressed the precise question of whether hepatitis B vaccine caused Ms. Capizzano’s rheumatoid arthritis. In light of Althen II, the chief special master decided Ms. Capizzano’s case both under the five-prong Stevens framework and under a new disjunctive four-prong approach that he designed to satisfy what he perceived to be the requirements of Althen II. Capizzano II, 63 Fed. Cl. at 230; Capizzano I, 2004 U.S. Claims LEXIS 149, at \*59. The parties were in

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(Cont’d. . .)

hepatitis B vaccine and RA. Capizzano I, 2004 U.S. Claims LEXIS 149, at \*87. Despite rejecting Dr. Bell’s testimony, the chief special master nonetheless found that hepatitis B vaccine can cause RA based on other evidence discussed below.

agreement that Ms. Capizzano could not satisfy the second prong of the Stevens test, involving a showing that “the association between the vaccine and the alleged injury is reported by peer-reviewed medical literature.”<sup>4</sup>

In formulating his new four-prong approach, the chief special master focused on the Althen II holding that “[c]ausation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” 58 Fed. Cl. at 280. Under the chief special master’s new approach, Ms. Capizzano was required to demonstrate the presence of one of the following four types of evidence to satisfy the “logical sequence of cause and effect” requirement of Althen II: epidemiologic studies; rechallenge; presence of pathological markers or genetic predisposition; or general acceptance in the scientific and medical communities that hepatitis B vaccination can cause rheumatoid arthritis. Capizzano I, 2004 U.S. Claims LEXIS 149, at \*59. The chief special master noted that there may be other means of proving causation in fact, but that he was unaware of any. Id. at \*47-48.

Applying his four-prong approach, the chief special master found “that petitioner has not proven by a preponderance of the evidence any of these means of establishing causation, or any other method proposed by petitioner, and thus failed to prove that the hepatitis B vaccine caused her RA.” Id. at \*59. As noted, Ms. Capizzano presented diagnoses from her four treating physicians. These doctors attributed her rheumatoid arthritis to her hepatitis B vaccination. The chief special master rejected these diagnoses, reasoning that they were based primarily on the temporal relationship between the vaccination and the onset of Ms. Capizzano’s rheumatoid arthritis. Id. at \*88 n.42. The chief special master concluded:

Petitioner has not presented an epidemiologic study, nor has she presented evidence of general acceptance—i.e., that the medical community is currently “seeing” or “talking about” a potential relationship between the vaccine and the injury. Furthermore, factually she has not established that she experienced a rechallenge event or that she possesses the genetic markers that her expert testified were necessary to link the development of the disease to the vaccine that she received on May 3, 1998. Finally, she has failed to show that the mechanism proposed by her expert is linked to the occurrence of her RA because evidence shows that the mechanism is more conceptual and theoretical than “actual.”

Id. at \*96.

Ms. Capizzano appealed the chief special master’s decision to the Court of Federal Claims, which rendered a decision in the case on December 7, 2004. Capizzano II. Under the Vaccine Act, “the Court of Federal Claims may set aside the decision of a special master only if the special master’s fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion.” Turner v. Sec’y of Health & Human Servs., 268 F.3d 1334, 1337 (Fed. Cir. 2001) (citing 42 U.S.C. § 300aa-12(e)(2)(B)). Applying this standard of review, the Court of Federal Claims affirmed both the chief special master’s findings of fact and legal conclusions. Capizzano II, 63 Fed. Cl. at 231. The court determined that the disjunctive four-prong test employed by the chief special master was not contrary to law and affirmed the special master’s factual findings with respect to each factor as not arbitrary or capricious. Id. The court observed, “Given the number of persons receiving hepatitis B vaccine and the percentage of the population developing RA, there are bound to be persons receiving the vaccine who would, in any event, develop RA.” Id. at 230. Ms. Capizzano timely appealed the Court of Federal Claims’ decision to this court.

## DISCUSSION

### I.

We have jurisdiction over this appeal pursuant to 42 U.S.C. § 300aa-12(f). In an appeal from a decision of the Court of Federal Claims in a Vaccine Act case, we apply the same standard of review that the Court of Federal Claims applied to the special master's decision. Turner, 268 F.3d at 1337; accord Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). "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." Althen III, 418 F.3d at 1277-78 (citing Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1524 (Fed. Cir. 1991)); accord Turner, 268 F.3d at 1337. We also determine anew whether the chief special master's findings of fact were arbitrary or capricious. Lampe, 219 F.3d at 1360; accord Turner, 268 F.3d at 1337.

### II.

On July 29, 2005, after briefing in this appeal was completed, we issued our decision in Althen III. In Althen III, we affirmed the decision of the Court of Federal Claims in Althen II. 418 F.3d at 1282. In doing so, we held "that the special master's application of the Stevens test was contrary to law." Id. at 1281. We stated that "[t]he 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." Id. at 1280. We continued:

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 [Althen’s petition] involves the possible link between [tetanus toxoid] 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.

Id.

Finally, in Althen III, we set forth a three-part test for determining causation-in-fact in off-Table Vaccine Act cases. We held that a 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.

Id. at 1278.

Our task in this case is straightforward. We must determine whether the decision of the Court of Federal Claims sustaining the decision of the chief special master is consistent with Althen III. In other words, does the four-prong test employed by the chief special master in this case pass muster under Althen III?

### III.

As noted above, the chief special master decided Ms. Capizzano’s case under both the five-part Stevens test and the four-prong test he developed following the Court of Federal Claims’ decision in Althen II. Capizzano II, 63 Fed. Cl. at 230; Capizzano I,

2004 U.S. Claims LEXIS 149, at \*59. Applying his new four-part test that he devised in response to Althen II, the chief special master denied Ms. Capizzano's claim for failing to satisfy any of the four means of showing a "logical sequence of cause and effect" (epidemiologic studies, rechallenge, pathological markers, general acceptance). Capizzano I, 2004 U.S. Claims LEXIS 149, at \*59.

Viewing the case through the lens of Althen III, it seems clear—and the parties to do not dispute—that the chief special master and the Court of Federal Claims denied Ms. Capizzano's claim because they in effect determined that she had failed to meet the second prong of Althen III by not demonstrating "a logical sequence of cause and effect showing that the vaccination was the reason for the injury."<sup>5</sup> 418 F.3d at 1278. There is no dispute that the first and third prongs of Althen III were satisfied.

Ms. Capizzano argues that the requirement of epidemiologic studies, rechallenge, pathological markers, or general acceptance is inconsistent with Althen III and impermissibly raises a claimant's burden. She further argues that the combination of (i) her affidavit concerning the timing and severity of her symptoms, (ii) her medical records, (iii) the diagnoses of four physicians who treated her, (iv) the VAERS data, and (v) the lack of anything else but coincidence that could have caused her RA constitute more than enough evidence to satisfy the second prong of Althen III. In any event, Ms. Capizzano urges, even in the absence of evidence satisfying the second prong of Althen III, satisfying the first and third prongs, combined with the elimination of other

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<sup>5</sup> We say "in effect determined" because when they rendered their decisions in this case, neither the chief special master nor the Court of Federal Claims had the benefit of Althen III.

causes, necessarily establishes “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.”

The government responds that epidemiologic studies, rechallenge, pathological markers, and general acceptance are merely four ways to satisfy the second prong of Althen III. The government argues that what the second prong requires varies from case to case. Further, the government urges that although medical records and medical opinion could be enough to satisfy the second prong of Althen III in some cases, they were insufficient in this case. According to the government, Ms. Capizzano needed to present a reputable scientific explanation for receiving rheumatoid arthritis from the hepatitis B vaccine.

In Althen III, we pointed to our decision in Knudsen, which explained that “to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” Althen III, 418 F.3d at 1280 (quoting Knudsen, 35 F.3d at 549). We then stated that “[w]hile [Althen’s petition] involves the possible link between [tetanus toxoid] 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.” 418 F.3d at 1280 (emphases added).

Turning to the chief special master’s new four prong test, we conclude that 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 III. We think such an approach is inconsistent with allowing “the use of circumstantial evidence envisioned by the preponderance standard.” Id. In our view, it thus impermissibly raises a claimant’s burden under the Vaccine Act and hinders “the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” Id.

“A logical sequence of cause and effect” means what it sounds like—the claimant’s theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1).<sup>6</sup>

In the present case, the first prong of the Althen III test was satisfied by the finding that the hepatitis B vaccine can cause RA. Capizzano I, 2004 U.S. Claims LEXIS 149, at \*59. The third prong was satisfied by the finding that Ms. Capizzano’s RA appeared within days of receiving the vaccine. Id. at \*2-3. As far as the second prong is concerned, in our view, the chief special master erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of Ms. Capizzano’s injury. See id. at \*3. The fact that these physicians’ diagnoses may have

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<sup>6</sup> As already seen, in Althen III, we held that a petitioner’s burden with respect to causation

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.

relied in part on the temporal proximity of Ms. Capizzano's injuries to the administration of the vaccine is not disqualifying. See id. at \*88 n.42. We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong. In other words, if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative. Moreover, Althen III explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether "a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 418 F.3d at 1280; see also 42 USC § 300aa-13(a)(1) ("The special master or court may not make . . . a finding [of causation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.").

We recognize, as the Court of Federal Claims observed, that the immense number of people receiving the hepatitis B vaccine statistically results in instances where individuals suffer an initial onset of rheumatoid arthritis shortly after receiving the vaccine, but not as the result of the vaccine. Capizzano II, 63 Fed. Cl. at 230. However, the statute requires only that the claimant show that it is more likely than not that this claimant's RA was caused by the vaccine. See Althen III, 418 F.3d at 1279 ("This court 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." (citing Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993))). The fact that there is a possibility that the rheumatoid arthritis that

appeared immediately after Ms. Capizzano received her vaccination was not caused by the vaccination does not prevent a finding that it is more likely than not that the vaccine caused the RA. See Althen III, 418 F.3d at 1280 (“[C]lose calls regarding causation are resolved in favor of injured claimants.”).<sup>7</sup>

The second prong of the Althen III test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to

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<sup>7</sup> In Lowry v. Secretary of Health & Human Services, 189 F.3d 1378 (Fed. Cir. 1999), we explained:

The Act’s National Vaccine Program was established to develop new vaccines, improve existing vaccines, and compensate individuals who have been injured by vaccines routinely administered to children. See H.R. Rep. 99-908, at 1, reprinted in 1986 U.S.C.C.A.N. 6344, 6344. Congress instituted this compensatory program because the traditional civil tort actions against vaccine manufacturers were producing undesirable results both with respect to the victims and the vaccine industry. See id., at 6-7, reprinted in U.S.C.C.A.N. at 6347-48. Congress found that the traditional tort system was not working for victims because it resulted in lengthy delays, high transaction costs, and sometimes no recovery. See id. Similarly, the high cost of litigation and difficulty of obtaining insurance was undermining incentives for vaccine manufacturers to remain in the vaccine market. In sum, Congress was concerned with the instability and unpredictability in the childhood vaccine market. See id. To deal with these problems, Congress established a federal “no-fault” compensation program under which awards were to be made to vaccine-injured persons “quickly” and with “generosity.” See id., at 1, reprinted in 1986 U.S.C.C.A.N. at 6344.

189 F.3d at 1381; accord Knudsen, 35 F.3d at 549 (“The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal compensation program under which awards are to be made to vaccine-injured persons quickly, easily, and with certainty and generosity.”) (internal quotation marks omitted).

conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence. See 42 U.S.C. § 300aa-13(a)(1)(B) (“Compensation shall be awarded . . . if the special master or court finds on the record as a whole . . . that there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine described in the petition.”).

## CONCLUSION

The chief special master rejected Ms. Capizzano’s claim under the Vaccine Act because she failed to establish causation for her off-Table injury using one of the prongs of the four-prong test that the chief special master formulated in the wake of Althen II. We hold that this was error. While each of the prongs in the chief special master’s test certainly could be probative of causation, we think that it is incorrect to require a petitioner to establish one of the four prongs in order to show causation. That is because, for the reasons stated above, we think that the special master’s four-prong test impermissibly heightens the burden of proof placed upon a petitioner in an off-Table injury case by restricting the way in which the petitioner can prove his or her case. The proper inquiry is whether a petitioner in an off-Table injury case establishes a logical sequence of cause and effect, the second prong of Althen III, by a preponderance of the evidence. That approach has not yet been followed in this case because there has not yet been, in the first instance, an analysis of the evidence presented by Ms. Capizzano

(i) under the teaching of Althen III and (ii) unencumbered by the constraints of the four-prong test formulated by the chief special master following Althen II.

Accordingly, the decision of the Court of Federal Claims affirming the decision of the chief special master rejecting Ms. Capizzano's claim for compensation is vacated. The case is remanded to the Court of Federal Claims to determine whether Ms. Capizzano has proven causation by a preponderance of the evidence based on the existing record.<sup>8</sup> If Ms. Capizzano has proven causation, judgment should be entered in her favor. If not, her claim should be denied.

#### COSTS

Each party shall bear its own costs.

VACATED and REMANDED.

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<sup>8</sup> We leave it to the Court of Federal Claims, after receiving the views of the parties, to decide whether, in the first instance, the matter should be decided by the chief special master. See 42 U.S.C. § 300aa-12(e)(2).