

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS**

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JANE DOE 93,	*	
	*	No. redactedV
Petitioner,	*	Judge Mary Ellen Coster Williams
	*	Special Master Christian J. Moran
v.	*	
	*	Filed: May 9, 2011
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, flu vaccine,
	*	transverse myelitis, remand
Respondent.	*	
	*	

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Ronald C. Homer, Sylvia Chin-Caplan & Amy Fashano, Conway, Homer & Chin-Caplan, P.C., Boston, MA., for petitioner;  
Glenn A. MacLeod, United States Dep’t of Justice, Washington, D.C. for respondent.

**PUBLISHED RULING FINDING ENTITLEMENT<sup>1</sup>**

Ms. Doe alleges that an influenza (“flu”) vaccine given to her on October 8, 2004, caused her to develop transverse myelitis, which was manifest approximately two months later. She seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa—1 et seq. (2006). An initial decision denied compensation. Decision, 2010 WL 4205677 (Fed. Cl. Spec. Mstr. Oct. 20, 2010). The Court of Federal Claims vacated this decision and remanded for further adjudication. 2011 WL 1515238.<sup>2</sup>

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<sup>1</sup> Previous actions in this case have been made available to the public under the Doe 93 caption. The undersigned special master intends to follow the same procedure with this ruling. Either party may file a motion regarding this topic within 14 days.

<sup>2</sup> The Court’s Opinion and Order was issued on April 7, 2011. It became available to the public on April 29, 2011.

## Background

As a petitioner claiming that a vaccine caused an injury not listed on the Vaccine Injury Table, Ms. Doe is required to meet three elements “(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 v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Of these three, only the second element is meaningfully disputed now.

For this remand, there is no argument about prong 1 and prong 3. For prong 1, the Court stated that “Althen’s Prong One merely requires a petitioner to ‘provide’ a medical ‘theory’ linking the vaccine to the injury. In addressing the requisite showing necessary for ‘providing’ a medical theory linking a vaccine to an injury, courts have interpreted Althen’s Prong One to require a biologically plausible medical theory.” 2011 WL 1515238, at \*16. A “biologically plausible medical theory” requires less evidence than the standard that was used in the initial decision, which was to present a reliable and persuasive medical theory. 2010 WL 4205677, at \*8-9. Under the standard set by the Court, the evidence supports a finding in favor of Ms. Doe. Ms. Doe’s expert, Dr. Tornatore, opined that the flu vaccine can cause transverse myelitis. Tr. 53-54. Respondent’s expert, Dr. Bielawski, testified that “it is a possibility that there are antigens in a flu vaccine that could cause autoimmune problems.” Tr. 129.<sup>3</sup> Thus, the evidence fulfills the Court’s standards.

There is also no dispute about Althen prong 3, the appropriate temporal relationship. The initial decision found that Ms. Doe met her burden, 2010 WL 4205677, at \*25, and this determination was not disturbed, 2011 WL 1515238.

Thus, two elements are found in Ms. Doe’s favor. The remaining element is the second element from Althen, which is “a logical sequence of cause and effect

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<sup>3</sup> The significance of the difference between the probability test and the plausibility test is reflected in the continued testimony of Dr. Bielawski. He stated: “But in terms of plausibility, I wouldn’t be able to say that a flu vaccine could cause a transverse myelitis. There is nothing that indicates in the literature that influenza vaccine causes transverse myelitis. So if you ask me is it possible, I wouldn’t want to absolutely say no, just like there’s a lot of things we don’t know at this point in science and medicine. But, is it probable, I would say no.” Tr. 129. The testimony about probability is not responsive to the test set out by the Court.

showing that the vaccination was the reason for the injury.” The initial decision found that Ms. Doe had not met her burden on this element. 2010 WL 4205677, at \*24-25. The Court vacated and remanded for further adjudication. 2011 WL 1515238, at \*21-23.

On remand, the parties were ordered to file briefs addressing Althen prong 2. Neither party requested an opportunity to file additional evidence. The parties complied with the order to file briefs and the case is ready for adjudication again.

### Analysis

Readjudication is required because the Court, after reviewing the initial decision, exercised its statutory authority to “remand the petition to the special master for further action in accordance with the court’s direction.” 42 U.S.C. § 300aa—12(e)(C). Additional guidance about the meaning of a remand is taken from Federal Circuit cases that have remanded matters to district courts because the Court of Federal Claims acts as “a reviewing judge.” Munn v. Sec’y of Health & Human Servs., 970 F.2d 863, 869 (Fed. Cir. 1992). In the context of evaluating a district court’s actions after a remand, the Federal Circuit has stated that “the district court’s actions on remand should not be inconsistent with either the letter or the spirit of the mandate.” Laitram Corp. v. NEC Corp., 115 F.3d 947, 951 (Fed. Cir. 1997).

Here, the mandate from the Court states that “the Special Master shall reassess whether Petitioner met Althen’s Prongs One and Two and whether she is entitled to compensation, consistent with the legal principles articulated in this opinion. In remanding this matter, the Court does not dictate any particular determination on causation.” 2011 WL 1515238, at \*23 (footnote 17 omitted).<sup>4</sup>

Consistent with the Court’s statutory authority, the Court provided the following additional direction.

- “On remand, the Special Master shall consider the pertinent and well-reasoned recent decision in Campbell v. Sec’y of HHS, No. 07-465V (Mar. 22, 2011).” 2011 WL 1515238, at \*23 n.17.
- Certain “non-vaccine decisions have no place in the analysis of Althen’s Prong One.” 2011 WL 1515238, at \*19 n.13.

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<sup>4</sup> As noted in the background section, the Court’s interpretation of Althen prong one has essentially resolved this issue in Ms. Doe’s favor.

- The special master should not consider the possibility that Ms. Doe suffered from a mycoplasma pneumoniae. 2011 WL 1515238, at \*20.

The Court also discussed an April 6, 2005 letter from Dr. Sriram, which is found in the record as exhibit 9 at 106-08. 2011 WL 1515238, at \*22. This piece of evidence was mentioned in the initial decision, 2010 WL 4205677, at \*17, although Dr. Sriram's April 6, 2005 letter was not addressed in the portion of the initial decision analyzing Althen prong 2. See 2010 WL 4205677, at \*24.

In this April 6, 2005 letter, Dr. Sriram stated that "At present my feelings are this is probably a questionable postinfectious, postvaccination etiology of an acute ascending myelopathy." Exhibit 9 at 106-08. The ensuing question is what is the significance of this letter?

It seems apparent that the Court found Dr. Sriram's April 6, 2005 letter to support Ms. Doe's claim that the etiology of her transverse myelitis was the vaccination.<sup>5</sup> In the context of discussing Dr. Sriram's April 6, 2005 letter, the Court quoted Campbell:

Any expectation that treating physicians will record the precise biological theories behind their belief that a patient's condition was caused by a particular trigger is discordant with the reality of medical treatment. Doctors are and must be concerned with treating patients, not with articulating the precise biological theories upon which they base their diagnoses.

2011 WL 1515238, at \*22, quoting Campbell, No. 07-465V, at 22.

As a statement of a treating doctor, Dr. Sriram's opinion should be carefully considered, given that there has already been a finding that Ms. Doe has satisfied Althen prong 1. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Dr. Sriram's April 6, 2005 letter, when viewed in accordance with the legal principles set forth in the Court's order and in Campbell,

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<sup>5</sup> While this was not the assessment of the undersigned at the time of the initial decision, the view of the appellate authority is controlling. See Northern Helex Co. v. United States, 634 F.2d 557, 560 (Cl. Ct. 1980).

satisfies Ms. Doe's obligation regarding Althen prong two. Ms. Doe, therefore, has met all three prongs of Althen and is entitled to compensation.<sup>6</sup>

### **Conclusion**

Ms. Doe is entitled to compensation and the case will move to the process of determining the amount of compensation.

IT IS SO ORDERED.

s/ Christian J. Moran  
Christian J. Moran  
Special Master

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<sup>6</sup> Respondent has not offered a specific factor unrelated to the flu vaccine as a cause of Ms. Doe's transverse myelitis.