

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

CHRISTOPHER LANE,

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Petitioner,

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No. 19-501V

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Special Master Christian J. Moran

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v.

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Filed: June 7, 2024

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Diana L. Stadelnikas, Maglio, Christopher & Toale, Sarasota, FL, for petitioner;
Sarah B. Rifkin and Madelyn Weeks, United States Dep't of Justice, Washington,
DC, for respondent.

PUBLISHED RULING FINDING ENTITLEMENT TO COMPENSATION¹

Christopher Lane alleges that an influenza (“flu”) vaccine caused him to develop immune thrombocytopenia and seeks compensation through the National Childhood Vaccine Injury Compensation Program. The Secretary opposes this claim.

Each party retained an expert. Mr. Lane’s claim was supported by a hematologist, Jerry Spivak. The Secretary’s opposition was based upon opinions from a pediatric hematologist, Cindy Neunert. Both parties advocated through

¹ Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

memoranda. A review of this material shows that Mr. Lane has established that he is entitled to compensation.

I. Events in Mr. Lane's Life²

Mr. Lane was born in 1976. Exhibit 14 at ¶ 1. Before the vaccination, his health was fine. Id. at ¶ 3.³

When he was 41 years old, he received a flu vaccine on November 1, 2017. Exhibit 1 at 2, 4, 6. Mr. Lane also received two other vaccines, a hepatitis A vaccine and a typhoid vaccine. Id. The focus of Mr. Lane's claim is on the flu vaccine. Pet'r's Br. at 2 (Mr. Lane "seeks compensation for injuries sustained as a result of the covered influenza vaccination administered on November 1, 2017"); see also Exhibit 37 at 5-7.

Mr. Lane had a dental appointment on November 6, 2017. The sparse notes do not mention any problem with his gums. Exhibit 24 at 4-5.

Mr. Lane sought medical attention from an urgent care center on November 11, 2017. He reported a petechiae rash had started "a couple of days ago." Exhibit 8 at 10. He also reported that his "gums ha[d] begun bleeding easily." Id. He was sent to an emergency room.

² The parties generally agree that the medical records accurately memorialize events happening contemporaneously with the creation of the medical records. Based upon this general agreement, the recitation of Mr. Lane's medical history is presented summarily. For a more complete description, see Pet'r's Br., filed Dec. 30, 2022, at 3-5; Resp't's Br., filed Apr. 24, 2023, at 2-5.

³ Although as mentioned in the previous footnote, the parties generally agree about Mr. Lane's health, the parties may have a dispute about the accuracy of one medical record. When Mr. Lane was hospitalized, he informed a doctor that he was feeling weak for three-to-four months. Exhibit 5 at 570. Based at least in part on this history, the Secretary argues that Mr. Lane had thrombocytopenia before the vaccination. Resp't's Br. at 11.

The Secretary's contention regarding pre-existing thrombocytopenia is rejected for two reasons. Foundationally, the Secretary's apparent acceptance of a report about weakness existing for three months is inconsistent with the Secretary's practice of only crediting information conveyed to a medical professional contemporaneously with the event's occurrence. In numerous cases in which a petitioner has claimed a shoulder injury, the Secretary has not accepted similar histories. More importantly, Dr. Neunert did not opine that Mr. Lane's thrombocytopenia started before the vaccination. See Exhibit A at 9. This leaves the Secretary's argument without expert support.

In the emergency room, Mr. Lane told a triage nurse that he had “developed red spots all over [his] body on 11/6/17.” Exhibit 2 at 9. When a physician’s assistant examined him, Mr. Lane stated that his rash appeared “3 days ago after vaccines.” *Id.* at 2. A laboratory test revealed that his platelet count was critically low. Exhibit 2 at 5. He was admitted to the hospital.

This stay at the hospital lasted until November 14, 2017. Exhibit 5 at 579 (discharge report).⁴ During this hospitalization, he was diagnosed with immune thrombocytopenia (“ITP”). *Id.* at 570. In this litigation, Dr. Spivak and Dr. Neunert agree with the diagnosis of ITP. Exhibit 37 at 3, Exhibit A at 5.

As Mr. Lane was being treated for his ITP, he told different medical personnel about the beginning of his problems. For example, Mr. Lane informed a nurse practitioner that “He had no problems and was completely asymptomatic until yesterday [November 10, 2017] when he noticed some rash and bruising of his lower legs and feet. The rash got progressively worse.” Exhibit 5 at 568. He told a hematologist, Dyanesh Ravindran, that he had received vaccinations and had been well “until 4 days ago [November 7] when he started noticing bruising.” *Id.* at 572.

Dr. Ravindran did not comment upon a possible causal relationship between the vaccinations and Mr. Lane’s ITP. Exhibit 5 at 572; see also *id.* at 580 (note from November 13, 2017, stating that “We do not have any results of workup yet”). However, another doctor treating Mr. Lane, Samantha Mason, wrote that his ITP was “likely secondary to vaccinations.” *Id.* at 578.

After Mr. Lane was discharged from the hospital, he continued to have problems. He was hospitalized again from November 29, 2017 to December 5, 2017, during which he received an infusion of platelets. Exhibit 5 at 5-8.

Conservative treatments did not fully remedy Mr. Lane’s problems. Thus, he underwent a splenectomy. Exhibit 7 at 79 (Feb. 9, 2018).⁵

⁴ The pages of Exhibit 5 are not labeled consistently. Any citations refer to the PDF page number.

⁵ Some petitioners with ITP have difficulty establishing that their ITP met the Vaccine Act’s severity requirement. See, e.g., Wright v. Sec’y of Health & Hum. Servs., 22 F.4th 999 (Fed. Cir. 2022); Michie v. Sec’y of Health & Hum. Servs., No. 19-453V, 2023 WL 10410004 (Fed. Cl. Spec. Mstr. Dec. 4, 2023). Mr. Lane’s ITP, unfortunately, was long-lasting. The Secretary did not argue that Mr. Lane failed to meet the severity requirement. See Resp’t’s Rep., filed July 24, 2020.

The degree to which Mr. Lane is continuing to experience sequela to his ITP appears uncertain. Compare Pet'r's Br. at 5 with Resp't's Br. at 5.

II. Procedural History

This case's course during litigation has been straightforward. Mr. Lane started the case by filing his petition on April 4, 2019. He periodically submitted medical records.

When the medical records were complete, the Secretary examined the evidence. The Secretary recommended that compensation be denied. Resp't's Rep., filed July 24, 2020. The key deficiency, in the Secretary's view, was that Mr. Lane lacked an expert report. Id. at 9. In addition, the Secretary found the causal statement of Dr. Mason insufficient. Id. at 10.

A status conference was held during which Mr. Lane expressed an interest in obtaining a report from an expert. To facilitate this process, a draft set of instructions were proposed. Order, issued July 30, 2020. After neither party commented upon the instructions, they became final. Order, issued Aug. 14, 2020.

Roughly one year later, Mr. Lane filed the first report of Dr. Spivak.⁶ Beginning in 1972, Dr. Spivak served at the Johns Hopkins University School of Medicine in various roles, ascending to the title of professor before becoming a professor emeritus in 2019. Exhibit 38 (curriculum vitae). He directed the division of hematology from 1980 to 1992. Id. He is board-certified in internal medicine and hematology. Id.; see also Exhibit 37 (report) at 1. When Dr. Spivak submitted his first report, he had treated three patients with immune thrombocytopenia in the last five years. Exhibit 37 at 1.

The Secretary responded by presenting the first report of Dr. Neunert. Exhibit A (filed Dec. 20, 2021). Dr. Neunert graduated from medical school in 2001. Exhibit B (curriculum vitae) at 2. When she submitted her curriculum vitae, she was serving as an associate professor of pediatrics in the division of hematology / oncology / bone marrow transplant at Columbia University. Id. at 1. "The focus of [her] career has been to understand patient-related outcomes in ITP." Exhibit A (report) at 1. She has led various groups investigating ITP. She reported that she has "taken care of more than one hundred patients with ITP, and [she]

⁶ Some of the delay was attributable to hematologists responding to the coronavirus pandemic. See Pet'r's Status Rep., filed Nov. 13, 2020.

see[s] patients from across the United States in consultation for a second opinion with respect to diagnosis and management of ITP.” Id.

Each party submitted a second report from his expert. Exhibit 76 (Dr. Spivak’s report, filed May 10, 2022); Exhibit C (Dr. Neunert’s report, filed July 11, 2022).

When the parties completed the disclosure of expert opinions, they were directed to file briefs. Order, issued Aug. 31, 2022. Mr. Lane argued his case via a primary brief, filed Dec. 30, 2022, and a reply brief, filed May 24, 2023. In between, the Secretary presented his arguments. Resp’t’s Br., filed Apr. 24, 2023. Neither party requested an opportunity to present oral testimony. With the submission of the reply brief, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “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 v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

For causation-in-fact claims, petitioners bear a burden “to show by preponderant evidence that the vaccination brought about [the vaccinee’s] 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.” Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

The analysis is contained in five sections. The heart of the analysis concerns the three Althen prongs, which are found in sections IV.B. through IV.D. Following these sections, there is a short section addressing the lack of alternative cause. Section IV.E. The analysis begins with an assessment of Dr. Spivak's and Dr. Neunert's credentials.

A. Qualifications of Experts

As a preliminary matter, the parties dispute the relative qualifications of Dr. Spivak and Dr. Neunert. Mr. Lane argues that Dr. Neunert's career of treating pediatric cases of ITP diminishes her ability to opine in Mr. Lane's case because he was an adult (41 years old) when he developed the disease. Pet'r's Br. at 12-13; Pet'r's Reply at 3-6. The Secretary defends Dr. Neunert's knowledge of ITP without critiquing Dr. Spivak's qualifications. Resp't's Br. at 15-16.

The differences between Dr. Spivak's qualifications and Dr. Neunert's qualifications are differences in degree, not in kind. Although Dr. Neunert treats children, Mr. Lane has not persuasively shown that the causal mechanisms for ITP differ for children and adults. Although Dr. Spivak's treatment of adults makes his specialization a tighter fit to the circumstances of Mr. Lane's case, Dr. Spivak has also seen significantly fewer cases of ITP (three cases in the last five years versus more than a hundred over a career). Under these circumstances, the undersigned declines to favor Dr. Spivak or Dr. Neunert solely due to his or her qualifications.

B. *Althen* Prong One

According to Mr. Lane, the "dispute in the instant case centers primarily on prong one." Pet'r's Reply at 1. Mr. Lane meets his burden of proof largely due to a supporting epidemiologic study. For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020).

A group of German researchers investigated whether various drugs could induce thrombocytopenia. They meticulously searched for adults with thrombocytopenia around Berlin from October 2000 to March 2009. Garbe at

823.⁷ Upon identifying this population, the researchers determined whether they had “drug exposures during 1 week before the index date.” Id. at 830. “Index date” corresponds to the earlier of either the drop in platelet levels or the clinical manifestation of thrombocytopenia. Id. at 823. The researchers matched these participants with controls in a “case-control approach.” Id.

Garbe and colleagues identified the influenza vaccine as a drug with a “definite or probable causal relationship in suspected drug-induced immune thrombocytopenia.” Id. at 825 (table 1). “In the case-control analysis, influenza vaccination was associated with a statistically significant 4-fold risk.” Id. at 829. The authors advised that in evaluating the causes of thrombocytopenia, “particular attention should be paid to vaccines.” Id. at 830.

As an epidemiologic study, Garbe weighs heavily in favor of finding that an influenza vaccine can cause thrombocytopenia. Against this evidence, the Secretary raises two points. Resp’t’s Br. at 10.

Based upon an opinion from Dr. Neunert, the Secretary argues that because the Garbe researchers had identified only three cases of ITP following flu vaccination, “a true association could not be determined.” Resp’t’s Br. at 10; see also Exhibit C at 6. However, the article contradicts the Secretary’s assertion. The Garbe researchers, who included one person who worked at an institute for epidemiology, found their results “statistically significant.” Exhibit 42 at 829. The Secretary has not demonstrated that Dr. Neunert is qualified to call into question the results of an epidemiologic study.

The Secretary’s second challenge to Garbe appears to be the presentation of a different epidemiologic study. See Resp’t’s Br. at 8-9, citing Lafaurie.⁸ In that study, a group of French researchers used databases to find patients, aged 65 and older, who developed thrombocytopenia. Exhibit D at 444. These researchers did not find an increased adjusted incident rate ratio. Id. at 445 (table 2).

The presence of Lafaurie does, indeed, weaken the value of Garbe, but only by a bit. Due to contradictory results, it probably cannot be said that the proposition that the flu vaccine can cause thrombocytopenia has been established

⁷ Garbe et al., Drug-induced immune thrombocytopaenia: results from the Berlin Case-Control Surveillance Study, 68 EUR J. CLIN PHARMACOL 821 (2012); filed as Exhibit 42.

⁸ Lafaurie et al., Research Letter: Risk of Immune Thrombocytopenia After Influenza Vaccine, 182 JAMA INTERNAL MEDICINE 444 (2022); filed as Exhibit D.

with scientific certainty. Reasonable people, such as Dr. Spivak and Dr. Neunert, might come to different conclusions in good faith. But, Mr. Lane's burden is neither scientific certainty nor general consensus. Rather he must establish that the flu vaccine "can cause" thrombocytopenia. See Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006) (accepting the question "can [the] vaccine(s) at issue cause the type of injury alleged" as "identical to the first prong of the Althen test"). The Garbe study suffices.

Dr. Spivak proposed various theories by which the flu vaccine can cause thrombocytopenia, such as immune complex formation. Exhibit 37 at 6; see also Pet'r's Br. at 37-38. Dr. Neunert appears not to have addressed these theories in detail and did not specifically address immune complex formation. See Exhibit A at 8, Exhibit C at 4. Likewise, the Secretary has not challenged the sufficiency of immune complexes as a theory. See Resp't's Br. at 14.

Under the circumstances in which an epidemiologic study supports a finding that a vaccine can cause an injury and in which the Secretary has not meaningfully contested a proposed theory, an in-depth exploration of the theory is not required. The epidemiologic study persuasively shows that the flu vaccine can cause thrombocytopenia. How that occurs---whether by immune complex formation or some other means---is much less important than the showing that it does occur.

For these reasons, Mr. Lane has met his burden of proof regarding prong one. Thus, the remaining Althen elements are considered.

C. *Althen* Prong Two

A petitioner must present preponderant evidence showing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. The opinions of treating doctors can be quite probative. Cappizano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, Mr. Lane has support from a doctor who treated him, Dr. Mason. She stated that Mr. Lane's ITP was "likely secondary to vaccinations." Exhibit 5 at 578. This statement weighs strongly in favor of Mr. Lane's claim.

To oppose Dr. Mason, the Secretary emphasizes that Dr. Ravindran, a hematologist, did not affirmatively agree with Dr. Mason's opinion. Resp't's Br. at 12, citing Exhibit 5 at 580. The Secretary's characterization is accurate. However, it is also equally true that Dr. Ravindran did not negate or contradict Dr.

Mason’s opinion. Dr. Ravindran could be described as neutral or unopinionated on the topic of what caused Mr. Lane’s ITP.

In sum, the affirmative evidence favoring vaccination as a cause for Mr. Lane’s thrombocytopenia outweighs the neutral evidence. Mr. Lane has met his burden of proof regarding prong two.⁹

D. Althen Prong Three

The timing prong actually contains two parts. A petitioner must show the “timeframe for which it is medically acceptable to infer causation” and the onset of the disease occurred in this period. Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff’d without op., 503 F. App’x 952 (Fed. Cir. 2013).

As to the expected temporal interval, the parties may or may not agree about the minimum amount of time for which an inference of causation is appropriate. Dr. Spivak’s analysis of the expected temporal relationship begins by pointing out that the Secretary has recognized that a different vaccine, the mumps-measles-rubella (“MMR”) vaccine, can cause thrombocytopenia that appears at least seven days and not more than 30 days after the vaccination. Exhibit 37 at 7; see also 42 C.F.R. § 100.3 ¶ V.A. Dr. Spivak also cites four case reports about a total of ten adults developing thrombocytopenia one to 17 days after receiving flu vaccine. Id.; see also Pet’r’s Br. at 49. The Garbe group “look[ed] at drug exposures during 1 week before the index date.” Exhibit 41 at 830.

Dr. Neunert appears to accept that the pathogenesis of thrombocytopenia induced by the MMR vaccine would resemble the pathogenesis of thrombocytopenia induced by the flu vaccine. Exhibit A at 9. In her second report, Dr. Neunert opines that an onset more rapid than seven days is unlikely to happen in adults, compared to children who frequently receive the MMR vaccine. Exhibit C at 7. She did not address the case reports Dr. Spivak cited.

⁹ To an extent, the Secretary may be suggesting that Mr. Lane was burdened with showing that the typhoid vaccine did not cause his ITP. Resp’t’s Br. at 11. However, the Secretary has not identified any evidence that the typhoid vaccine can cause ITP. Thus, Mr. Lane was not required to knock down a straw man that the Secretary did not erect.

As to the onset of Mr. Lane's thrombocytopenia, the parties and their experts again have some disagreement. Some of the disagreement is probably attributable to inconsistencies in the histories that Mr. Lane provided in November 2017.

Medical Records about the Onset of Mr. Lane's Thrombocytopenia					
#	Cite	Date Given	Context	History	Implied Onset
	Ex. 1 at 2, 4, 6.	11/1/2017	Date of vaccination		
	Ex. 24 at 4-5	11/6/2017	Dental appointment	No bleeding in gums noted.	
1	Ex. 8 at 10.	11/11/2017	Urgent Care	a petechiae rash had started "a couple of days ago."	11/9/2017
2	Ex. 2 at 9.	11/11/2017	Triage nurse in emergency room	"developed red spots all over [his] body on 11/6/17."	11/6/2017
3	Ex. 2 at 2	11/11/2017	Physician's assistant in emergency room	A rash appeared "3 days ago after vaccines."	11/8/2017
4	Ex. 5 at 568	11/11/2017		"He had no problems and was completely asymptomatic until yesterday [November 10, 2017] when he noticed some rash and bruising of his lower legs and feet. The rash got progressively worse."	11/10/2017

Medical Records about the Onset of Mr. Lane's Thrombocytopenia					
5	Ex. 5 at 572	11/11/2017	Hematologist, Dyanesh Ravindran	Doing well "until 4 days ago [November 7] when he started noticing bruising."	11/7/2017

These histories, which were given around the same day, do not line up with precision. Do these inconsistencies mean that Mr. Lane did not suffer from thrombocytopenia? No; objective evidence establishes that his platelet counts were low. Exhibit 5 at 570; see also Exhibit 37 at 3, Exhibit A at 5. Thus, the question for the second part of the third Althen prong is determining when, among these range of options, Mr. Lane first displayed a symptom of his thrombocytopenia. A reasonable inferential answer is that Mr. Lane first manifested symptoms of his thrombocytopenia on November 8, 2017.

November 8, 2017 is seven days after November 1, 2017, the date of vaccination. Thus, Mr. Lane's onset falls within the seven-day period the experts accepted based upon the Vaccine Injury Table for MMR vaccine.

Moreover, the Federal Circuit has cautioned that special masters should not set "hard and fast deadlines" for the appropriate temporal relationship. Paluck v. Sec'y of Health & Hum. Servs., 786 F.3d 1373, 1383 (Fed. Cir. 2015). This admonition carries force in Mr. Lane's case with respect to both parts of the third Althen prong. Based upon case reports and Garbe, a more in-depth analysis could find that the minimum amount of time for an influenza vaccine to cause thrombocytopenia is six days. Alternatively, there is evidence that Mr. Lane's thrombocytopenia did not manifest until November 10, 2017. Exhibit 5 at 563. This date is unquestionably within the period Dr. Spivak and Dr. Neunert accept as one for which an inference of causation is appropriate.

Accordingly, for these reasons, Mr. Lane has satisfied the third Althen prong.

E. Alternative Cause

As explained in the preceding sections, Mr. Lane satisfied each Althen prong, demonstrating that the flu vaccine was the cause-in-fact of his thrombocytopenia. In this situation, the Secretary has an opportunity to identify an

alternative cause. However, the Secretary has not. See Resp't's Br. Thus, Mr. Lane is entitled to compensation.

V. Conclusion

With preponderant evidence, Mr. Lane showed that he is one of the rare people who experienced a serious adverse reaction to a vaccine. His injury is unfortunate. Congress created the Vaccine Program to compensate people like Mr. Lane. A status conference to discuss compensation remains set for **June 18, 2024 at 11:00 A.M.**

IT IS SO ORDERED.

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