In the United States Court of Federal Claims

No. 10-251V
(Filed: September 1, 2017)[1]

EMILY TARSELL, as the Executrix of the Estate of CHRISTINA TARSELL,	*	**National Childhood Injury Vaccination Act, 42 U.S.C. §§ 300aa-1 et seq.; Gardasil; Human Papillomavirus; Cardiac Arrhythmia; Causation in Fact; Sudden Death.**
Petitioner,	*	
v.	*	
THE UNITED STATES,	*	
Respondent.	*	

Mark T. Sadaka, Mark T. Sadaka, LLC, 155 North Dean Street, 4th Floor, Englewood, New Jersey, 07631, for Petitioner.

Benjamin C. Mizer, Rupa Bhattacharyya, Vincent J. Matanoski, Gabrielle M. Fielding, Ann D. Martin, United States Department of Justice, Civil Division, Torts Branch, P.O. Box 146, Benjamin Franklin Station, Washington, D.C., 20044, for Respondent.

OPINION AND ORDER

WILLIAMS, Judge.

This matter comes before the Court on Petitioner's motion for review of the Special Master's decision denying her claim that the human papillomavirus ("HPV") vaccine Gardasil caused her daughter, Christina, to develop a cardiac arrhythmia that worsened with each vaccine and ultimately caused Christina to die of cardiac arrest at age 21. The Special Master found that

[1] Pursuant to Vaccine Rule 18 of the Rules of the United States Court of Federal Claims, the Court issued its Opinion under seal to provide the parties an opportunity to submit redactions. The Court did not accept Petitioner's proposed redactions. Accordingly, the Court publishes this Opinion.

Petitioner failed to establish causation by preponderant evidence, identifying the shortcomings in Petitioner's case as follows:

> Ms. Tarsell has not persuasively established a basic proposition of her claim, that Christina did not experience an arrhythmia until after the first dose of the HPV vaccine. Without this foundation, the rest of Ms. Tarsell's claim cannot stand. In addition, even if Christina's arrhythmia did arise after the vaccination, the proposed theory contains too many leaps and unsupported assumptions to be persuasive. Furthermore, a study of Christina's heart tissue that pathologists at the Centers for Disease Control and Prevention ("the CDC") conducted showed that Christina did not experience damage in the way her experts' theories predicted.

Tarsell v. Sec'y of Health & Human Servs., No. 10-215V, 2016 WL 880223, at *1 (Fed. Cl. Spec. Mstr. Feb. 16, 2016) ("Decision").

Because the Special Master impermissibly elevated Petitioner's burden of proof and misapplied the legal standard, the Court remands the matter to the Special Master.

Factual Background[2]

Christina was born on November 8, 1986. Other than treatment for hypothyroidism, Christina's pre-Gardasil medical history was unremarkable. See Pet'r's Ex. 1, at 5-72 (Christina's 1996-2006 medical records from Johns Hopkins Physicians); Pet'r's Ex. 2, at 73-89 (Christina's 2005-2007 medical records from Bard College Student Health Services).

Christina regularly participated in athletics. Tr. 21.[3] Before her first Gardasil vaccine on August 22, 2007, her pulse was checked during physicals and routine medical visits many times, by various healthcare providers, and there was no indication of an irregular heartbeat. The Special Master identified six measurements of Christina's pulse in pre-Gardasil medical appointments in his decision. Decision at *2. Petitioner claims that "Christina's pulse was evaluated at least 12 times by her physicians before the administration of Gardasil." Mot. for Rev. 13. This Court's review of Christina's pre-vaccine medical-record evidence indicates that Christina's pulse was measured at least 30 times without detection of an arrhythmia. App. A;[4] Pet'r's Ex. 1, at 5, 7, 8, 10–14, 16–22, 24–28, 32–40.

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[2] The factual background is derived from the Special Master's Compensation Decision, the Special Master's Findings of Fact, and medical records filed by Petitioner. Tarsell v. Sec'y of Health & Human Servs., No. 10-215V, 2016 WL 880223 (Fed. Cl. Spec. Mstr. Feb. 16, 2016) ("Decision"); Tarsell v. Sec'y of Health & Human Servs., No. 10-251V, 2012 WL 1608741 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) ("FF"); Pet'r's Exs. 1-10.

[3] Unless otherwise noted, citations to the transcript ("Tr.") refer to the November 13-14, 2014 evidentiary hearing before the Special Master.

[4] The Court lists these measurements in Appendix A to this decision. Bold text indicates the six measurements that appear in the Special Master's decision.

On August 22, 2007, Christina received her first dose of the Gardasil vaccine from her gynecologist, Dr. Julie Jacobstein, at the doctor's office in Maryland, near Petitioner's home. Pet'r's Ex. 3, at 108-10. Shortly after receiving this dose, Christina returned to New York to begin her junior year at Bard College.

Christina underwent a sports physical at Bard College on September 12, 2007. Pet'r's Ex. 2, at 87-88. At this physical, the doctor noted that Christina's cardiovascular system was operating normally. Id. at 88. Specifically, the doctor's notes indicated "Hearts," "Murmurs," and "Pulses" were all evaluated and identified as "normal," and Christina was cleared to participate in athletics at Bard. Id.[5]

On November 20, 2007 - - approximately two months after that physical - - Christina saw Dr. Christine Lafferman, an internist, for sinus congestion while visiting her family in Maryland. During that appointment, Dr. Lafferman felt Christina's pulse and detected an irregular heart rate. Pet'r's Ex. 4, at 136. This was the first time a physician or other healthcare provider detected that Christina had an arrhythmia. Decision at *2. That afternoon, Dr. Lafferman referred Christina for an electrocardiogram ("EKG"), which confirmed Christina was in a state of cardiac arrhythmia. See Pet'r's Ex. 4, at 142. Dr. Lafferman discussed these findings with Dr. Medeshie[6] and instructed Christina to avoid "caffeine & coffee & chocolate." Id. at 136.[7]

Later on November 20, 2007, Christina returned to Dr. Jacobstein's office to receive her second Gardasil vaccine. See Pet'r's Ex. 3, at 124. Although the Special Master found that "Dr. Lafferman also administered the second dose of the HPV vaccination," the record reflects that a member of Dr. Jacobstein's staff with the initials "KB" administered Christina's second dose of Gardasil. See Decision at *2-3 (internal citation omitted); Pet'r's Ex. 3, at 99, 124. Dr. Lafferman did not administer any dose of Gardasil to Christina.

On December 27, 2007, Christina saw Dr. Lafferman, her internist, for a follow-up visit, and Dr. Lafferman again detected an irregular heartbeat. Pet'r's Ex. 4, at 135. Dr. Lafferman again ordered an EKG, which confirmed that Christina was again in a state of cardiac arrhythmia that same day. Id. at 141. Dr. Lafferman ordered that Christina undergo a transthoracic

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[5] The Special Master stated that Christina "played tennis even though during one sports physical, a doctor detected an irregular pulse." Decision at *1. It is unclear from the Special Master's decision when this "one sports physical" occurred or which doctor detected this "irregular pulse." The medical-record evidence only reflects one sports physical on September 12, 2007, which predates the detection of an arrhythmia. Pet'r's Ex. 2, at 87-88.

[6] This spelling reflects the Court's interpretation of Dr. Lafferman's handwritten notes. See Pet'r's Ex. 4, at 135-36.

[7] After reviewing copies of Christina's EKGs, both expert cardiologists agreed that the premature contractions originated from Christina's right ventricle outflow tract ("RVOT"). Tr. 67–68 (Dr. Eldar, testifying that Christina exhibited a "premature beat, because it [came] much earlier than expected," and that he believed that the extra beat came from the lower part of the heart rather than the upper), 502 (Dr. Yeager, testifying that the EKGs showed "premature ventricular beats" that came from the right side of the heart).

echocardiogram in New York, and noted that Christina has "[n]o exercise intolerance." See id. at 135. To treat Christina's sinus congestion, Dr. Lafferman referred Christina to an otolaryngologist, Dr. Karl W. Diehn, who saw Christina that same day, and determined that Christina had "[p]robable allergic rhinitis," a type of inflammation of the mucous membrane of the nose denoting an allergic reaction. See rhinitis, allergic, Dorland's Illustrated Medical Dictionary (32d ed. 2012). Dr. Diehn recommended that Christina have an allergy evaluation "at her earliest convenience." Pet'r's Ex. 5, at 143-44.

Christina underwent a transthoracic echocardiogram on February 12, 2008, at The Heart Center in Rhinebeck, New York, which indicated that the structure of her heart was normal. Pet'r's Ex. 4, at 139. After this echocardiogram, Dr. Lafferman did not recommend any follow-up cardiovascular testing.

On June 3, 2008, Christina received her third and final dose of Gardasil at Dr. Jacobstein's office. Heyman Aff. ¶ 4; Pet'r's Ex. 3, at 99. Within four days of receiving her final Gardasil vaccination, Christina exhibited various symptoms. On June 5, 2008, Christina developed between 2 and 12 red dots on the right side of her neck below her ear, which persisted until June 19, 2008. Tarsell v. Sec'y of Health & Human Servs., No. 10-251V, 2012 WL 1608741, at *4 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) ("FF"). From June 6 to June 12, 2008, Christina felt tired. Id. at *5. From June 7 to June 12, 2008, Christina felt both dizzy and faint, and experienced near-fainting spells. Id. at *4. Christina returned to New York on June 12, 2008.

Upon returning to New York, Christina worked as a gallery assistant at the Bard Center for Curatorial Studies and Hessel Museum of Art on June 14, June 15, June 18, and June 19, 2008. Pet'r's Ex. 22, at 277. On June 19, 2008, Christina left work at 5:15 p.m., and spent that evening dining with her apartment mates, retiring to her room around 1:00 a.m. Pet'r's Ex. 6, at 152–53. This marks the last time Christina was seen alive. On June 23, 2008, at approximately noon, Christina's body was found by an apartment mate, who called 911. Id. at 146. The record reflects that Christina died sometime after 1:00 a.m. on June 20, 2008, and before 12:00 p.m. on June 23, 2008. Neither Christina's autopsy nor her certificate of death identifies the date or time of her passing. See Pet'r's Ex. 7, at 154; Pet'r's Ex. 8, at 158-61. Although acknowledging that the time of death was uncertain within this time span, the Special Master pinpointed the time of her death as "June 21, 2008 at approximately noon." FF at *6.

On June 24, 2008, Dr. Kari Reiber, M.D., performed an autopsy and concluded that Christina died of cardiac arrest of an unknown cause. Pet'r's Ex. 8, at 158. She noted that Christina had slight splenomegaly and acute pulmonary edema, but noted no other abnormalities. Id. at 158–61. In her final autopsy report, issued on August 13, 2008, Dr. Reiber included the following:

> **IV. RECENT VACCINATION AGAINST HPV (GARDASIL).**
> **A. THIRD DOSE RECEIVED ON 6/6/2008.**
> **B. DEATH REPORTED TO FDA/CDC VIA VAERS (VACCINE ADVERSE EVENT REPORTING SYSTEM); VAERS E-REPORT NUMBER: E – 24085**

Id. at 158.[8]

Dr. Reiber took tissue samples from Christina's organs and performed a microscopic examination of multiple sections of the heart, "including right atrium in the area of the sinus node (x6), interventricular septum in the area of the AV node (x4) . . . ." Dr. Reiber noted that the "right and left ventricles show no significant histopathological alteration. There is no evidence of ischemic change or myocarditis." Id. at 161. Christina's body was not tested for autoantibodies before she was cremated on June 26, 2008. See Pet'r's Ex. 7, at 154; Pet'r's Ex. 108, at 9.

Approximately 10 months after completing her autopsy report, Dr. Reiber sent four tissue samples to the CDC for analysis. Pet'r's Ex. 10, at 169-70. The CDC's Pathology Report indicates that material from Christina's heart, lung, spleen, and cerebral cortex was examined. Id. The CDC performed "[i]mmunohistochemical (IHC) testing" for staphylococcus aureus, a bacterium, on Christina's lung tissue, and found no evidence of infection. Id. at 169-70. The CDC performed a "microscopic examination" of her heart tissue sample - - from an unidentified part of her heart - - and found that "[s]ections of myocardium show no conspicuous inflammatory cell infiltrates." Id. at 170.

Christina's death was reported to the Center for Disease Control and the Food and Drug Administration through the filing of several reports with the Vaccine Adverse Event Reporting System ("VAERS"). Pet'r's Ex. 11.

Procedural History

On April 19, 2010, Petitioner filed a petition under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 et seq. ("Vaccine Act") claiming that the Gardasil vaccine, administered in three doses on August 22, 2007, November 20, 2007, and June 3, 2008, caused Christina to develop a cardiac arrhythmia that worsened with each vaccination and ultimately led to Christina's death at age 21, in June 2008. The Special Master held an evidentiary hearing from November 13-14, 2014, and denied Petitioner's entitlement claim.

Petitioner filed a Motion for Review on March 16, 2016. Oral argument was held on August 18, 2016.[9]

Discussion

Jurisdiction and Standard of Review

In Vaccine Act cases, the Court of Federal Claims has "jurisdiction to undertake a review of the record of the proceedings" and may: (1) uphold the findings of fact and conclusions of law and sustain the special master's decision; (2) set aside any of the findings of fact or conclusions of law "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 (3) "remand the petition to the

[8] Dr. Reiber's report misidentifies the date of Christina's third Gardasil vaccination - - which occurred on June 3, 2008 - - as June 6, 2008, in the image above.

[9] This case was reassigned to the undersigned on March 30, 2017. Citations to the transcript of oral argument conducted by Judge Wolski are indicated by "Oral Arg. Tr."

special master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(A)-(C) (2012); Doe 93 v. Sec'y of Health & Human Servs., 98 Fed. Cl. 553, 564-65 (2011).

"Findings of fact of the special master are reviewed under the arbitrary and capricious standard, conclusions of law are reviewed under the not in accordance with law standard, and discretionary rulings are reviewed under the abuse of discretion standard." Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, 618 F.3d 1339 (Fed. Cir. 2010) (internal citation and quotation marks omitted). The Court's role is not to "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal citation and quotation marks omitted). However, the Court has "a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, 'considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision.'" Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1380 (Fed. Cir. 2015) (quoting Hines ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)) (alteration in original).

Burden of Proof under the Vaccine Act

In the seminal case of Althen v. Secretary of Health & Human Services, the Federal Circuit articulated the petitioner's burden to demonstrate causation-in-fact as follows:

> [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.

418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioner must prove causation-in-fact "by a preponderance of the evidence." 42 U.S.C. § 300aa-13(a)(1)(A) (2012). The Federal Circuit "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." Althen, 418 F.3d at 1279 (internal citation and quotation marks omitted). Petitioner's claim must be "substantiated by medical records or medical opinion . . . ." Id. at 1279 (emphasis in original). "It is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the Court meet the standards of the laboratorian." Bunting v. Sec'y of Dep't of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991) (internal citation and quotation marks omitted).

The Federal Circuit "adopt[ed] the Restatement rule for purposes of determining vaccine injury, that an action is the legal cause of harm if that action is a substantial factor in bringing about the harm, and that the harm would not have occurred but for the action." Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) (internal citation and quotation marks omitted).

To effectuate Congress's intent and advance the objectives of the Vaccine Act, causation is determined on a case-by-case basis, as follows:

> Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain. Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms.
>
> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. 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." The program is supposed to be "fair, simple, and easy to administer."

Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994) (internal citations omitted).

The Vaccine Act permits proof of causation through "the use of circumstantial evidence envisioned by the preponderance standard." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (internal citation and quotation marks omitted). As the Federal Circuit has consistently reiterated, under the Vaccine Act, "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280; see Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1261 (Fed. Cir. 2011); Rickett v. Sec'y of Health & Human Servs., 468 F.App'x 952, 958 (Fed. Cir. 2011); Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009); Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007).

If the petitioner provides preponderant evidence that the vaccine caused petitioner's injury under the Althen test, the burden then shifts to the Secretary of the Department of Health and Human Services to prove, by a preponderance of the evidence, that a factor unrelated to the vaccination actually caused the injury. 42 U.S.C. § 300aa-13(a)(1)(B). If the government fails to meet this burden, the petitioner is entitled to compensation. de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). "So long as the petitioner has satisfied all three prongs of the Althen test, she bears no burden to rule out possible alternative causes." Id. (internal footnote and citation omitted).

The Special Master Did Not Properly Apply the Vaccine Act's Evidentiary Standards

For ease of reference, this Court addresses the Althen factors in the same order as the Special Master i.e. Althen Prongs Three, One, and Two. The Special Master addressed Althen Prong Three at the outset because he concluded that Petitioner failed to demonstrate that Christina received the Gardasil vaccines before she experienced cardiac arrhythmia. The Special Master viewed this failure as a sufficient basis to deny Petitioner's claim but found that this was "not the only problem with Ms. Tarsell's case" and addressed all Althen factors. See Decision at *8.

Althen Prong Three: The Special Master Raised Petitioner's Burden of Showing a Proximate Temporal Relationship Between Gardasil and Christina's Arrhythmia

The linchpin of the Special Master's decision denying compensation appears to be "timing." See id. at *7. The Special Master explained: "[t]he order of presentation begins with timing because a gap in Ms. Tarsell's evidence is most readily apparent in the context of attempting to identify when Christina started to suffer arrhythmia." Id. The Special Master found:

> Ms. Tarsell has not persuasively established a basic proposition of her claim, that Christina did not experience an arrhythmia until after the first dose of the HPV vaccine. Without this foundation, the rest of Ms. Tarsell's claim cannot stand.

Id. at *1.

In reaching this conclusion, the Special Master ignored medical-record evidence from Christina's treating physicians that showed she did not have an arrhythmia prior to her vaccine. Instead of assessing medical-record evidence, the Special Master invoked the experts' candid but unremarkable conclusion that it was possible that Christina's arrhythmia could have been present before it was detected. From this, the Special Master determined that because the onset of Christina's arrhythmia was "unknown," Petitioner failed to prove that Christina did not have arrhythmia before she received the vaccine. Id. at *7-8. This conclusion disregards Christina's extensive medical-record evidence and medical history, which indicates that her arrhythmia was detected for the first time on November 20, 2007 - - ninety days after her first HPV vaccine - - and for the second time on December 27, 2007 - - thirty-seven days after her second HPV vaccine.

The Special Master's approach to analyzing onset placed an overly onerous burden of proof on Petitioner as illustrated by the following colloquy. During oral argument on Petitioner's motion, Judge Wolski asked Respondent's counsel to explain how a petitioner could ever meet her burden of proving onset of arrhythmia:

> THE COURT: So, in other words then, your position is what I stated earlier, which is even if it could be shown with scientific certainty that a vaccine can cause arrhythmia, you would never -- unless somebody happened to have the chance of an EKG or a pulse detecting -- I mean, that's really the only way that you could determine that the onset was not afterwards, would be if somebody had an EKG prior to the vaccine, right?
>
> MS. MARTIN: Well, it's not just an EKG. I mean, the --
>
> THE COURT: But you're saying the pulse -- the pulse not catching it doesn't matter. I mean, if the pulse showed that she had it beforehand, we wouldn't even be having this discussion. It didn't.
>
> MS. MARTIN: Right.
>
> THE COURT: But you're saying it's because it's a false negative and misses things. Well, the EKG doesn't -- the holter thing doesn't miss things. So, you're saying that the only way that a person can win -- even if there's scientific certainty that a vaccine would cause arrhythmia, the only way a person could win a case like that is if they happen to have, for

> no apparent reason, the holter done to demonstrate that despite it not being shown on any pulses, they still had arrhythmia prior to the vaccine.
>
> MS. MARTIN: I don't think that we are right now setting a standard for what would have to be required in order to show it. What the Special Master would have to do is look at the evidence before him. When you look at this evidence --

Oral Arg. Tr. 56-57.

During this same colloquy, counsel for Respondent acknowledged that there was no evidence that Christina had arrhythmia before she received the vaccine:

> THE COURT: Now, what is the evidence that there was arrhythmia prior to the vaccine?
>
> MS. MARTIN: There is no evidence that there is arrhythmia prior to the vaccine.
>
> THE COURT: And what is the evidence that there was arrhythmia after the vaccine?
>
> MS. MARTIN: So, there is -- November 22nd, there was definitely arrhythmia.

Id. at 57. This admission is fully supported by the record.

In concluding that Petitioner failed to demonstrate temporal proximity between Christina's vaccine and death because Petitioner did not prove the date of onset, the Special Master relied on Hopkins ex rel. Hopkins v. Secretary of the Department of Health & Human Services, 84 Fed. Cl. 517 (2008), stating:

> When a petitioner cannot establish the onset of the injury the vaccine allegedly caused, the petitioner cannot fulfill the third Althen prong. See Hopkins v. Sec'y of Health & Human Servs., 84 Fed. Cl. 517, 524–27 (2008) (denying motion for review).

Decision at *7.

In Hopkins, the Court of Federal Claims denied the petitioners' claim that their injured son, Finn, suffered from bilateral sensorineural hearing loss due to vaccines because the petitioners failed to establish that Finn's vaccines preceded his injury. However, Finn's hearing was never tested at all prior to his receipt of these vaccinations - - which he received when he was just over 18 months old. 84 Fed. Cl. at 525. In contrast, here 12 years of medical records document Christina's normal cardiac rhythm prior to her first dose of Gardasil on August 22, 2007.[10]

[10] In her motion for review, Petitioner claims that "Christina Tarsell had her pulse measured on the day she first received her first Gardasil vaccine . . . ." Mot. for Rev. 18. However, the record from this medical visit indicates that Christina's gynecologist, Dr. Jacobstein, recorded Christina's blood pressure, but not her pulse, when she received her first Gardasil vaccine on August 22, 2007. See Pet'r's Ex. 3, at 110.

Christina was evaluated for cardiac arrhythmia - - by stethoscope and pulse readings - - some 30 times prior to the first administration of Gardasil. See Pet'r's Ex. 1, at 5, 7, 8, 10–14, 16–22, 24–28, 32–40. The parties' expert cardiologists - - Dr. Eldar and Dr. Yeager - - acknowledge that individuals suffering from cardiac arrhythmia are not in a constant arrhythmic state, but they agree that if Christina had been in an arrhythmic state during her pre-vaccine appointments, her right ventricular outflow tract-ventricular premature complex ("RVOT-VPC") arrhythmia very likely would have been detected by a healthcare provider feeling her pulse or using a stethoscope. Tr. 72, 501.

As Dr. Eldar, Petitioner's expert cardiologist and electrophysiologist, testified:

> Q. So what do you think about the possibility of healthcare providers missing an arrhythmia five times? Do you think it's likely?
>
> A. If it was there, it's very unlikely that they missed it.

Id. at 170 (emphasis added).

In assessing whether a petitioner's disorder existed prior to receipt of a vaccine, it is appropriate for a special master to assess whether it was "more likely than not" that the disorder was pre-existing, based upon record evidence. In W.C. v. Secretary of the Department of Health & Human Services, the Federal Circuit affirmed the special master's conclusion that the petitioner failed to demonstrate the requisite timing regarding onset, stating:

> The special master carefully considered the evidence in the record, drew plausible inferences, and articulated a rational basis for his determination that, more likely than not, Petitioner's lesions existed before he received the influenza vaccination . . . .

704 F.3d 1352, 1359 (Fed. Cir. 2013) (emphasis added). Here, the Special Master did not assess the evidence in the record to make a finding that the onset of Christina's cardiac arrhythmia "more likely than not" predated her first Gardasil vaccine. Instead, he concluded that the onset of Christina's cardiac arrhythmia was "unknown" because the date of onset could not be ascertained with a degree of accuracy he required - - beyond what was reflected in her pre-vaccine record.

In addition, the Special Master did not follow the Federal Circuit's instruction that proof of onset is to be considered in the context of a "disorder's etiology:"

> 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.

de Bazan, 539 F.3d at 1352. Here, both Petitioner's and Respondent's expert cardiologists testified to the difficulty - - indeed, the near impossibility - - of identifying the date of onset of arrhythmia. When asked when Christina's arrhythmia started, Petitioner's expert cardiologist and electrophysiologist, Dr. Eldar, testified:

> Well, the only thing that I can say is it wasn't found before it was found. So, the first time that I know that she was looked -- that it was looked into, she had it, and that happened after she got the -- the Gardasil, but -- yeah, so I cannot say exactly when it started, but I know that when they checked it, when they checked her, and both times were after -- of course, after she began to receive the Gardasil, and both times she had these VPCs.

Tr. 120; see also id. at 500 (Dr. Yeager testifying that arrhythmia is "discovered" at a certain time, and that "in general, it's impossible for us to say exactly when it starts").

In sum, in a case where all experts agree that the onset of cardiac arrhythmia is difficult to pinpoint and no medical record suggests that Christina had cardiac arrhythmia prior to receiving the vaccine, the Special Master erred in concluding that, because the onset of Christina's arrhythmia was "unknown," Petitioner had not sufficiently proven her claim.

In finding that Petitioner failed to demonstrate that Christina's vaccine preceded her arrhythmia, the Special Master did not assess whether Petitioner demonstrated, by a preponderance of the evidence, a "proximate temporal relationship between the vaccination and the injury" in the traditional manner required to satisfy Althen Prong Three. The requirement of a "'temporal relationship' between the vaccination and the injury is designed to ensure that it is 'medically acceptable to conclude that the vaccination and the injury are causally linked.'" Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (quoting de Bazan, 539 F.3d at 1352). Petitioner can meet her burden of proving that Christina's arrhythmia arose within an acceptable time frame after she received the Gardasil vaccines via medical-record evidence or expert opinion. Althen, 418 F.3d at 1279.

The Special Master is instructed to re-evaluate Althen Prong Three consistent with Althen, de Bazan and W.C. The Special Master shall consider the totality of the evidence to determine whether it is more likely than not that the onset of Christina's arrhythmia predated her first Gardasil vaccine and if not, whether Christina's arrhythmia and cardiac arrest occurred within a medically appropriate time after her vaccines.

Althen Prong One: The Special Master Impermissibly Elevated Petitioner's Burden to Provide a Medical Theory Causally Linking Gardasil to Arrhythmia

In analyzing Althen Prong One, the Special Master required that Petitioner prove that her theory of how Gardasil "can cause" cardiac arrhythmia was "more likely than not," instead of requiring that Petitioner provide a "medical theory of causation linking the vaccine to the injury." Petitioner presented a theory connecting Gardasil to Christina's development of a cardiac arrhythmia and subsequent death, which can be summarized as follows:

> Christina Tarsell died from an arrhythmia induced by autoantibodies to the L-type calcium channel receptor.
>
> Homology (molecular mimicry) between proteins is the first step required for cross-reactivity. According to peer-reviewed literature, L1 protein of HPV 16 antigen shares homology with human proteins associated with cardiac function. In our case, the L-1 protein shares similarity with the L-type calcium channel receptor. In genetically susceptible individuals like Christina, the body mounts an immune

> system response to both the L-1 protein and the L-type calcium channel receptor resulting in cross-reactivity.
>
> Autoantibodies bound to the L-type calcium channels in Christina's heart making them dysfunctional resulting in an influx of calcium into the heart cells. The increased concentration of calcium in the heart cells caused her premature ventricular contractions. After each additional Gardasil vaccination, more calcium entered the heart cells resulting in a worsening of her arrhythmia and ultimately her death.

Mot. for Rev. 16.[11]

The Special Master interpreted Moberly ex rel. Moberly v. Secretary of the Department of Health & Human Services, 592 F.3d 1315 (Fed. Cir. 2010), to require Petitioner to demonstrate her theory by a preponderance of the evidence, reasoning:

> The Federal Circuit has stated that petitioner's burden of proof is "more likely than not," not mere plausibility. Moberly, 592 F.3d 1315, 1322 (Fed. Cir. 2010). Decisions from the Court of Federal Claims have followed Moberly. M.S.B. by Bast v. Sec'y of Health & Human Servs., 117 Fed.Cl. 104, 123 (2014), appeal dismissed, 579 Fed.Appx. 1001 (Fed.Cir.2014); Taylor v. Sec'y of Health & Human Servs., 108 Fed.Cl. 807, 819 (2013).

Decision at *15 (internal footnote omitted).

However, the phrase "more likely than not" that the Special Master quotes from Moberly addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act, not a petitioner's burden to provide a medical theory causally linking the vaccine to the injury. In this passage that the Special Master quotes from Moberly, the Federal Circuit stated:

> While the petitioners acknowledge that the statute requires proof of causation by a preponderance of the evidence, they appear to be arguing for a more relaxed standard. They repeatedly characterize the test as whether Molly's condition was "likely caused" by the DPT vaccine. By that formulation, however, they appear to mean not proof of causation by the traditional "more likely than not" standard, but something closer to proof of a "plausible" or "possible" causal link between the vaccine and the injury, which is not the statutory standard. Similarly, the petitioners object to the use of the term "causation in fact" by the special master and the Court of Federal Claims, because they claim that proof that a vaccine "in fact" caused an injury would require conclusive scientific evidence. But this court has regularly used that term to describe the causal requirement for off-Table injuries and has made clear that the applicable level of proof is not certainty, but the traditional tort standard of "preponderant evidence."

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[11] Petitioner, in her Motion for Review, abandoned the beta andrenergic theory of causation raised before the Special Master.

Moberly, 592 F.3d at 1322 (internal footnote and citation omitted).

The focus of the Federal Circuit's opinion in Moberly was Prong Two - - the "did cause" Althen factor, not the "can cause" factor. Indeed, it appears that the Special Master in Moberly acknowledged the biological plausibility of the petitioner's theory by accepting that the vaccine at issue "may cause" the alleged injury. The Federal Circuit stated: "[w]hile accepting that the DPT vaccine may cause seizures in some cases, the special master concluded that the evidence of record was insufficient to prove that in Molly's case the second DPT vaccination caused the seizure condition that led to her injury." Id. at 1323 (emphasis added).

In any event, by requiring Petitioner to prove that the Gardasil vaccine "more likely than not" can cause arrhythmia imposed a more exacting burden on Petitioner under Prong One than the biological plausibility standard consistently reiterated by the Federal Circuit. Andreu, 569 F.3d at 1375 ("The first prong was satisfied because Tornatore, the Andreus' expert, presented a 'biologically plausible' theory establishing that toxins in the whole-cell pertussis vaccine can cause seizures." (internal footnote omitted)); Doe/11 ex rel. Child/Doe/11 v. Sec'y of Dep't of Health & Human Servs., 87 Fed. Cl. 1, 5 (2009), aff'd sub nom. Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349 (Fed. Cir. 2010) ("Petitioners had satisfied their burden under Althen's first prong, in that they proffered a biologically plausible medical theory causally connecting the vaccination and the injury.").[12]

Petitioner's expert in immunology and autoimmunity, Dr. Shoenfeld, and Petitioner's expert in cardiology and electrophysiology, Dr. Eldar, provided the framework of Petitioner's theory of causation.[13] See, e.g., Pet'r's Exs. 36, 100, 138. Although in their reports, Respondent's experts challenge Petitioner's theory as being unsupported by medically acceptable evidence, see, e.g., Resp't's Exs. FF, VV, ZZ, AAA, during the evidentiary hearing Dr. Phillips and Dr. Yeager[14] acknowledged the biological plausibility of the following elements of Petitioner's theory of causation:

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[12] In summarizing his determination on Prong One, the Special Master noted that, in the appeal of Contreras v. Secretary of Health & Human Services, 121 Fed. Cl. 230 (2015), the Secretary argued that the Contreras trial court's formulation of a petitioner's burden on Prong One as requiring a biologically plausible theory was not consistent with Moberly. Decision at *15 n.16. However, in deciding Contreras on appeal, the Federal Circuit did not address the Secretary's argument that the Prong One burden requires an evidentiary showing of more than a biologically plausible theory. 844 F.3d 1363, 1368-69 (Fed. Cir. 2017). As such, the formulation of Prong One articulated in Althen - - that Petitioner must provide a biologically plausible theory - - remains alive and well.

[13] Dr. Yehuda Shoenfeld was accepted as Petitioner's expert in the fields of immunology and autoimmunity. Tr. 188. Dr. Michael Eldar was accepted as Petitioner's expert in the fields of cardiology and electrophysiology. Id. at 40.

[14] Dr. S. Michael Phillips was accepted as Respondent's expert in immunology and epidemiology. Id. at 338. Dr. Scott Yeager was accepted as Respondent's expert in pediatric cardiology. Id. at 491.

- **Molecular Mimicry**: Dr. Phillips recognized that molecular mimicry is "a plausible study which is a respected theory in medicine . . . ." Tr. 418. He also acknowledged that there is "literature that supports the concept" that molecular mimicry can lead to autoimmune disease. Id. at 421.

- **Homology and the LQAGL Pentamer**: Dr. Phillips acknowledged that the HPV vaccine contains the LQAGL pentamer. Id. at 389-90. He also confirmed that the LQAGL pentamer is located in the L-type calcium channel, inside the cellular membrane. See id. at 394-97.

- **Cross-Reactivity and Cellular Damage**: Dr. Phillips acknowledged that some antibodies have the ability to permeate the cellular membrane. Id. at 401. Dr. Phillips further testified that cross-reactivities, leading to autoimmune disease, can occur without producing cellular damage in the form of cellular infiltrates. See id. at 433-38.

- **Increased Intracellular Calcium and Cardiac Arrhythmia**: Dr. Yeager agreed that increased amounts of intracellular calcium "will affect the electrical characteristics of the cell" and can cause arrhythmia in the cardiomyocyte. Id. at 556.

- **Autoantibodies and Arrhythmia**: Dr. Yeager testified that "[i]n the general sense of arrhythmia, there is no question that [autoantibodies] can [cause arrhythmia]." Id.

- **Arrhythmia and Death**: Dr. Yeager acknowledged that ventricular tachycardia-type arrhythmia can become lethal. See id. at 551.

In addition, Petitioner submitted case reports (see, e.g., Pet'r's Ex. 122), clinical data (see, e.g., Pet'r's Ex. 98), epidemiological evidence (see, e.g., Pet'r's Ex. 95) and peer-reviewed literature (see, e.g., Pet'r's Ex. 97) to support her medical theory articulated by Dr. Shoenfeld and Dr. Eldar. Despite this testimony of Respondent's experts and medical literature, the Special Master found that "the proposed theory contains too many leaps and unsupported assumptions to be persuasive." Decision at *1. The Special Master elaborated:

> In finding that Ms. Tarsell has not presented reliable evidence to make her theory persuasive, the undersigned does not intend to suggest that either Dr. Shoenfeld or Dr. Eldar were insincere. To the contrary, all the experts generally appeared to express their honestly held opinions about the theoretical basis for the HPV vaccine to cause a fatal arrhythmia and generally expressed those opinions respectfully. Ms. Tarsell's case falls short of the preponderance of evidence standard due to a lack of support.

Id. at *16.

Although faulting Petitioner for failing to "present reliable evidence to make her theory persuasive," the Special Master did not express any Daubert-type concern about the credibility of Dr. Shoenfeld, the chief architect of Petitioner's theory, or the reliability of his theory. Respondent's expert immunologist and epidemiologist, Dr. Phillips, described Dr. Shoenfeld as

"a brilliant man and very, very productive, and I'm not criticizing in any way what he is saying . . . ." Tr. 381.

Apparently the Special Master rejected Petitioner's theory that Gardasil can cause lethal cardiac arrhythmia based on what he characterized as the Secretary's "challenges" to that theory:

> Here, Dr. Shoenfeld described his theory as "plausible," meaning that it can occur. It is true that the Secretary has not presented evidence to show that the molecular mimicry theory is impossible. Yet, the Secretary has raised sufficient challenges to the theory that Ms. Tarsell has not met her burden of proof.

Decision at *16 (internal footnote and citation omitted).

The Special Master identified the following "sufficient challenges to the theory" to support his conclusion that Petitioner failed to meet her Prong One burden:

> • The likelihood that LQAGL homology could be an inconsequential coincidence in light of the relative commonness of pentamer level homology between invasive organisms and the human proteome,
>
> • The likelihood that a human's immune system would recognize and respond to the five particular amino acids LQAGL when the HPV 16 contains thousands of amino acids,
>
> • The likelihood that any antibodies produced in response to the LQAGL pentamer would cross the cell membrane,
>
> • The likelihood that antibodies to LQAGL would inflict autoimmune damage to the calcium channel that would appear as bigeminy, not Brugada syndrome or Timothy's syndrome as genetic studies would predict.

Id.

These "challenges" do not go to the biological plausibility of Petitioner's theory - - they question the "likelihood" of certain aspects of the theory actually occurring. In assessing the "likelihood" of Petitioner's theory, the Special Master confused the standard imposed under Althen Prong One - - biological plausibility - - with the standard imposed under Althen Prong Two - - that the vaccine "more likely than not" caused the claimed injury. As this Court recognized in Doe 93:

> Whether a medical theory is "biologically plausible" is a far different inquiry than whether a medical theory is legally persuasive based on a preponderance of the evidence. Althen's requirement that a theory linking the vaccine to the injury be biologically plausible does not mean that a petitioner must prove, as the Special Master determined, that it is more likely than not that a vaccine actually can cause the claimed injury.

98 Fed. Cl. at 566-67 (emphasis in original). In requiring Petitioner to marshal evidence that would defeat Respondent's "challenges" to the theory in the context of assessing the biological plausibility of Petitioner's theory, the Special Master went too far.

On remand, the Special Master should assess whether Petitioner provided a biologically plausible theory without requiring Petitioner to demonstrate that particularized manifestations of this theory actually occurred.

Althen Prong Two: The Special Master Failed to Consider the Totality of the Evidence in Concluding that Petitioner Did Not Establish a Causal Relationship Between Gardasil and Christina's Death

Petitioner claims that Gardasil was a substantial factor and the but-for cause of Christina's death. Specifically, Petitioner contends that Christina's overactive immune system responded to Gardasil by producing autoantibodies that cross-reacted with the L-type calcium channel, damaging the channel, and disrupting the normal functioning of Christina's conduction system, which caused a RVOT-VPC arrhythmia and ultimately led to Christina's cardiac arrest.

The Special Master concluded that even if Petitioner proffered a persuasive theory of how Gardasil "can cause" arrhythmia and established that Christina's arrhythmia began after her first HPV vaccine, her claim would still fail because she did not establish "a logical sequence of cause and effect" linking Gardasil to Christina's death. Decision at *17 (internal quotation marks omitted). The Special Master examined Petitioner's evidence of causation under three "factors:" (1) "Treating Doctors," (2) "Challenge-Rechallenge," and (3) "Response as Predicted by the Causal Theory." Id. at *17-18. On review, this Court concludes that the Special Master failed to consider the totality of the evidence in assessing whether Petitioner met Althen Prong Two.

Evidence in Christina's Medical History

In his decision, the Special Master did not consider evidence Petitioner cited as crucial to the first element of her theory - - that Christina was predisposed to autoimmunity. As articulated by immunologist Dr. Shoenfeld, a genetic susceptibility to autoimmunity was essential to Petitioner's theory of causation. Tr. 192, 227. The Special Master addressed hypothyroidism in his Findings of Fact - - stating: "[i]n 2004, she was seen for weight gain, fatigue, and potential hypothyroidism. In February 2005, tests of Christina's thyroid were normal." FF at *3 (internal citations omitted). But the Special Master's decision did not mention any personal or family history of hypothyroidism, contain any reference to Christina's various allergies or treatment for hypothyroidism, or address Petitioner's expert's opinion that Christina suffered from autoimmune-induced hypothyroidism and was genetically susceptible to autoimmunity.

Although Christina's medical records contain evidence that Christina suffered from hypothyroidism, the experts appear to dispute whether hypothyroidism is sufficient to establish a predisposition to autoimmunity.[15] In Dr. Shoenfeld's opinion, Christina was prone to developing an autoimmune disease because she "had already one autoimmune disease, she had a family history of thyroid disease or she has a family genetic preponderance for autoimmunity." Tr. 240-41.

[15] Dr. Renee Howard, a pediatrician, evaluated Christina for hypothyroidism in 2004 and 2005, diagnosing Christina as having "borderline hypothyroidism," and prescribing Synthroid to treat this condition. See Pet'r's Ex. 1, at 9-14. Although Christina had not been prescribed Synthroid since 2005, Dr. Shoenfeld testified that the discontinuation of prescription treatment for hypothyroidism does not mean that Christina did not suffer from hypothyroidism or indicate that she did not have a genetic disposition to autoimmunity. Tr. 240-41.

Respondent's expert Dr. Yeager appeared to require that Christina have "systemic" autoimmune disease to trigger a predisposition to autoimmunity. See Resp't's Ex. ZZ, at 2.

Christina's medical record further demonstrates that she was allergic to two antibiotics, Cefzil and Augmentin. See, e.g., Pet'r's Ex. 1, at 24; Pet'r's Ex. 2, at 84. Dr. Shoenfeld opined that "some of the vaccine contains antibiotics and, therefore, if the subject is allergic to antibiotic, [she] will develop side effects" and explained that "subjects who are allergic . . ., are more prone to develop autoimmune diseases after vaccines." Tr. 200-01. Based on Christina's medical and family history of hypothyroidism, her allergies to antibiotics including Cefzil and Augmentin, and her seasonal allergies, Dr. Shoenfeld opined that Christina was susceptible to developing vaccine-induced autoimmunity. Id. at 205, 246-47.

Because the Special Master's analysis of Althen Prong Two contains no reference to Christina's hypothyroidism and no discussion of her predisposition to autoimmunity, the Special Master did not adequately consider the totality of the evidence relevant to whether the Gardasil vaccines did cause Christina's death. On remand, the Special Master shall examine whether the evidence establishes Christina's predisposition to autoimmunity.

On remand, the Special Master shall consider the medical records from Christina's treating physicians.

Evidence Considered by the Special Master Under the Rubric "Treating Physicians"

In considering Prong Two, the Special Master also failed to take into account medical-record evidence from Christina's treating physicians. In his analysis of "Treating Physicians," the only doctor the Special Master mentioned was Dr. Reiber, the pathologist who performed Christina's autopsy. The Special Master discussed Dr. Reiber's submission of a VAERS report and stated that "[t]he submission of a VAERS report is not necessarily evidence that the doctor considers the vaccination to have caused the injury being reported." Decision at *17. He then noted that Petitioner "did not present any argument based upon either the VAERS report or Dr. Reiber's notation that the HPV preceded Christina's death." Id. From this, the Special Master reached the perplexing conclusion that "[t]he opinions of treating physicians do not favor a finding of causation." Id. Dr. Reiber was not a "treating physician" for Christina; she is a pathologist who examined Christina's body to determine cause of death.

In analyzing Prong Two, the Special Master does not mention any of Christina's treating physicians - - internist Christine Lafferman, pediatrician Renee Howard, gynecologist Julie Jacobstein, otolaryngologist Karl Diehn, and various physicians at Bard College student health services - - whose diagnoses, treatments, and notations are reflected in contemporaneous medical records. See id. The Federal Circuit has emphasized the high probative value of medical records and medical-opinion testimony as evidence of causation-in-fact:

> [M]edical 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.

Capizzano, 440 F.3d at 1326 (second alteration in original) (internal citation and quotation marks omitted).

In relating Christina's medical history, the Special Master erroneously found that "Dr. Lafferman also administered the second dose of the HPV vaccination on November 20, 2007." Decision at *3. But Dr. Lafferman did not administer any dose of the Gardasil vaccination to Christina. The record indicates that a person with the initials "KB" from Dr. Jacobstein's office, Christina's gynecologist, administered the second dose of Gardasil that day. See Pet'r's Ex. 3, at 124. It is not clear from the decision whether or how the Special Master's erroneous finding - - that Dr. Lafferman administered the second dose of Gardasil to Christina after detecting an arrhythmia and confirming the arrhythmia via an EKG - - impacted the Special Master's analysis of Petitioner's claim. A treating physician's decision to administer or withhold a vaccination can be highly probative of causation. See Andreu, 569 F.3d at 1376 ("A treating doctor's recommendation to withhold a particular vaccination can provide probative evidence of a causal link between the vaccination and an injury a claimant has sustained." (internal footnote omitted)).

Evidence Considered by the Special Master Under the Rubric "Challenge-Rechallenge"

Petitioner argues that the Special Master ignored "[P]etitioner's challenge-rechallenge evidence." Mot. for Rev. 22. "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." Capizzano, 440 F.3d at 1322.

In rejecting Petitioner's challenge-rechallenge argument - - finding that "it is not clear that Christina's case fulfills the challenge-rechallenge paradigm" - - the Special Master did not assess Petitioner's challenge-rechallenge evidence. See Decision at *17. Rather than analyze such evidence and determine whether Petitioner sufficiently stated a challenge-rechallenge event, the Special Master relied upon his conclusion that:

> [T]he onset of Christina's arrhythmia is unknown. She may have had an undetected arrhythmia for many years. If so, the first dose of the HPV vaccination did not cause the arrhythmia.

Id. Thus, based upon his analysis of onset, the Special Master found that Petitioner failed to establish that Christina's first dose of Gardasil caused her initial arrhythmia or that the second and third doses worsened her condition and ultimately caused her death. Because the Special Master erred in concluding that Petitioner failed to prove causation because the onset of Christina's arrhythmia was unknown without assessing medical-record evidence, the Special Master's reliance on this onset analysis to reject Petitioner's challenge-rechallenge evidence was also erroneous.

Some of Christina's 12-year medical-record evidence that was not referenced by the Special Master reflects the worsening of Christina's symptoms with each subsequent vaccination. Christina received her first dose of Gardasil on August 22, 2007. Twenty-one days after receiving Gardasil, Christina's pulse was evaluated and marked as "normal." Per Dr. Shoenfeld's theory, this "is expected, because it's too short of a time to mount the autoantibody response, which is the basics for our plausible mechanism of inducing the arrhythmia. It takes at least three weeks, but you need to mount a high titer." Tr. 328. On November 20, 2007, ninety days after Christina received her first dose of Gardasil, Dr. Lafferman detected an arrhythmia for the first time in Christina's 20-year medical history, which was confirmed via EKG that same day.

On June 3, 2008, Christina received her third Gardasil vaccination. Pet'r's Ex. 3, at 99. Dr. Shoenfeld testified that the third Gardasil vaccine acted as a "boost," rapidly increasing the number of autoantibodies and resulting in Christina's development of symptomatic cardiac arrhythmia. Tr. 329-30. Within four days of receiving her third dose of Gardasil, Christina experienced dizziness, faintness, tiredness, and episodes of near-fainting for approximately five days, which are all known symptoms of cardiac arrhythmia. FF at *4; Pet'r's Ex. 25. According to Dr. Shoenfeld, after dose three, "the reaction will be much faster, and even you can get it even after a week or ten days." Tr. 211. Eighteen days after her third Gardasil vaccination, Christina died of a lethal cardiac arrhythmia.

Despite entering several Findings of Fact relevant to Petitioner's claim of challenge-rechallenge (e.g., that Christina was dizzy, tired, and experienced near-fainting spells within one week of her third dose of Gardasil), the Special Master does not mention any of these findings in analyzing whether Gardasil did cause Christina's death. On remand, the Special Master is instructed to consider whether Christina experienced challenge-rechallenge events with subsequent Gardasil vaccinations, based upon the record.[16]

Evidence Considered by the Special Master Under the Rubric "Response As Predicted by the Causal Theory"

In finding that his third factor, "Response as Predicted by the Causal Theory," did not weigh in favor of causation-in-fact, the Special Master stated:

> The essence of the theories Ms. Tarsell presented is that the HPV vaccination prompted an autoimmune attack on . . . the L1 calcium channel.
>
> * * *
>
> However, what the theories predicted was not found. Doctors from the CDC examined tissue taken during Christina's autopsy. Upon microscopic examination, they reported: "Sections of myocardium show no conspicuous inflammatory cell infiltrates." Ms. Tarsell had no persuasive evidence for this discrepancy.
>
> Consequently, even if Ms. Tarsell had demonstrated the reliability of any theory causally connecting the HPV vaccinations to fatal arrhythmia as an abstract proposition, there is little persuasive evidence that this theory played out in Christina's case.

[16] Although the Special Master relied upon the Chao study as providing evidence against a finding of causation, the findings from the Chao study do not apply to individuals with preexisting diagnoses of autoimmune disorder and thus may not apply to Christina if the Special Master finds she had the requisite pre-existing autoimmune condition or predisposition. Chao researchers eliminated from their consideration all records with indications of preexisting autoimmune disorders. See Pet'r's Ex. 109, at 3. As the Federal Circuit recognized, "epidemiological studies are designed to reveal statistical trends only for a carefully constructed test group. Such studies provide no evidence pertinent to persons not within the parameters of the test group." Moberly ex rel. Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010).

Decision at *18 (internal citations omitted).

Although the Special Master concluded that "what the theories predicted was not found" because doctors at the CDC found "no conspicuous inflammatory cell infiltrates," Dr. Shoenfeld testified that the theorized mechanism of causation would not necessarily result in observable cellular infiltrates in Christina's heart. Id. (internal quotation marks omitted); Tr. 221. Testimony from Respondent's expert immunologist and epidemiologist, Dr. Phillips, indicates cross-reactivities may not produce cell damage, as follows:

> Q. Have you ever -- in your career or in your research, have you ever -- have you ever encountered a cross-reactivity that doesn't produce cell damage?
>
> A. We see cross-reactivities all the time, and many of them don't.

Id. at 433. In addition, Dr. Phillips acknowledged that HPV DNA fragments have been detected in the bloodstream and spleen of vaccine recipients, a circumstance which in Petitioner's view indicates that cross-reactivity occurs. Id. at 431-32; Pet'r's Ex. 36, at 8.

Further, it is understandable that there is no evidence as to whether Christina produced autoantibodies which damaged the L-type calcium channels, because Christina was never tested for such autoantibodies. As Dr. Shoenfeld testified, "Christina died after the HPV vaccine and we will not be able to look for these autoantibodies in her blood." Pet'r's Ex. 108, at 9. According to Dr. Shoenfeld, there is no standard test that can detect damage to the L-type calcium channels via autoantibodies. Dr. Shoenfeld testified that, in order to test for such damage and these autoantibodies, "[y]ou have to build the diagnostic kit, and if I would not build such a diagnostic kit, I cannot diagnose it properly, I mean, to detect the autoantibody." Tr. 221.

On remand, the Special Master is instructed to consider all evidence on a logical sequence of cause and effect linking Gardasil and Christina's death - - including Christina's treating physicians, her medical records, challenge-rechallenge evidence, expert opinion, and epidemiological studies, in assessing whether Petitioner met her burden under Prong Two.

Conclusion

Petitioner's motion for review is **GRANTED**. The Special Master's decision denying compensation is **VACATED**, and the case is **REMANDED** to the Special Master for further proceedings consistent with this decision. The Court makes no factual findings of its own.

On remand, the Special Master shall reassess whether Petitioner met Althen's Prongs One, Two, and Three and whether she is entitled to compensation, consistent with the legal principles articulated in this opinion.

Pursuant to 42 U.S.C. § 300aa-12(e)(2), the Court allows 90 days for the completion of proceedings on remand.

The Clerk shall not disclose this decision publicly for 14 days.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Judge

TARSELL V. SECRETARY OF HEALTH & HUMAN SERVICES (10-251V)

APPENDIX A: MEDICAL-RECORD EVIDENCE OF CHRISTINA'S PULSE MEASUREMENTS[17]

	Date	Pulse	Record
1	4/25/1996	84	Ex. 1 at 40
2	11/21/1996	116	Ex. 1 at 39
3	12/9/1996	76	Ex. 1 at 38
4	2/7/1997	104	Ex. 1 at 37
5	6/2/1997	120	Ex. 1 at 36
6	7/9/1997	96	Ex. 1 at 35
7	10/20/1997	104	Ex. 1 at 34
8	11/5/1997	96	Ex. 1 at 33
9	1/22/1998	110	Ex. 1 at 32
10	5/31/1998	92	Ex. 1 at 25
11	8/19/1998	100	Ex. 1 at 28
12	12/2/1998	88	Ex. 1 at 27
13	4/28/1999	96	Ex. 1 at 26
14	6/4/1999	48	Ex. 1 at 24
15	11/27/2000	84	Ex. 1 at 22
16	1/16/2001	80	Ex. 1 at 21
17	4/15/2001	88	Ex. 1 at 20
18	**8/14/2001**	**72**	**Ex. 1 at 19**
19	**7/18/2002**	**60**	**Ex. 1 at 18**
20	**11/29/2002**	**70**	**Ex. 1 at 17**
21	1/16/2003	80	Ex. 1 at 16
22	5/20/2004	60	Ex. 1 at 14
23	9/20/2004	76	Ex. 1 at 13
24	10/18/2004	76	Ex. 1 at 12
25	11/16/2004	86	Ex. 1 at 11
26	11/27/2004	70	Ex. 1 at 17
27	12/15/2004	96	Ex. 1 at 10
28	**2/28/2005**	**76**	**Ex. 1 at 8**
29	**6/16/2005**	**104**	**Ex. 1 at 7**
30	**6/23/2006**	**84**	**Ex. 1 at 5**

[17] Pet'r's Ex. 1 at 5, 7–8, 10–14, 16–22, 24–28, 32–40.