In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

TYLER JOSSART,	*	
	*	No. 15-1377V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Filed: May 22, 2024
	*	
Respondent.	*	

Danielle Strait, Maglio Christopher & Toale, Seattle, WA, for petitioner; Debra A. Filteau Begley, United States Dep't of Justice, Washington, DC for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Tyler Jossart suffered from a variety of health problems, such as diarrhea, nausea, headaches, and syncope, before he received a dose of the human papillomavirus vaccine in November 2012. About one month after the vaccination, one of his treating doctors, Grace Chelimsky, said he suffered from "borderline" postural orthostatic tachycardia syndrome ("POTS").

In the pending case, an expert in neurology whom Mr. Jossart retained, Lawrence Steinman, has contended that Mr. Jossart not only had POTS in

[1] Because this Decision 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 Decision 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.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

December 2012, but also the myriad of symptoms Mr. Jossart experienced for about one year were also manifestations of an undiagnosed case of POTS. Dr. Steinman further opines that Mr. Jossart's POTS worsened, and the HPV vaccination significantly aggravated his disease. Dr. Steinman proposed that the mechanism by which HPV vaccination harmed Mr. Jossart was molecular mimicry.

The Secretary denies that Mr. Jossart is entitled to compensation through the Vaccine Program and relies upon two experts. An expert in POTS, Christopher Gibbons, maintains that Mr. Jossart did not suffer from POTS in 2012 or 2013. A second witness, Lindsay Whitton, an expert in immunology, opines that the evidence does not support a finding the HPV vaccination can aggravate POTS.

On both the question of whether Mr. Jossart suffered from POTS in 2012-2013 and the question of whether the HPV vaccination can aggravate POTS, the Secretary's positions are persuasive. As to the first issue (diagnosis), the evidence is admittedly close. However, Dr. Gibbons has well explained that Mr. Jossart did not meet the diagnostic criteria for POTS, regardless of Dr. G. Chelimsky's designation of him as suffering "borderline POTS." Dr. Gibbons demonstrated that Mr. Jossart symptoms in 2012 and 2013 were generally not consistent with how POTS manifests. This evidence outweighs the report from Dr. G. Chelimsky.

Even if Dr. G. Chelimsky's report about "borderline POTS" were credited as persuasive, Mr. Jossart's case would still falter. On the issue of whether the HPV vaccine can cause or aggravate POTS, the record, taken as a whole, heavily weighs against petitioner. One strong piece of evidence on this topic is a statement from the American Autonomic Society. This group of experts, which includes Dr. Gibbons and Dr. G. Chelimsky, concluded the evidence does not support a causal connection between HPV vaccination and POTS. Against this evidence, Dr. Steinman's theory about molecular mimicry is unpersuasive.

Accordingly, Mr. Jossart's claim in the Vaccine Program is denied. A full explanation follows. This explanation begins with a discussion of POTS. (Section I). This discussion provides a context for the summary of events in Mr. Jossart's life. (Section II). After that summary, Section III outlines the procedural history and Section IV sets forth the standards for adjudication. The reasons for denying compensation are found in two parts. Section V finds that Mr. Jossart did not establish with preponderant evidence that he suffered from POTS in 2012-2013. Section VI finds that Mr. Jossart did not persuasively show that the HPV vaccine significantly aggravated his hypothetical POTS.

I. POTS[2]

An understanding of medical terminology will assist in evaluating whether Mr. Jossart suffered from POTS and whether an HPV vaccine can worsen POTS. For this introduction, the undersigned tends to rely upon Dr. Gibbons because he is the testifying expert who specializes in POTS and because his testimony was not rebutted.

The autonomic nervous system regulates aspects of life that happen unconsciously. For example, the autonomic nervous system controls a person's digestion and heart rate. Dorland's Illustrated Medical Dictionary, 1365 (33rd ed. 2019) at 1829; Tr. 347. A person's heart rate can be measured in beats per minute, which is often abbreviated "bpm." The heart rate (or pulse) can be easily measured. A rapid heart rate is called "tachycardia." Dorland's at 1838.

When a person has a problem in his (or her) autonomic nervous system, the person suffers from "dysautonomia." Dorland's at 569, Tr. 347. In Dr. Gibbons's view, "dysautonomia" is a broad and a vague term. Tr. 347. He contrasted "dysautonomia" with "autonomic dysfunction." Id. However, Dorland's defines "autonomic dysfunction" as "dysautonomia." Dorland's at 570.

A person can have dysautonomia because he (or she) has had a disruption to the nerves of the autonomic nervous system. In such a case, the person has suffered "autonomic damage." Tr. 348. However, dysautonomia can be caused by problems other than damage to the nerves, such as when a medication causes dysfunction in the autonomic nervous system. Id. Thus, dysautonomia and autonomic damage are not synonyms.

"Orthostatic" refers to a person's condition when standing erect. Dorland's at 1329. "Orthostatic intolerance" is not feeling well when a person stands up. "Orthostatic intolerance" is a symptom, not a disease itself. Tr. 349.

"Postural orthostatic tachycardia syndrome" is a condition in which a person does not feel well when standing up and these symptoms are linked to an elevated heart rate. Dorland's at 1815, Tr. 350; see also Yalacki v. Sec'y of Health & Hum. Servs., No. 14-278V, 2019 WL 1061429, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), mot. for rev. denied, 146 Fed. Cl. 80 (2019). The way a person does not feel well can vary but may include problems such as dizziness. The variability in

[2] For additional information about POTS, see Pet'r's Prehear'g Br., filed Aug. 31, 2020, at 4-6; Resp't's Prehear'g Br., filed Jan. 13, 2021, at 30-34.

presentation is reflected in the term "syndrome," because a syndrome means "a set of symptoms that occur together; the sum of signs of any morbid state; a symptom complex." Dorland's at 1789, Tr. 312.

The medical community has attempted to define POTS by establishing diagnostic criteria. A criterion cannot be that the person's heart rate goes up when standing because an increase in heart rate when standing is normal. Tr. 350. In other words, a simple elevation in heart rate on standing would not differentiate people with an abnormal condition from people who are normal. To determine who suffers from an excessive degree of tachycardia, the medical community has determined that in adolescents, the increase in heart rate must be at least 40 beats per minute. Exhibit A-1 (Freeman et al, Consensus statement on the definition of orthostatic hypotension neurally mediated syncope and the postural tachycardia syndrome), Exhibit 36 (Bennarroch, Postural Tachycardia Syndrome: A Heterogenous and Multifactorial Disorder); Tr. 350-51, 356.[3] The primary way to determine how much a person's heart rate increases on standing is through a tilt table test. Tr. 354. A person whose heart rate does not meet the minimal criterion might have "orthostatic intolerance." Exhibit 36 at 1; Tr. 234-35.

Similarly, researchers have looked at the symptoms that sometimes occur with the increase in heart rate while standing. According to research performed by Dr. G. Chelimsky and others, adolescents with POTS can have symptoms that adolescents without POTS also have. Exhibit 50 (Chelimsky et al., Comorbid Conditions Do Not Differ in Children and Young Adults with Functional Disorders with or without Postural Tachycardia Syndrome); Tr. 353. This overlap, in turn, means that testing is needed to diagnose a person properly. Tr. 353-54.

A person with POTS may be further classified as suffering from one of three subtypes of POTS. Dr. Gibbons explained the separation of POTS into subtypes represents a "cognitive construct." Exhibit A at 1; accord Tr. 320. However, the subtypes overlap. Exhibit A-5 at 7; see also Tr. 293 (Dr. Steinman's testimony that the subtypes of POTS do not make sense to him).

The subtypes of POTS correspond to different suspected etiologies, at least in part. It might be possible that more than one pathologic process needs to happen (even in the same individual) for POTS to develop. Tr. 418. Among the three subtypes of POTS, the easiest to understand is hypovolemia. In that subtype,

[3] As discussed in section VI.B. below, Dr. Steinman questions the authoritativeness of the consensus statement.

dehydration causes postural tachycardia, and the doctors treat it by giving fluids. Tr. 251. The distinction between neuropathic POTS and hyperadrenergic POTS is less clear. Exhibit A-5 (Arnold et al., Postural tachycardia syndrome – Diagnosis, physiology and prognosis) at 5 ("In our experience, these 'subtype' labels are not clinically helpful").

While Dr. Steinman stated that the subtype of POTS was not important to his opinion, Tr. 225, 286, Dr. Steinman has proposed an autoimmune etiology. Exhibit 51 (Dr. Steinman's report) at 17; see also Exhibit A-5 at 6 (discussing immune-mediated POTS). However, most cases of POTS have not been recognized as autoimmune in origin. Tr. 338 (Dr. Gibbons).

In any type of POTS, the person suffering from POTS might experience anxiety. But, anxiety can cause postural tachycardia as well. Exhibit A (Dr. Gibbons's report) at 10; Tr. 251, 426. Similarly, a person can have somatization and POTS.[4] Tr. 433, 447.

Treatments for POTS have been difficult to identify. In general, doctors try to minimize medications and to maximize exercise. Tr. 392. According to a recent article Dr. Gibbons wrote, at least six months of rigorous exercise are needed to resolve POTS. Exhibit A-7 (Gibbons et al., The recommendations of a consensus panel for the screening diagnosis, and treatment of neurogenic orthostatic hypotension and associated supine tension), Tr. 467.

II. Events in Mr. Jossart's Life

Mr. Jossart experienced health problems for many years before he received the HPV vaccine that allegedly caused his health to deteriorate in November 2012. Thus, this recitation of evidence is necessarily lengthy. The length, however, does not reflect a significant dispute between the parties in the sense that the parties generally agree that the medical records accurately describe events that happened contemporaneously with the creation of the medical records.[5] Thus, the medical records are the primary source and the testimony of Mr. Jossart and his mother providing supplemental information. This recitation of evidence also notes the

[4] "Somatization" means "the conversion of mental experiences or states into bodily symptoms." Dorland's at 1705.

[5] The recitation of evidence, at times, draws from the parties' presentation of facts. See Pet'r's Prehear'g Br. at 3-6, 10-23; Resp't's Prehear'g Br. at 1-21.

opinions from Dr. Steinman and Dr. Gibbons, the two experts who testified about Mr. Jossart's diagnosis.

Because some evidence refers to events in Mr. Jossart's life that correspond to his grade level, the following chart helps to translate grades into years.

Grade	Fall	Spring
7	2008	2009
8	2009	2010
9	2010	2011
10	2011	2012
11	2012 (vaccine)	2013
12	2013	2014

The presentation of events in Mr. Jossart's life is divided into three periods. The first is his health before the vaccination. The second is his health during his junior and senior year of high school during which he received the allegedly causal vaccination. The third period concerns medical history more distant from the vaccination.

A. Before Vaccination

1. Early Life, including Middle School

While Mr. Jossart was in middle school, Ms. Jossart was concerned that her son was missing too many days of school. Exhibit 5 at 126. Specific problems included ongoing left foot pain, a recent event during which Mr. Jossart could not breathe while in school, and "asthma."[6]

[6] The Secretary questioned whether Mr. Jossart suffered from asthma. As the Secretary noted: "In November 2006, he was evaluated for possible laryngeal spasms, which might explain his shortness of breath that occurred with exercise or when he was 'upset or crying.'" Resp't's Prehear'g Br. at 2, n.1, quoting Exhibit 31 at 46. A breathing test to assess whether a person suffers from asthma, spirometry, was performed on May 19, 2006, and was normal. Exhibit 31 at 18-19. Mr. Jossart was later tested for possible sports-induced asthma and this testing revealed that a paradoxical vocal cord movement at the height of exercise affected Mr. Jossart's breathing. Id. at 32.

According to the medical history created in 2013, Mr. Jossart experienced a syncopal event when he was in seventh grade. Exhibit 4 at 127 (Feb. 5, 2013). In the second half of Mr. Jossart's seventh grade year, he complained about problems with coughing, wheezing, abdominal pain, headaches, and symptoms reported as asthma. See Exhibit 4 at 84-119, Exhibit 7 at 460-61.

Similar problems continued into 2011. Some of these medical records indicate that Mr. Jossart was diagnosed as having migraines. Exhibit 5 at 3-8, 52-53. But, in his oral testimony, Mr. Jossart did not specifically recall who diagnosed him as having migraines but believed it was Dr. Wendy Barton who diagnosed him. Tr. 24.

Although not documented in any records created while Mr. Jossart was in middle school, Mr. Jossart later stated he was bullied during middle school. Exhibit 14 at 6 (April 22, 2013); Exhibit 31.12 at 1416 (Apr. 11, 2013); Tr. 31, 128.

Dr. Steinman opined that the various health problems Mr. Jossart experienced in middle school were manifestations of POTS. Tr. 269-72. However, no doctor treating Mr. Jossart during middle school suggested he was suffering from POTS.

2. First Year, Second Year, and the Start of the Third Year of High School

In anticipation of beginning high school, Mr. Jossart had a 15-year-old well-child examination with his pediatrician, Dr. Barton. The record reports a history of, among other problems, reflux, vocal cord dysfunction, allergic rhinitis, contact dermatitis, abdominal pain, malabsorption, and mild persistent asthma. Exhibit 5 at 64 (July 26, 2011). Ms. Jossart again expressed concern that abdominal issues were causing her son to miss school. Id. at 65. Mr. Jossart informed Dr. Barton that he "has had a couple of times where he felt tremulous. A couple of the episodes were before he [had] eaten and one was after." Id. at 66. Dr. Barton stated that the tremulousness was likely due to mild anxiety or possibly low blood sugar. Id. at 68; see also Tr. 26.

According to a therapist's record created in 2013, 2012 was a stressful time for Mr. Jossart and his family as his mother was ill. Exhibit 14 at 5-6 (detailing his mother's illness), Tr. 96.

On February 3, 2012, Mr. Jossart sought care at Dr. Barton's office because he was vomiting and experiencing chest pain. Exhibit 5 at 58.[7] With Dr. Barton, Mr. Jossart "[d]enie[d] tachypnea, shortness of breath and labored breathing. Denie[d] palpitations, tachycardia, bradycardia or irregular heart beats." Id. Dr. Barton assured Mr. Jossart and his mother that "these symptoms do not appear to represent a serious or threatening condition." Id. at 59. She recommended that if the symptoms did not improve as anticipated, then Mr. Jossart should seek additional care. Id.

On his way home from Dr. Barton's office, he was in the car feeling anxious and short of breath. His mother brought him to the Theda Clark emergency room. Exhibit 7 at 425. A CT scan suggested an esophageal rupture and free air in Mr. Jossart's mediastinum. Id. at 427-28. "Mediastinum" refers to the area between the lungs. Dorland's at 1103. (The medical term for air in the mediastinum is "pneumomediastinum." Dorland's at 1449.) The doctor at Theda Clark arranged for Mr. Jossart's transfer to Children's Hospital of Wisconsin, Milwaukee ("CHOW"). Exhibit 7 at 426.

An ambulance transported Mr. Jossart from Theda Clark to CHOW. The record notes Mr. Jossart was "feeling like he was going to pass out." Exhibit 31.2 at 109.

The doctor in CHOW's emergency room, Casey Calkins, obtained a history consistent with what is stated above. Dr. Calkins stated it "sounds like hyperventilation." Exhibit 31.01 at 57; see also Tr. 92, 192. An esophagram did not detect a pneumomediastinum. Exhibit 31.01 at 6. Mr. Jossart was admitted for a 23-hour observation with an expectation that he would "return to the GI clinic for further workup of his retching episodes." Id. at 59.

After discharge, Mr. Jossart followed up with Dr. Barton. Exhibit 5 at 55 (Feb. 6, 2012). He "hasn't felt anxious with all of this." Id. Dr. Barton ordered an echocardiogram to rule out Marfan's syndrome. Id. at 56. It was normal. Id. at 31. Dr. Barton was also waiting the results of his upcoming GI evaluation. Id. at 56.

[7] The episode in February might have started with throwing up at McDonald's. Tr. 44. But, this testimony was vague about when the incident at McDonald's happened.

On February 7, 2012, Mr. Jossart returned to CHOW, more specifically to the Pediatric Surgery Clinic. Exhibit 31.02 at 111. "Throughout the last several months, he has had increasing episodes of retching and emesis in which he [typically] expresses mucus only." Id. This doctor, Amy Wagner, determined that Mr. Jossart has "chronic emesis and retching, which has resulted in pneumomediastinum." Id. at 112. Dr. Wagner contacted her gastrointestinal colleagues, including Dr. Goday, and they agreed to admit him at CHOW.

While in the hospital, Mr. Jossart sought care for his "lifelong" issues with vomiting and retching, recent chest pain, and frequent coughing. Exhibit 31.02 at 132, 154. Dr. Goday performed a fluoroscopic esophagram, which could detect problems in the esophagus that might contribute to vomiting. The results were normal. Exhibit 31.02 at 175 (February 8, 2012). He was discharged on February 8, 2012. Exhibit 31.02 at 155.

A sinus CT showed chronic sinusitis. Exhibit 7 at 410 (Feb. 16, 2012). He eventually underwent an operation for his sinuses. Exhibit 2 at 9, 16 (June 5, 2012).

In the ninth and tenth grades, which correspond to August 2010 to June 2012, Mr. Jossart was fine at school. He earned mostly A's and liked his teachers. Tr. 34, 136, 139. He participated in physical education classes without any restrictions. Tr. 37, 140. Besides playing sports in physical education classes, Mr. Jossart played soccer. Tr. 37-38, 138. But, by summer of his tenth grade, he was not feeling well with running. Id.

While he played soccer, he seems to have enjoyed playing music more. He played the mellophone in marching band. Tr. 36. His school's marching band was famous and competed to play in parades before New Year's Day college football games. Tr. 35. He performed the choreographed routines while carrying his instrument, which weighed 4-5 pounds. Tr. 36, 137. He also received private tutoring for a different instrument, the French horn. Tr. 137.

Mr. Jossart attended school dances. He had friends and a girlfriend. Tr. 32, 136, 138.

As he was starting his junior year, his school life was about the same. He was taking Advanced Placement classes as well as physical education. Tr. 145-46. His extracurriculars included playing in the marching band and playing French horn in the concert band. Id.

Mr. Jossart had numerous visits between February 2012 and late October 2012 for seemingly normal illnesses and evaluation for his longstanding gastrointestinal issues. Exhibit 5 at 33-50 (records of Dr. Barton).

Dr. Barton directed Mr. Jossart to consult a gastroenterologist and, accordingly, Mr. Jossart saw Jeffrey Goldman on July 31, 2012. Exhibit 6 at 14-17, Tr. 194. The chief complaint was "Postprandial nausea and recent diarrhea." ("Prandial" refers to a meal. Dorland's at 1484). Dr. Goldman's history recounted in detail the events of February in which Mr. Jossart was evaluated for a pneumomediastinum and underwent various tests at CHOW. Dr. Goldman recommended seeking testing from an allergist for food allergies. Exhibit 6 at 17.

Upon the referral from Dr. Goldman, Mr. Jossart sought treatment with an allergist, Anita Gheller-Rigoni, to evaluate possible eosinophilic esophagitis versus a food allergy. Exhibit 6 at 3 (August 7, 2012). As part of that consultation, Ms. Jossart, on behalf of her son, completed a new patient questionnaire. Id. at 26-29, Tr. 42-43, 152. Ms. Jossart informed Dr. Gheller-Rigoni that Mr. Jossart had nausea, vomiting, and chest pressure for many years, but "worse for the past year." Exhibit 6 at 29. On a review of symptoms, Ms. Jossart circled or underlined various items including cough, shortness of breath, exercise-induced symptoms, chest pain, stress, anxiety, and muscle pain. Id. at 26.

Another item circled was "fainting spells." Id. When questioned about this entry, Mr. Jossart testified that he did not recall fainting before August 2012. Tr. 43. Ms. Jossart explained that perhaps Mr. Jossart had passed out in the shower from having a gastrointestinal issue. But, fainting did not happen on a "regular basis." Tr. 152-53; see also Tr. 196 (Ms. Jossart describing Mr. Jossart falling over in the shower on an unspecified date). The testimony that Mr. Jossart did not faint frequently is consistent with another portion of the new patient questionnaire in which Ms. Jossart indicated that Mr. Jossart had not lost consciousness. Exhibit 6 at 28.

The new patient questionnaire suggested that Mr. Jossart might have asthma. See id. (several checkmarks for asthma symptoms); see also Tr. 42 (Mr. Jossart discussing his belief that his asthma was worsening in early 2012), 192 (Ms. Jossart associating breathing issues with exercised-induced asthma). But, during the August 7, 2012 appointment, Mr. Jossart underwent another spirometry. The results were, again, normal. Exhibit 6 at 24.

In addition to the spirometry, Dr. Gheller-Rigoni tested him for various skin and food allergies. These results were negative. Exhibit 6 at 5, 25; Tr. 42 (describing the allergist's work up as unremarkable).

October 29, 2012 Incident[8]

Shortly before lunch, Mr. Jossart had trouble breathing, he was feeling shaky, he was experiencing chest pain, and he was experiencing shortness of breath. A friend took him to the friend's car, where Mr. Jossart passed out for less than one minute.[9]

Mr. Jossart did not seek treatment on that day. Instead, the next day, Ms. Jossart brought him to the emergency department at Theda Care. Exhibit 7 at 316-17 (consent form); see also Tr. 79. Mr. Jossart told the doctor about his condition the day before as well as "similar symptoms this past February . . . [and] states that he was diagnosed with pneumomediastinum at that time but had been forcefully vomiting prior to that finding." Exhibit 7 at 319. In the emergency department, Mr. Jossart denied fever, nausea, vomiting, cough, numbness, tingling, or weakness. Id. A chest X-ray did not detect a pneumomediastinum. Id. at 323. The doctor discharged him from the emergency room to home with a diagnosis of "chest pain" and instructions to follow up with Dr. Barton. Id. at 323-24.

The appointment with Dr. Barton happened on November 1, 2012. Dr. Barton wrote that "Tyler's complex past history including pneumomediastinum is well known to me." Exhibit 5 at 30. The history Dr. Barton obtained is consistent with information presented above. Mr. Jossart also told Dr. Barton that he "has also been having joint pain all day most days for as long as he can remember [and] mostly notices hip/knee and ankle pain with ankles being the worst." Id.[10] Dr.

[8] Evidence about Mr. Jossart's health on October 29, 2012 comes from a report he gave at Theda Care emergency room on October 30, 2012 (Exhibit 7 at 318-28), a report he gave to Dr. Barton on November 1, 2012 (Exhibit 5 at 30-31), his testimony (Tr. 79-82), and his mother's testimony (Tr. 191-98).

[9] The source of information about the duration of Mr. Jossart's loss of consciousness is the November 1, 2012 report to Dr. Barton. Exhibit 5 at 30.

[10] This report of frequent joint pain seems unusual. See Exhibit 5 at 67 (July 26, 2011 report: "range of motion of joints are normal except stiffness and tenderness with range of motion of the left ankle"); Id. at 70 (July 13, 2011 report: "No joint pains or weakness"); Id. at 127 (June 24, 2008 report: "Gait and range of motion of joints are normal.").

Barton was informed that Mr. Jossart had an appointment with a gastrointestinal specialist at CHOW set for December. Id. at 31.

Dr. Barton's November 1, 2012 plan consisted of multiple items:

> -we will get a forty-eight hour Holter monitor
>
> -I would like to refer him to cardiology for an evaluation
>
> -Discussed with the family including Tyler that we need to consider if anxiety is playing some role in his chest pain symptoms
>
> -Continue to pursue the GI workup as is already in place through his specialist.
>
> -I suggested to Tyler that he not use his inhaler when he developed chest pain if he does not feel shortness of breath as this will just increase his heart rate and make him more shaky.

Id.

With respect to Dr. Barton's suggestion that anxiety might be playing a role, Mr. Jossart and his mother testified that they did not remember. Tr. 85, 201-02.

The first step of Dr. Barton's plan was implemented through a visit to Theda Clark hospital. Mr. Jossart received a Holter monitor. See Exhibit 7 at 277-81; see also Tr. 40. A Holter monitor detects the frequency and duration of cardiac rhythm disturbances. Dorland's at 1158. According to Dr. Steinman, a Holter monitor could be useful in determining whether a person suffers from POTS in the sense that it gives information about "the heart rate while you're living your life." Tr. 268. But, a Holter monitor is not as specific as a tilt table test. Id.

For Mr. Jossart, his average heart rate was 96. Exhibit 7 at 281. The minimum heart rate was 45 and the maximum heart rate was 187. The maximum heart rate occurred while he was sitting watching a movie. Id.[11] The follow-up, which occurred after the allegedly causal vaccination, is discussed below.

[11] Dr. Gibbons stated that the Holter monitor indicated that Mr. Jossart had episodes of bradycardia. Tr. 367, 391. However, the basis for this assertion is not readily apparent.

Around this time, Mr. Jossart started a part-time job at a local department store as a cashier. Tr. 85, 146; see also Exhibit 70 at 4 (job application, dated Nov. 3, 2012).[12] He worked about 20 to 30 hours per week through the holiday season. Exhibit 70 at 10 (payroll records).

Before the first vaccination, Mr. Jossart missed two days of school in September, three plus a partial day of school in October, and two days of school in November 2012. Exhibit 72 at 1-3, Id. at 32-33.

Although the next critical event for Mr. Jossart's claim is his vaccination, a pause in his story is worthwhile. By November 2012, Mr. Jossart had seen numerous doctors for a multitude of complaints, primarily gastrointestinal. None of the doctors had suggested that he suffered from POTS. However, the expert retained for this litigation, Dr. Steinman, has opined that he suffered from POTS.

B. Vaccination through Completion of High School

1. November 2012 through March 2013, which includes the HPV Vaccination

On November 26, 2012, Mr. Jossart received his first of two HPV vaccinations and received an influenza trivalent vaccination from Dr. Barton's office. See, e.g., Exhibit 52 at 2 (showing Mr. Jossart's vaccination history prior to December 15, 2016); Exhibit 24 at 1; see also Tr. 47-48. It appears that the reason Mr. Jossart visited Dr. Barton was to receive the vaccines. Tr. 154.

Four days later, Mr. Jossart was seen at CHOW in, apparently, a pediatric cardiology clinic. A registered nurse, Amy Marks, reviewed his systems and recorded that he had "a syncopal episode in his [friend's] car. Felt dizzy while eating lunch, friend took him outside for air, went to his [friend's] car and sat down and then passed out." 31.02 at 184 (Nov. 30, 2012). He was later seen by an advanced practice nurse in pediatric cardiology, Mary Butler. Exhibit 31.02 at 182 (Nov. 30, 2012).[13] The purpose of the appointment was to evaluate his chest pain, which started eight months ago. Ms. Butler noted that the 48-hour Holter was within normal range. Ms. Butler's assessment was that he had "Chest pain" and an "Isolated episode of syncope, probable vasovagal in nature." Id. at 183. Ms.

[12] Mr. Jossart had testified that he had begun working during the summer. Tr. 46. That testimony reflects an inaccurate memory as the payroll records indicate that he started working around November 10, 2012. Exhibit 70 at 10.

[13] Mr. Jossart's attorney referred to Ms. Butler as a "cardiologist." Tr. 40.

Butler concluded that Mr. Jossart had a "non-cardiac cause of chest pain." Id. She did not recommend any follow-up.

Around December 2, 2012, Mr. Jossart attended a professional football game and sat outside for an extended time. Exhibit 5 at 27. He developed a cough, shortness of breath, and tightness in his chest. Id. Then on December 3, 2012, he was sitting in a hallway and developed trouble breathing. Id. He "went out" for about 10 seconds. Id. After he woke, he was still having trouble breathing. Id.

The report about Mr. Jossart's health on December 2-3, 2012 comes from information Mr. Jossart and his father delivered to Dr. Barton on December 5, 2012. Exhibit 5 at 26-27; see also Tr. 88. Dr. Barton explained that "the episode where he was having difficulty breathing," but exhibited normal breathing while passed out, was "highly suggestive of anxiety. . . . [Dr. Barton] would like him to see a therapist to review some anxiety coping techniques." Exhibit 5 at 27.

Mr. Jossart did not remember Dr. Barton suggesting a therapist. To him, the originator of the idea to see a therapist was his mother. Tr. 50. Ms. Jossart, however, stated that in December 2012, she did not think Tyler had anxiety. In her view, her other son had anxiety but Tyler did not. Nevertheless, if just to rule out anxiety, Ms. Jossart planned to take Tyler to a therapist. Tr. 144, 150, 156.

Mr. Jossart's involvement with a therapist around this time appears limited to two visits. Ms. Jossart brought him to see Frank Cummings, a psychologist. Ms. Jossart knew Dr. Cummings because other family members were seeing him. Tr. 51, 150. Mr. Jossart's first appointment with Dr. Cummings was on December 15, 2012. Exhibit 71 at 2-3. The reason for the referral was "to redress anxiety symptoms." Id. at 2. Dr. Cummings's history refers to Mr. Jossart's "struggl [ing] with multiple medical issues over the last several months." Id. Dr. Cummings wrote that Mr. Jossart "appeared somewhat nervous throughout the interview and seemed to relate well to this examiner." Id. During the December 15, 2012 session, Mr. Jossart completed a standardized test, the Behavior Assessment System for Children, Second Edition. Id. at 5-34; see also Tr. 97. Dr. Cummings's "Axis I" diagnosis was "Generalized Anxiety Disorder." Exhibit 71 at 3. Dr. Cummings scheduled another visit with him.

The second (and final) visit with Dr. Cummings was a few weeks later. The results of the psychological testing suggested "co-morbid medical (somatization) and attention/concentration problems." Exhibit 71 at 4. Dr. Cummings carried forward the diagnosis of "Generalized Anxiety Disorder" and anticipated another

outpatient therapy session "to enhance Tyler's emotional, social, and self-control competencies." Id.[14]

Another therapy session with Dr. Cummings did not happen. Mr. Jossart testified that their personalities did not click, and he felt uncomfortable talking to Dr. Cummings. Tr. 51, 97-98.

Around the time that Mr. Jossart was seeing Dr. Cummings, he was also seeing a pediatric gastroenterologist, Gisela Chelimsky.[15] As discussed below, her records greatly contribute to the outcome of Mr. Jossart's claim that the HPV vaccine caused his pre-existing POTS to worsen.

The first visit occurred on December 6, 2012. The history portion states that Dr. Barton has referred him "for follow up of nausea with every meal and daily." Exhibit 31.03 at 232. The purpose of this visit was not for fainting or dizziness. Tr. 52; see also Tr. 157 (Ms. Jossart: the purpose of the visit was for "GI and headache"). Dr. G. Chelimsky's history focused on his gastrointestinal problems: "He started with vomiting 2 years ago. . . . He vomits about 1-2/every 2 weeks." Exhibit 31.03 at 232. "He gets chest pain feels like pressure or heavy aching." Id. "He fainted twice in the past year. The episodes happened sitting. . . . He does not get dizzy routinely." Id., Tr. 87. "There is a history of headache for 12 months or more." Id. at 233. "There is history of hypermobile joints associated with more than 3 painful joints for over 3 months. He has seen somebody about his ankle." Id. Overall, Dr. G. Chelimsky spent 80 minutes with Mr. Jossart of which more than 50 percent was counseling for possible cause and evaluation. Id. at 235.

Dr. G. Chelimsky's assessment was that Mr. Jossart had "chronic nausea and vomiting. He also has headaches and hypermobility. Probably due to migraine and POTS. Need to rule out delayed gastric emptying and malrotation." Id. at 235.

Dr. G. Chelimsky's plan included nine points. She prescribed a medication, cyproheptadine. Exhibit 31.03 at 235. Dr. Steinman stated that cyproheptadine is a medicine for allergies and inhibits neuroinflammation. Tr. 318; see also

[14] When Dr. Steinman was asked about Dr. Cummings's diagnosis of "Generalized Anxiety Disorder," Dr. Steinman did not persuasively refute the appropriateness of the diagnosis. Tr. 324-28.

[15] Because Mr. Jossart saw Dr. Grace Chelimsky and Dr. Thomas Chelimsky, this decision includes the first initial of the first name.

Dorland's at 452. It may not have required a prescription. Tr. 324. Dr. Gibbons agreed that cyproheptadine is used for a variety of reasons, such as allergies, chronic nausea, migraines, and cyclic vomiting. Tr. 382. However, Dr. Gibbons cautioned that cyproheptadine is contraindicated for POTS. Id.

Dr. G. Chelimsky also ordered two tests: a brain MRI and a test for gastric emptying. Exhibit 31.03 at 235. These were both negative. Id. at 262-63.

In the December 6, 2012 appointment, Dr. G. Chelimsky advised that Ms. Jossart could call with any questions or concerns. Exhibit 31.03 at 235. Ms. Jossart did just that on December 14, 2012. She called to inform Dr. G. Chelimsky that "Tyler's symptoms (blacking out and breathing difficulty) are getting worse." Id. at 261. Dr. G. Chelimsky relayed that Mr. Jossart "should take 2 grams of salt twice daily for the black outs and [minimum] of 3 qts of fluid." Id. at 264.

In the third week of December, Mr. Jossart missed four days of school. Exhibit 72 at 4. He also went to the emergency room at Theda Clark due to abdominal pain and headache. Exhibit 7 at 187-88. In the emergency room, Mr. Jossart's orthostatic vitals were measured. His pulse while lying down was 89, while sitting was 104, and while standing was 105. Id. at 190. His evaluation included laboratory work and X-rays, which were normal. The doctor discharged him home with a plan to see Dr. Barton. Id. at 195.

The follow-up with Dr. Barton did not change Mr. Jossart's course as Dr. Barton generally continued the plans set in place by other doctors. See Exhibit 5 at 20-21 (Dec. 19, 2012). For example, Dr. Barton endorsed the plan for an autonomic evaluation, which Dr. G. Chelimsky had included in her nine-point plan.

Autonomic Testing, including Tilt Table Test

The results of the autonomic testing, which occurred on January 3, 2013, are perhaps the most critical pieces of evidence regarding Mr. Jossart's claim that the HPV vaccination worsened pre-existing POTS. The parties and their experts primarily focused on the tilt table test, although Mr. Jossart underwent other types of testing as well.

Dr. Gibbons explained how a tilt table testing is usually conducted. In advance of the test date, patients are advised to stop certain medications. They should also fast the day of the tilt table test. Tr. 358. When patients arrive, they lie down on a table for a long time to get comfortable. During this acclimation to the environment, the doctor obtains baseline information. Tr. 359-60. After this, the

table is tilted 70 degrees for a heads-up test. Tr. 360. Patients are monitored essentially second-by-second. Id. Tests usually last for either 10 minutes (when doctors are looking for POTS) or 50 minutes (when doctors are looking for syncope). Id. at 361.

Mr. Jossart's appointment took approximately 2.5 hours. See Tr. 417, citing Exhibit 62 at 2 and 4. Dr. Steinman did not note any concerns about how the test was conducted. Tr. 235.

At baseline, Mr. Jossart's heart rate was 97 bpm. After 10 minutes of tilt, his heart rate rose to 109 beats per minute. After 50 minutes, the maximum heart rate was 130 beats per minute, which was at 36-38 minutes. Exhibit 62 at 36; Exhibit 31.03 at 229-31; Tr 372-74. The maximum amount of increase was 33 bpm (130-97). Dr. G. Chelimsky stated that the tilt portion "did not meet the criteria for [POTS]." Exhibit 62 at 38. Instead, she characterized it as a "borderline normal study." Id.

During the tilt table test, Mr. Jossart displayed a hypertensive response. Id. ("Hypertensive" means high blood pressure. Dorland's at 885-86, Tr 361.) Dr. G. Chelimsky stated that this elevation in blood pressure reflected an anxiety, migraine or pain. Exhibit 62 at 38.

As discussed extensively below, Dr. Steinman and Dr. Gibbons interpret the results of the tilt table test differently. In short, Dr. Steinman views the results as consistent with a diagnosis of POTS. Dr. Gibbons opines that the results are incompatible with a diagnosis of POTS.

In addition to the tilt table test, Mr. Jossart underwent two other tests. A quantitative sudomotor axon reflex test ("QSART") measures the amount of sweat at four different locations. Tr. 369. A purpose is to detect whether the peripheral autonomic nervous system is damaged. Id. For Mr. Jossart, the "QSART responses were exaggerated at all sites but the forearm with hung up responses at the distal and proximal leg." Exhibit 31.03 at 231. Dr. G. Chelimsky interpreted this aspect as suggesting a "very early mild autonomic neuropathy vs. normal variant." Id.

The last test was a Valsalva maneuver, which measures breathing under different conditions to assess changes in heart rate. Tr. 370; see also Dorland's at 1087. For Mr. Jossart, the results of the Valsalva maneuver were normal. Exhibit 31.03 at 229, 231; Tr. 375.

In addition to what is mentioned above, Dr. G. Chelimsky's interpretation suggested that rare endocrine causes should be excluded and a thermoregulatory sweat test could be considered. Exhibit 31.03 at 231.

On January 6, 2013, Mr. Jossart developed chest pain at around 10:00 AM. While sitting on a chair at around 11:40 AM, he passed out and experienced shortness of breath. Exhibit 7 at 162; see also Tr. 161. His parents brought him to the emergency room where a nurse obtained that history at 12:54 PM. Exhibit 7 at 162. The nurse observed that Mr. Jossart was anxious and breathing rapidly. Id. When a doctor saw him at approximately 1:00 PM, Mr. Jossart relayed the onset of chest pain, shortness of breath, and a slight headache. Id. at 151-52. The doctor's history does not mention passing out. Id. As part of the physical examination, the doctor noted that Mr. Jossart was hyperventilating. Id. at 155. After additional evaluations, the treating doctor stated, "the anxiety reaction hyperventilation are considered the most likely etiology for his symptoms today." Id. at 160. The ER doctor also recommended a follow-up care with Mr. Jossart's regular doctor.

The next day, before Dr. Barton saw Mr. Jossart, his mother telephoned Dr. G. Chelimsky's office. Dr. G. Chelimsky increased the amount of cyproheptadine and salt that Mr. Jossart should be taking. Exhibit 31.03 at 311-13.

Mr. Jossart's father brought him to Dr. Barton's office on January 8, 2013. Exhibit 5 at 16; see also Tr. 162. Dr. Barton recorded that "Tyler still describes that he does not feel anxious, but the emergency room personnel did comment that he seemed anxious in the ER setting." Id. at 17. Dr. Barton also memorialized that Mr. Jossart "had the autonomic testing done last week with the result not discussed yet." Id. As part of Dr. Barton's examination, she observed that Mr. Jossart "currently does not appear anxious." Id. Dr. Barton stated that "there is still some concern that anxiety is playing a factor in this even if it is secondary to his underlying health problems. I think we need to consider treatment for this depending on how the upcoming appointments go." Id. at 18.

In this January 8, 2013 appointment, Mr. Jossart received a second dose of the HPV vaccine. Id.; see also Exhibit 52 at 2; Exhibit 66. Mr. Jossart testified that when he received the second dose of the vaccine, he had a cold. Tr. 57. Likewise, Ms. Jossart recalled that because he was not feeling well, she thought a second dose of the vaccination was not appropriate. Tr. 162-63.

Around this date, the number of hours that Mr. Jossart was working in the department store decreased. Exhibit 70 at 10. The decrease in hours may have

been due to the end of the holiday shopping season and/or Mr. Jossart's illness. See Tr. 110.

Mr. Jossart followed up with Dr. G. Chelimsky on January 17, 2013. Exhibit 31.04 at 361-64. Dr. G. Chelimsky's history included: "With the cyproheptadine he is able to eat a little better, and headaches are slightly better. Tried salt twice, tolerated the p.m. dose and then in a.m. vomited saliva with salt after the second dose." Id. at 362. "He gets headaches, palpitations, shaky lightheaded when getting up to switch classes or when sitting. Sometimes he gets chest pain (he had seen cardiologist in the past and per Tyler he had random increase in [heart rate])." Id.

Dr. G. Chelimsky spent "70 minutes… counseling on symptoms, possible diagnosis and treatment options." Id. at 364. She assessed Mr. Jossart with "borderline POTS, significant orthostatic symptoms, migraines, and nausea." Id.; see also Tr. 164-65 (Ms. Jossart's reaction to discussion with Dr. G. Chelimsky). Mr. Jossart testified that in this conversation, he did not know much about POTS, but he was happy to have some reason for his symptoms. Tr. 59.

Dr. G. Chelimsky adjusted the amount of salt and increased the amount of cyproheptadine. Exhibit 31.04 at 365. She recommended water jogging and recumbent bicycling. Id.

Mr. Jossart returned to Dr. Barton's office on January 20, 2013. Exhibit 5 at 13-14. He tested positive for influenza B and was prescribed Tamiflu. Id.

Upon a referral from Dr. Barton, Mr. Jossart saw two neurologists on February 5, 2013. Exhibit 31.04 at 461-65, see also Tr. 60-61. The primary neurologist was Asima Husain and the reviewing neurologist was Thomas Chelimsky, who is the husband to Dr. Gisela Chelimsky.[16]

Like other medical records, Dr. Husain's history notes that Mr. Jossart has had nausea and headaches for several years. Exhibit 31.04 at 461. Dr. Husain also wrote about a series of episodes when Mr. Jossart lost consciousness. One episode occurred in October 2012 during school lunch. Another episode occurred during a

[16] The Secretary asserted that Mr. Jossart's record included the diagnosis of POTS when he saw Dr. Husain. Resp't's Prehear'g Br. at 16. Although the results of the autonomic testing appear a few pages before Dr. Husain's report (Exhibit 31.04 at 458-60), whether Dr. Husain was aware of Dr. G. Chelimsky's conclusions is difficult to say.

hot shower. Another episode occurred two nights ago, when he was awakened from sleep at 4:30 AM. His breathing was fast, and he passed out for about 45 seconds. Id.

Dr. Husain got additional information about dizziness. Id. at 462. Dr. Husain recorded that Mr. Jossart has dizziness "lasting for 20-30 min on average and at most 2 hours . . . . With the longer spells [dizziness] can occur standing or sitting, more with prolonged standing. Usually notices [symptoms] when walking between classes, lightheaded and 'shaky' and [headache]." Id.

Dr. Husain's diagnoses included "Complex and Atypical Migraine," "Postural Tachycardia Syndrome," "Syncope," and nausea. Id. at 464. Dr. Husain's assessment stated that Mr. Jossart has "multiple complex dysautonomias including migraines. He also has POTS. In this case, migraine has a larger role in his dizzy spells rather than the POTS." Id. Dr. Husain's plan included 14 points. Dr. Husain ordered a EEG. She also changed his medications, adding Elavil, Florinef, and gabapentin, but discontinuing cyproheptadine. Id.[17]

Ms. Jossart called Dr. G. Chelimsky's office on February 13, 2013 and on February 15, 2013. She reported an instance of passing out and dizziness both times. Exhibit 31.05 at 528, 550. In response to the second call, the office suggested that Mr. Jossart seek a counselor or therapist for support. Id.

An in-person visit with Dr. G. Chelimsky occurred on February 22, 2013. Exhibit 31.05 at 602. Although in the previous week, Ms. Jossart had reported problems, Dr. G. Chelimsky now documented an improvement: "He has been doing much better [from] the POTS side since he is on fludrocortisone and salt. No more fainting and less dizzy. Started exercising." Id. Apparently, Dr. G. Chelimsky ordered an upper endoscopy, which was normal. Id. at 603.

For the remainder of February 2013 and into March 2013, Mr. Jossart periodically saw Dr. G. Chelimsky and his mother called her office. A predominant problem was worsening migraine headaches. See, e.g. Exhibit 31.06 at 667 (Dr. G. Chelimsky prescribing a medication for migraines on February 27, 2013), Exhibit 31.07 at 895 (visit to the hospital for migraine on March 1, 2013); Exhibit 31.08 at 987 (a telephone call describing his excruciating headaches on

[17] Elavil is a brand name form of amitriptyline. Dorland's at 592. Amitriptyline, in turn, is an antidepressant used for chronic pain. Dorland's at 63. Flurinef is a brand name form of fludrocortisone acetate. Dorland's at 711. Fludrocortisone acetate is a type of salt. Id. at 712. Gabapentin treats seizures. Id. at 745.

March 20, 2013), Tr. 89 (Mr. Jossart's testimony that he was experiencing "pretty regular headaches, maybe a little more often than normal"), 167 (Ms. Jossart's testimony about his increased migraines).

During March 2013, Mr. Jossart also sought treatment from a rheumatologist, David Klein, at Dr. Barton's request. Exhibit 1 at 5. Mr. Jossart reported that "he has joint pain everywhere." Id. Mr. Jossart also informed Dr. Klein that "He exercises 3 times a week. Part of the time is in a pool, where he does aerobics. He has a history of POTS syndrome that has moved his exercise to either stationary bike, rowing, or aerobics in the pool." Id. at 5-6. Dr. Klein memorialized that Mr. Jossart had missed school and has a 504 plan in place. (More details about Mr. Jossart's academic performance in the first quarter of 2013 are provided below.) Dr. Klein summarized a great deal of information, including results of various laboratory tests, which the family brought with them to the appointment. Dr. Klein's discussion begins: "This young man presents with a variety of issues and complaints which he again seems to be hyperfocused on. I believe that his correct diagnosis is fibromyalgia and myofascial pain." Id. at 10. Dr. Klein recommended continuing amitriptyline and gabapentin and expanding his exercise. Id. Dr. Klein "encouraged [Mr. Jossart] to continue to address his issue but to remain active in school and socially." Id. at 11.

In the beginning of 2013, Mr. Jossart was not attending school often due to his illness. See Exhibit 72 at 4, 32. In February 2013, Mr. Jossart was being considered for an IEP. Id. at 11-15. At Ms. Jossart's request, Dr. G. Chelimsky supported the family's request for an IEP by writing a letter to explain POTS. Tr. 170, 213; Exhibit 72 at 27-28 (Dr. G. Chelimsky's letter, dated March 8, 2013). Some of the accommodations included an opportunity to make up missed homework or quizzes. Tr. 169.

At the end of March 2013, Mr. Jossart told Dr. G. Chelimsky that his dizziness had improved as it now occurred only when he stood up and he was exercising more. Exhibit 31.09 at 1055. He also said that his last severe "POTS attack" was two weeks ago. Id. On the other hand, his headaches were worse, lasting up to 4-5 hours per day each day. Id. Dr. G. Chelimsky was considering admitting him to the hospital for pain management of his headaches via "DHE." Id. at 1057. "DHE," in this context, probably stands for "dihydroergotamine." See Dorland's at 511.

2. April 2013: Hospitalizations

On April 3, 2013, Ms. Jossart brought Mr. Jossart to the emergency department at Theda Clark shortly before noon. Exhibit 7 at 97 (nurse's triage note). Ms. Jossart informed the emergency room doctor that Mr. Jossart's medications changed on March 28, 2013 and he "has experienced an increase in episodes of syncope since." Id. at 86. The doctor was informed that Mr. Jossart has a "history significant to postural orthostatic tachycardia syndrome." Id. Other recent history included: "Today at 0645 he was standing and fell face down onto the floor (unwitnessed). He did not go to school and states at 0945 that he developed tachypnea with cramping in his hands. At 1100 today he developed left sided chest pain with palpations." Id. at 87. Mr. Jossart also reported headaches. While Mr. Jossart was waiting treatment in the emergency department, his mother informed a nurse that she thought he passed out. Id. at 97.

A doctor in Theda Clark examined Mr. Jossart. As part of this process, his orthostatic vital signs were taken:

> Lying: blood pressure 126/58 and pulse 121;
> Sitting: blood pressure 125/60 and pulse 131;
> Standing: blood pressure 142/74 and pulse 122.

Exhibit 7 at 89 (April 3, 2013). Mr. Jossart was also determined to be hyperventilating. Id. at 96. He was treated with IV fluids. Id.

The doctor from Theda Clark arranged for Mr. Jossart to be transferred to CHOW. Id. at 95-96. He departed at approximately 4:30 PM. Id. at 96.

At around 6:30 PM, Mr. Jossart provided a history to Dr. Li at CHOW. Exhibit 31.10 at 1206. "In regards to POTS symptoms, he typically faints twice a week related to change in positions, however he can go up to 1-2 weeks without fainting. He has noticed increased frequency of fainting over past 1 week." Id. "Also fainted yesterday and again today while in Theta Clark ED (while laying in bed)." Id.

Dr. Li recorded that during the March 27, 2013 visit with Dr. G. Chelimsky, she changed Mr. Jossart's medications: "Started nadolol, increased gabapentin to 600 mg QHS (from 300 mg) and restarted cyproheptadine 4 mg BID. He stopped nadolol due to SOB after trying for 1-2 days. 3 weeks prior he stopped

amitriptyline due to palpitations."[18] Exhibit 31.10 at 1206. Ms. Jossart informed Dr. Li that Dr. G. Chelimsky "has plans to have Tyler established with Pain Service to help with his chronic [headaches] and fibromyalgia. He has not used DHE in the past." Id.

Based upon this information and an examination, Dr. Li stated that Mr. Jossart's increased "symptoms may be secondary to recent changes in medications and he would likely benefit from adjusting his home medication regimen. Joint pain most likely secondary to fibromyalgia …. Headache may be secondary to POTS or migraine given positive family history." Id. at 15.

Mr. Jossart was admitted to the hospital. He remained from April 3, 2013 to April 8, 2013. Exhibit 31.10 at 1203-06 (discharge summary); Tr. 173. He saw multiple doctors.

A pain management specialist, Stacy Peterson, was consulted for headaches and generalized pain. Exhibit 31.10 at 1232-36. Dr. Peterson obtained a history going back approximately 3-4 years, when Mr. Jossart had developed nausea and some vomiting. "For his headaches, he had no history of headaches until approximately 1.5 years ago following a concussion." Id. at 1232. "His headaches are constant although [they] vary in intensity." Id. "In terms of medical therapy[,] he has tried amitriptyline for his pain and headaches which improved his headaches in the 4-5 weeks he was on it however he was unable to tolerate it due to side effects. He is currently on gabapentin that has been minimal benefit." Id. at 1233. "He also has a history of POTS with syncope which is well detailed in his primary notes. This has improved with the addition of florinef to his medications." Id.

Dr. Peterson recommended four steps. Id. at 1236. She wanted to discontinue gabapentin and to start Cymbalta. She suggested that Mr. Jossart begin to see a "therapist for CBT [presumably cognitive behavioral therapy]." Last, Dr. Peterson recommended consultation with "our multidisciplinary team including Psychology and [physical therapy]." Id.

A child psychiatrist, Beth Long, was consulted. Exhibit 31.10 at 1213. Mr. Jossart and Ms. Jossart stated that Mr. Jossart was "recently diagnosed with POTS in early February. However, he and his mother report symptoms for several years. Tyler states he was beginning to think he was 'crazy' because none of the doctors he met with could diagnose or identify a specific medical concern until he met with

[18] "Nadolol" is a medication for high blood pressure. Dorland's at 1212.

Dr Chelimsky." Id. Dr. Long hoped to address Mr. Jossart's "difficulty adjusting to [this] new diagnosis and psychosocial issues impacting medical condition." Id.

With respect to past mental health services, Mr. Jossart reported that he "attended 2 therapy sessions but stopped when he was told his symptoms were all psychological. However, he does appear open to intervention and meeting with someone locally." Id. at 1215. For academics, Mr. Jossart reported that formerly, he was "a straight A student. Now receiving A's, C's, D's based on tests not being completed." Dr. Long noted the 504B plan and that Mr. Jossart "no longer has to complete homework." Id. at 1216. Dr. Long's impression was that "Tyler appears to be an excellent candidate for outpatient intervention and support in the context of coping with chronic illness." Id.

The discharge report, which is dated April 8, 2014, recounted that the neurology team concluded that Mr. Jossart did not meet the criteria for fibromyalgia. Exhibit 31.10 at 1204. Similarly, the respiratory service determined that Mr. Jossart's tachypnea was "probably secondary to nadolol." Id. The discharge plan was for Mr. Jossart to see a doctor in the pain management unit on April 30, 2014. Id. at 1205.

Before Mr. Jossart could attend that appointment, he had other health problems. On April 10, 2013, he experienced shortness of breath while sitting and sought care in the emergency department of Theda Clark about 30-60 minutes later. Exhibit 7 at 60 (doctor's record), 68 (triage nurse's record). His respiratory rate was 52 and the triage nurse advised him to slow his breathing and as he was hyperventilating. Id. at 68. Approximately 20 minutes after Mr. Jossart's arrival, Ms. Jossart reported that Mr. Jossart "passed out while [i]n [h]er car[] for approx. 30 seconds." Id. at 69. A coworker in the emergency department gave Mr. Jossart "a sternal rub and [he] became wide awake when being done." Id.

The doctor in Theda Clark discussed Mr. Jossart's case with Dr. G. Chelimsky. She recommended a transfer to CHOW. Id. at 67. After a discussion among the doctors and Ms. Jossart, they planned for Ms. Jossart to stop at home to pack a few things before driving her son to CHOW in her car. Id. at 69.

Mr. Jossart was again hospitalized at CHOW. This second hospitalization lasted from April 10, 2013 to April 13, 2013. Exhibit 31.11 at 1406-11 (discharge summary).

At CHOW on August 10, 2013, Mr. Jossart and his mother discussed his history and current symptoms with a doctor at approximately 6:30 PM. Exhibit 31.11 at 1403. This note recounts three episodes of syncope occurring on this date:

> The [patient] woke today 7am, took 16oz water prior to getting up and felt dizzy upon standing. He proceeded to the bathroom and sat down on bathroom floor b/c of lightheadedness. He got into the shower and 'fainted' in shower. He woke up on floor of shower without evidence of trauma, then continued getting ready for his day. He then went outside after breakfast to scrape his car due to ice for about 15min then after returning inside 'passed out' in the kitchen hitting his left elbow and left knee. Both falls he felt light headed prior with tunnel vision, rapid heart rate, difficulty breathing in prior to losing consciousness. Neither episode was witnessed. He stayed home from school and mother returned home to take care of him. At approximately 1030am he suddenly felt himself breathing fast, had difficulty getting air in so mom took him to the ER at theda clark.
>
> In the ED, he had one episode while lying on a gurnee at approx 45 degrees where he felt like he was 'blacking out' noticing it hard to hear mom, who thought he appeared 'semi-conscious' before he was completely unresponsive. This was noted in ED tech notes saying pt pox[19] levels dropped to 80%, opens eyes with sternal rub. [They] say this is different from other episodes which usually occur with position change. He has also never had 3 episodes in 1 day.
>
> Otherwise no[] change in health.

Exhibit 31.11 at 1403. The emergency department also recorded information about Mr. Jossart's history of syncope:

[19] "Pox" probably refers to "pulse oximetry," meaning a measurement of oxygen in the patient's arterial blood. See Dorland's at 1336.

> Syncope began 2-3 yrs ago with increased to multiple times per week since 2/12
>
> Typically occur mid-day, while changing positions from sitting to standing, at home and school
>
> He has usually close to 10 minutes of warning he might faint with symptoms of light headedness, weakness, shaking, trouble breathing in, heart racing; no diaphoresis, chest pain prior
>
> He never drops straight to the floor but is able to lower himself down so has never hit his head severely

Id. at 1404.

The doctor placed Mr. Jossart on "continuous pox" and discussed the case with the gastrointestinal service. Id. at 1406. The gastrointestinal service agreed to admit Mr. Jossart. Id.

A consultation with a gastroenterologist, Adrian Miranda, occurred late in the evening on April 10, 2013. Exhibit 31.11 at 1411. This history reported here is generally consistent with the history provided in the emergency department. Dr. Miranda assessed Mr. Jossart as having different conditions. Dr. Miranda wrote that Mr. Jossart has

> multiple problems including POTS, asthma, [nausea/vomiting], hypermobility syndrome and migraines who is having increased syncope and tachypnea. Also with episodes of hypoxia with syncope and syncope without posture changes which does not go along with diagnosis of POTS. Tachypnea and hyperventilation could be related to the episode of desaturations during ED visit.

Exhibit 31.12 at 1415. Dr. Miranda suggested a consultation with neurology.

The neurologist, Christopher M. Inglese, saw Mr. Jossart on April 11, 2013 at approximately noon. Dr. Inglese recorded that Mr. Jossart was "officially [diagnosed] [with POTS] on 2/2012, tilt table/qsart." Exhibit 31.12 at 1424. Dr. Inglese recorded the information he was provided about the context for syncopal episodes:

> Started to have syncopal episodes 4 yrs ago (once a month) with increased frequency since October 2012, currently 2x / month. These events are usually position dependent with lightheadedness, also occasionally palpitation and tachypnea. He usually is able to lower himself and remembers the events. Most of these events are associated with peak of [his] migraine which he has daily as per [patient].

Id.

The impressions and recommendations reflect how Mr. Jossart was experiencing multiple problems:

> A) Syncopal episodes. Etiology most likely due to POTS but also "Syncopal Migraine" could be a contributing factor given his history of migraine, which is still uncontrolled
>
> -1) POTS:
>
> — Pt has been previously been treated with volume expansion (salt tablet + florinef + hydration) as well as Beta blocker for POTS. Continue with current management. Mestinon has not been tried, and this can be started as outpatient if the primary physician following the POTS management agrees.
>
> --2) Syncopal Migraine:
>
> --This could be a contributing factor to his syncope, he is usually at peak of his migraine intensity prior to pre-syncopal episodes. Depakote or Topamax could be considered for migraine prevention as he would currently quality for it. Depakote could also improve his mood. The headache unlikely to be due to rebound headache (NSAID <2d per week, no opiate use)
>
> * * *
>
> —4) ? Panic attack/anxiety/stress-related etiologies: as per psychiatry

Id. at 1430.

During this hospitalization, Mr. Jossart was seen by two psychiatrists in appointments separated by approximately 90 minutes. The reason for the successive consultations is not readily apparent.

The earlier appointment was with Dr. Long, who had seen Mr. Jossart during the previous hospitalization. Exhibit 31.12 at 1416 (April 11, 2013 at 2:55 P.M.). "Concerns remain for the role of psychosocial stressors, psychological factors and stress/anxiety in his presenting physical symptoms." Id.

To Dr. Long, "Tyler explained the events leading to this hospitalization including multiple episodes of 'fainting.' He acknowledged that his last episode was likely caused by hyperventilating but he states his attempt to slow his breathing are often unsuccessful." Id.

Dr. Long's assessment included that: "Although Tyler does not appear overly anxious or stressed, many of his symptoms do appear consistent with anxiety." Id. at 1417. Dr. Long described some of the challenges for a "17 year old with or without a disease." Id. She was hopeful that an outside psychologist could assist.

The second psychiatrist to consult on Mr. Jossart's situation was Ryan Byrne. Exhibit 31.12 at 1417 (April 11, 2013 at 4:18 PM). Dr. Byrne memorialized a history in which Mr. Jossart "has been dealing with POTS consistently over the last 2-3 years" and that over the last "'few months'" his symptoms have been worsening. Id. For Mr. Jossart's social history, Dr. Bryne wrote that Mr. Jossart "is looking forward to prom and is somewhat nervous about his upcoming ACT." Id. at 1421.[20]

Dr. Byrne's impression again illustrates the complexity of Mr. Jossart's case:

> We were asked to consult for evaluation of possible psych symptoms that could be contributing to the pt's presentation. Our findings are as follows: While writer gets the sense that the pt is downplaying his emotional

[20] Additional information about Mr. Jossart's attempts to take the ACT is discussed below. See Tr. 95 (Mr. Jossart's testimony that he missed the ACT test in April due to symptoms associated with fainting).

> struggles, he also does a good job of saying the "right things." In other words, he does not provide writer with a history that is consistent with anxiety or panic. However, when you look at the evolution of his symptoms, the temporal patterns (symptoms typically when preparing to go to school or early in the school day), his genetic loading (anxiety in family hx, mother dx'd with anxiety [too]) and the way he presents himself it seems that panic (and resulting avoidance) could be a major factor here. This does not imply that writer does not think the pt has POTS. Instead, this issue will be left mainly for the primary team as we work in parallel with their efforts. A search for a medically defined cause should still continue with an eye on his psychiatric symptomatology.

Id. at 1422. Dr. Byrne recommended continuing working with psychology, inside and outside the hospital. Id.

Mr. Jossart's course in the hospital was summarized in the discharging paperwork. He was advised not to drive a car due to the potential for a syncopal episode. Exhibit 31.11 at 1408.

As Dr. Byrne and others recommended, Mr. Jossart started to see a counselor. His first appointment was on April 22, 2013. Exhibit 14 at 3-7. The initial plan concluded that Mr. Jossart "struggles with a medical syndrome that affects his daily life. He will be helped to work with his thinking about how this affects him. He will also be helped to learn and practice anxiety management skills." Id. at 7. Mr. Jossart saw this counselor roughly one time per month or two times per month until September 22, 2014. Exhibit 14, passim. Topics included Mr. Jossart's health, how he was doing in school, problems with a girlfriend, and his applications for college.

Mr. Jossart saw two different doctors on April 30, 2013. First, he saw Dr. G. Chelimsky. Exhibit 31.13 at 1651-52. The subjective account begins: "Since he was last seen he had 2 admits to the hospital. He has a cardiac monitor and he reports he had 2 episodes of fainting time . . . One was in the shower a week after discharge, and was not wearing the monitor. Then he had another episode with the

monitor." Id. at 1651.[21] Dr. G. Chelimsky recorded that: "The pain is overall better, the dizziness is still there when getting up and when standing and bending." Id. Ms. Jossart stated that Mr. Jossart "started fainting more since gardisol immunization. Mom wonder is it was the immunization vs. Cyproheptadine." Id. (This reference to the HPV vaccination seems to be the first time a concern about the vaccination as causing adverse health consequences appears in a medical record). Dr. G. Chelimsky's assessment was that Mr. Jossart had "POTS, fatigue and migraines. He gets side effects from many medications. Not doing physical activity." Id. at 1652. Among other points, she recommended physical activity each day, provided a prescription for physical therapy, and encouraged rehabilitation at the Mayo Clinic program. Id.

The second appointment on April 30, 2013 was with the pain management specialists who had seen Mr. Jossart during his first hospitalization, Doctors Stacy Peterson and Jaya Varadarajan. Exhibit 31.14 at 1683-90. The purpose was to evaluate and to manage Mr. Jossart's headaches and chronic generalized pain. Id. at 1683. "We started him on Cymbalta earlier this month when he was seen as an inpatient. Since this time he reports improvement in his headache frequency which had been 7 days per week to 5 days per week and also in the intensity of his headaches." Id. at 1684.

Doctors Peterson and Varadarajan commented on the POTS diagnosis:

> He also carries a diagnosis of POTS with syncope which is well detailed in his primary notes. His history of POTS is somewhat unusual in the fact that his autonomic testing was not consistent with POTS. However, given the severity of his symptoms and inability to attend school on account of his symptoms he is currently being treated for POTS by Dr. Gisela Chelimsky. Since being home he has had 2 episodes of syncope (none witnessed) and many episodes of near syncope.

Id. at 1684. This discrepancy is repeated in their assessment:

> We spoke with Dr. Chelimsky today and she feels that based on his tilt table test he does not meet the criteria for POTS, however given the severity of his symptoms by

[21] The basis for the notation that Mr. Jossart experienced a syncopal episode while wearing a cardiac monitor is not readily apparent.

> report it is best to treat him with the florinef and salt tablets. As mentioned above she thinks that he needs to be more active and gave him a script for PT which we agree with.

Id. at 1687. Doctors Peterson and Varadarajan wrote: "As a group we elected to increase his Cymbalta dose today and agreed that he could wean the florinef and cyproheptadine over the next few weeks if he continues to improve, given the uncertainty of his POTS diagnosis." Id.

By the end of his junior year, Mr. Jossart was missing more school. Exhibit 72 at 8-10; see also Exhibit 14 at 14. He stopped participating in marching band. Exhibit 14 at 5.

3. May 2013 – September 2014: Completion of High School

On June 7, 2013, Mr. Jossart arrived at the Theda Clark emergency department at 11:34 P.M. Exhibit 7 at 43. June 7, 2013 was a Friday. The chief complaint was "Difficulty breathing." Id. at 47. In the history of present illness, the emergency room doctor, Christopher Hugo, recounted: "Of note the patient carries a diagnosis of POTS; however, on a consultation dated May 1st of this year, it actually states that he does not meet criteria for this." Id.

> It appears that … when he gets under stress [he] develops tachycardia, near syncope or syncopal episodes, and hyperventilation. He had an episode of these when he was scheduled to take the ACT test in April and was hospitalized. He is actually scheduled to take the ACT exam again tomorrow, has missed both attempts.

Id. Today, Mr. Jossart reported feeling short of breath at around 10:20 P.M when he stood up. Mr. Jossart's father informed Dr. Hugo that his wife and he "tried talking him through the hyperventilation at home but could not get him to calm down and thus he was brought to the Emergency Department for further evaluation." Id. As part of Dr. Hugo's examination, Dr. Hugo recorded under "PSYCHOLOGIC:" "He exaggerates the Emergency Department evaluation. When asked to slow down his breathing, he actually breathes more shallowly and rapidly and then gets worsening carpopedal spasm. . . . He is inappropriate and dramatic." Id. at 48. Mr. Jossart received lorazepam and he no longer hyperventilated. Mr. Jossart was discharged at approximately 1:30 AM on Saturday, June 8, 2013, with a plan to follow up with Dr. G. Chelimsky if his symptoms worsened.

Mr. Jossart did not take the ACT on Saturday, June 8, 2013. Tr. 95, 180. It appears that Mr. Jossart was given an accommodation for alternative testing in September 2013. See Exhibit 31.21 at 2708. Another fainting episode prevented him from completing the writing portion of the test. Tr. 95.

The medical records created after June 2013 tend to be less relevant in determining whether Mr. Jossart suffered from POTS and whether the HPV vaccine significantly worsened any condition. While these records have been reviewed, a detailed description is not required. For additional information, see Pet'r's Prehear'g Br. at 21 and Resp't's Prehear'g Br. at 18-21.[22]

In summer 2013, Mr. Jossart continued to see people at the dysautonomia clinic supervised by Dr. G. Chelimsky, such as Julie Banda, an advanced pediatric nurse practitioner. He also continued his counseling. Around this time, Ms. Jossart raised questions about whether the HPV vaccine might have caused POTS. Exhibit 14 at 18 (July 18, 2013 visit with counselor), Exhibit 31.16 at 2018, 2020. The professionals seem not to have affirmed Ms. Jossart's idea. Although Dr. G. Chelimsky had recommended a rehabilitation program at Mayo Clinic, Exhibit 31.08 at 918 (Mar. 25, 2013), Exhibit 31.09 at 1153 (April 1, 2013), Exhibit 31.13 at 1692 (April 30, 2013), Mr. Jossart did not attend. Tr. 61, 172.

Mr. Jossart started his senior year in high school in fall 2013. In his senior year, his health affected him academically and socially. He reduced his load of classes and did not take any Advanced Placement courses. Tr. 70, 178. He was not scheduled for any morning classes. Tr. 70. In part because he was less present at school, he drifted apart from friends. Tr. 70. His teachers focused on making sure he graduated on time. Tr. 179. As noted above, Mr. Jossart's attempts to complete a college entrance exam were mostly unsuccessful. See Tr. 95, 180.

He attended school only approximately 60 days. Tr. 180. He felt sad that his illness was causing him to miss activities like pep rallies. Tr. 70. His participation in band was limited. Tr. 71. Nevertheless, his bandmates recognized his efforts by giving him an award at graduation. Tr. 182.

In the fall of senior year, Ms. Jossart called Dr. G's Chelimsky's office to ask about "kids with POTS getting flu shots?" Ms. Jossart was "afraid to give him any vaccinations/chemicals with his system being so messed up." Exhibit 31.18 at 2323. In an exchange of telephone messages, Ms. Jossart was informed that Dr. G.

[22] The counseling records narrate events in Mr. Jossart's life well. See Exhibit 14, passim.

Chelimsky "strongly recommends that Tyler get the flu shot." Id. at 2346 (Sep. 16, 2013).

On Thursday, October 10, 2013, Ms. Jossart telephoned Dr. G. Chelimsky's office and said that Mr. Jossart got a flu shot on Wednesday. Exhibit 31.19 at 2462; see also Exhibit 14 at 35 (Oct. 10, 2013 report to counselor that Mr. Jossart had "increased POTS symptoms since receiving flu shot").[23] Ms. Jossart also told Dr. G. Chelimsky's office that he fainted on Thursday and Monday, and he was missing significant school. Exhibit 31.19 at 2461. She stated his symptoms were so severe, he needs help "walking down the hall." Id. Ms. Jossart stated that he is "completely non-functioning and home from school again today," and he was also having trouble breathing. Id. at 2484. In another email, she stated that Mr. Jossart fainted twice during the first week of school, and she suspected those events could be due to his schedule change. Id. at 2460.

Mr. Jossart returned to the dysautonomia clinic "for dizziness and syncope after a 4 month interval." Exhibit 31.19 at 2509. He saw Ms. Banda. As part of the history, Ms. Banda recorded: "His autonomic testing showed orthostatic intolerance, but did not meet heart rate criteria for POTS, and he is thought to have syncopal migraines." Id. Ms. Banda's successive reports repeat that Mr. Jossart did not meet the heart rate criteria for POTS. See, e.g., Exhibit 31.25 at 3399 (Mar. 4, 2014), Exhibit 31.29 at 3939 (Apr. 15, 2014), Exhibit 31.29 at 4050 (May 13, 2014), Exhibit 31.38 at 5302 (Aug. 11, 2015).

For colleges, Mr. Jossart applied to eight schools. Tr. 72, 181. Ms. Jossart asked Dr. G. Chelimsky to write a letter regarding the challenges / difficulties her son experienced while attempting to take the ACT. Exhibit 31.21 at 2708; Tr. 178. Dr. G. Chelimsky explained his health problem in a letter for Mr. Jossart to send to schools with his application. Exhibit 100; see also Tr. 214. He chose to attend the University of Wisconsin, Madison. Tr. 72.

In spring 2014, Mr. Jossart had appointments with cardiologists at Appleton Cardiology Thedacare, starting with James Mariano. In the first letter addressed to Dr. Barton, Dr. Mariano began by writing that Mr. Jossart "carries a diagnosis of postural orthostatic tachycardia syndrome. He was hoping I might be able to enroll

[23] Although the Secretary requested documentation regarding the flu vaccination, Mr. Jossart did not produce any. Whether Mr. Jossart actually received the flu vaccination is an academic point because he has not argued that any 2013 flu vaccination harmed him.

him in cardiac rehab." Exhibit 13 at 14 (May 13, 2014).[24] Dr. Mariano memorialized that he (Dr. Mariano) had reviewed the results of some tests but Dr. Mariano did not "have the results of his tilt table test or his sweat test. According to the notes that [Dr. Mariano had] available though, the findings were all consistent with postural orthostatic tachycardia syndrome." Id. On examination, "Blood pressure is 112/64 supine with heart rate of 72. Standing blood pressure is 110/80 with a heart rate of 104." Id. at 15. Dr. Mariano's impression was that Mr. Jossart "has a constellation of symptoms which could be related to postural orthostatic tachycardia syndrome." Id. at 15. Dr. Mariano stated that he was sending Dr. G. Chelimsky a copy of this letter and was willing to implement any exercise program that she recommended. Id. at 16.

Dr. G Chelimsky advised that she "did not have a 'model' for an exercise program." Exhibit 13 at 10. Dr. Mariano recommended that Mr. Jossart see a general cardiologist.

Robert Wilson, another doctor in this practice, saw Mr. Jossart on June 2, 2014. As part of the examination, Dr. Wilson recorded the following data about Mr. Jossart's heart rate and blood pressure:

> HR/BP supine: 102,116/68
> HR/BP sitting: 104,102/70
> HR/BP standing 110,112/76

Exhibit 13 at 7. Dr. Wilson interpreted these results: "Today in clinic his orthostatic vital signs were normal." Id. at 8. Dr. Wilson's impression included a comment about the POTS diagnosis:

> History of postural orthostatic tachycardia syndrome (POTS). The patient had autonomic testing done at Froedtert on 01/03/2013 that showed "orthostatic intolerance, not meeting heart rate criteria for POTS, did not replicate syncopal episodes, mildly impaired cardiac sympathetic adrenergic function, intact parasympathetic function, pseudomotor function was normal variant versus mild early neuropathy, elevated blood pressure during tilt."

[24] Cites to the pagination within exhibit 13 refer to the red numbers in the upper right corner.

Id. at 5. Ultimately, Dr. Wilson concluded that regular follow-up in cardiology was not required, in part, because Mr. Jossart was seeing consultants with greater expertise. Id. at 8.

He graduated on time from high school. Tr. 70, 182. Again, Mr. Jossart considered whether he should participate in a rehabilitation program at the Mayo Clinic but he declined. See Exhibit 14 at 61 (counselor's record dated June 23, 2014). Following his graduation, Mr. Jossart and his mother started an exercise routine to improve his conditioning. Tr. 182-83. Mr. Jossart and his mother attended a conference about POTS in Washington, DC over the summer. Exhibit 14 at 50. After participating in the National Dysautonomia Conference, Mr. Jossart informed his counselor that the conference was "'really good.'" Exhibit 14 at 66. Mr. Jossart "[c]onnected with many young people [who] also have dysautonomia. Learned more about Ehlers Danlos Syndrome. Thinks he may have this." Id.; see also Tr. 438-39.

C. More Recent Health Status

1. College

In his first three years of college, Mr. Jossart took fewer classes. Tr. 104 He received accommodations, like extra time to complete assignments. Tr. 73, 183. He attempted to join activities like the school newspaper and a fraternity but found that he could not keep up. Tr. 74. He watched Netflix. Tr. 104. For the spring semester in 2019, he studied in Japan. Tr. 18, 215.

Mr. Jossart spent six years in college, which is longer than he planned. Tr. 77, 103. In his last year, his health was better. Tr. 74, 103, 186.

While in college, his medical care transitioned from Dr. G. Chelimsky, who treats children and adolescents, to Dr. Tom Chelimsky, who treats adults. Tr. 75, 187. As part of this process, Mr. Jossart was required to undergo more testing. Tr. 76, 187, 423. At the time of the testing, Mr. Jossart was taking medications, about which doctors ordering the tests should have known. Tr. 423, 434.

Much like the testing that was conducted in January 2013, Mr. Jossart underwent a series of tests, including a tilt table test. QSART testing of the axon reflex and Valsalva maneuver were normal, and a deep breathing assessment was borderline normal. Exhibit 74 at 13.

The tilt table test showed an increase in his heartbeat of 40 to 50 beats per minute. Exhibit 74 at 13 (January 3, 2017). The doctor interpreting the results,

Juan Figueroa, stated that: "Tilt was positive for excessive postural tachycardia with orthostatic symptoms." Id. Dr. Tom Chelimsky, according to Mr. Jossart, stated that the increase in heart rate was consistent with POTS. Tr. 76. While Dr. Gibbons agreed that the tilt table test showed postural tachycardia, Tr. 435, he challenged the usefulness of the test due to the medications Mr. Jossart was taking. For example, Mr. Jossart had been taking fludrocortisone. According to Dr. Gibbons, fludrocortisone has a long half-life and when a person stops taking it, the person might become dehydrated. Tr. 422-23. Dehydration, in turn, can lead to tachycardia. However, it appears that Mr. Jossart did, in fact, stop taking fludrocortisone for five days. Exhibit 74 at 11.

2. Health in 2022 (Japan)

After graduating from college, Mr. Jossart moved to Japan where he is teaching English to students attending an international school. Tr. 16, 98. He is covered by Japan's national health insurance. Tr. 101.

Whether Mr. Jossart still suffers from symptoms associated with POTS is not clear. He does not see any doctors in Japan for POTS. Tr. 22. He suffers from gastrointestinal problems, but he has experienced those problems throughout his life. Tr. 19. He testified that perhaps twice per week he might experience dizziness. He associated dizziness with standing in a long line or running. Tr. 19-20, 105. He has not missed work or canceled plans to go hiking due to any of these symptoms. Tr. 19-20. His last episode of syncope was in the summer 2020, which was more than a year before he testified. Tr. 101.

Mr. Jossart has reduced his medication use. While in Japan, he stopped taking cyproheptadine on his own initiative without consulting a doctor. Tr. 106. He takes another medication, midodrine, only as needed, which is about once per year. Tr. 20, 102.

After learning about Mr. Jossart's current health through his oral testimony, Dr. Gibbons stated that this improvement is not consistent to damage to the autonomic nervous system. Tr. 493. To Dr. Gibbons, improvements in POTS among adults can take place after at least six months of regimented exercise. Tr. 466; exhibit A-5 (Arnold et al., Postural tachycardia syndrome – Diagnosis, physiology and prognosis). In his rebuttal testimony, Dr. Steinman did not comment on whether the improvement in Mr. Jossart's health is consistent with POTS.

III. Procedural History

Mr. Jossart initiated his claim for compensation in the Vaccine Program by filing a petition on November 13, 2015. He initially alleged that his POTS was caused-in-fact by a flu and HPV vaccine. Over the next few months, Mr. Jossart filed medical records and affidavits.

The Secretary evaluated this material and recommended that compensation be denied. Resp't's Rep., filed pursuant to Vaccine Rule 4, on April 22, 2016. The Secretary requested missing medical records, questioned the diagnosis, and argued that neither a treating doctor nor a retained expert opined that a vaccine harmed Mr. Jossart.

To facilitate the submission of meaningful reports from experts, the undersigned proposed a set of draft instructions on April 28, 2016. After neither party interposed any objection, the draft instructions became final on May 18, 2016. These instructions alerted the parties that the reports from any experts might serve as direct testimony at any hearing.

Mr. Jossart presented Dr. Steinman's first report on August 12, 2016. Exhibit 32. Consistent with the Instructions, Dr. Steinman began his report by describing his qualifications. Dr. Steinman, who often testifies in the Vaccine Program, is board-certified in neurology. He has experience in immunology and has written articles published in peer-reviewed journals on the topic of molecular mimicry. Exhibit 32 at 2; see also Exhibit 33 (curriculum vitae). In the last two decades, Dr. Steinman has cared for approximately a dozen patients with POTS. Id.

After this discussion of his qualifications, Dr. Steinman turned to Mr. Jossart's case. He stated, "there is a long history of anteceded illnesses pre-dating the Gardasil immunizations." Exhibit 32 at 4. Dr. Steinman emphasized that Dr. G. Chelimsky stated on January 17, 2013 that Mr. Jossart has "borderline POTS." Id. at 5. Dr. Steinman maintained that: "Though episodes of syncope antedated the Gardasil vaccinations, the record indicates that the frequency of these episodes intensified following the two Gardasil immunizations." Id. at 8.

Dr. Steinman proposed molecular mimicry as a theory to explain how the HPV vaccination can aggravate POTS. Id. at 12-15. Using a computer program, Dr. Steinman looked for sequences of amino acids in the HPV vaccination resembling (or mimicking) stretches of amino acids within adrenergic receptors.

Dr. Steinman indicated that when 7 out of 12 amino acids are the same, an immunologic cross reaction could occur. Id. at 14-15.

Finally, Dr. Steinman stated that the frequency of syncopal episodes increased in the first 4 months of 2013. Id. at 16. However, Dr. Steinman did not explain the temporal interval during which a cross reaction might be expected to occur.

Dr. Steinman's first report was discussed in an August 22, 2016 status conference. The parties agreed that Dr. Steinman's opinion shifted the case from a causation-in-fact claim to a significant aggravation claim. Accordingly, a new set of instructions were issued on August 25, 2016 and became final on September 9, 2016.

Dr. Steinman's second report is very similar to his first report. Compare Exhibit 32 with Exhibit 51. In his second report, Dr. Steinman disclosed that he discussed the case with Mr. Jossart's treating doctor, Dr. Chelimsky. Exhibit 51 at 5. Dr. Steinman added some details to his molecular mimicry. Id. at 16-18. The section on timing remained unchanged.

In response to an order, Dr. Steinman clarified he was not basing any opinion upon a tetanus-diphtheria-acellular pertussis vaccine, which was also given to Mr. Jossart in conjunction with a dose of the HPV vaccine. Dr. Steinman did not expand his discussion of timing. Exhibit 58.

The parties discussed Dr. Steinman's reports in an April 5, 2017 status conference. Mr. Jossart was again directed to obtain more information from Dr. Steinman about timing. He was also given an opportunity to discuss how his symptoms worsened in early 2013. Order, issued April 7, 2017.

Mr. Jossart filed some additional medical records on May 3, 2017. Exhibit 61-62. He also filed another affidavit from himself as well as affidavits from his mother and father. These affidavits generally describe Mr. Jossart's health in late 2012 and early 2013. Exhibits 63-65.

Another report from Dr. Steinman was filed on June 5, 2017, as Exhibit 67. In this report, Dr. Steinman disclosed his opinion about timing. Dr. Steinman stated that: "It should be understood as an initial matter that POTS does not have a sudden, acute onset that one can note on *one* day on a calendar." Exhibit 67 at 1. Based upon a history created on April 3, 2013, Dr. Steinman asserted that doctors prescribed different medications to Mr. Jossart because of worsening symptoms "between December 3, 2012 (or approximately seven days post-November 26,

2012, Gardasil vaccine) and January 3, 2013 (or about 38 days post vaccine)." Id. at 3. Dr. Steinman further argued that because the "immune response to Gardasil is persistent and prolonged," "one could potentially see an onset window extending out as many as 18 or 24 months." Id. at 4.

Mr. Jossart continued to submit factual material. For example, on July 14, 2017, he submitted employment records, records from a psychologist, and his high school records. Exhibits 70-72. On August 14, 2017, he filed updated records from Froedtert Hospital, which contained results of testing conducted on January 3, 2017. Exhibit 74.

The Secretary consistently asked for additional records, especially documents to confirm that Mr. Jossart received a second dose of the HPV vaccination on January 8, 2013. See, order issued Jan. 16, 2018; Resp't's Status Rep., filed Feb. 13, 2018. Eventually, the Secretary offered to proceed with reports from experts who would assume that Mr. Jossart received two doses of the HPV vaccination. Order, issued June 8, 2018.

The Secretary filed the first set of reports from Dr. Gibbons and Dr. Whitton on October 22, 2018. Like Dr. Steinman, Dr. Gibbons began with a recitation of his qualifications. Dr. Gibbons is board certified in neurology with a subspecialty in autonomic disorders. Exhibit A at 1; see also exhibit B (curriculum vitae). He served as the president of the American Autonomic Society. Id. He has written articles about autonomic disorders published in peer-reviewed journals and lectured other medical professionals on this topic. Id. Dr. Gibbons has treated hundreds of patients with POTS. Id.

After summarizing events in Mr. Jossart's life, Dr. Gibbons quoted an article defining the diagnostic criteria for POTS. A basic aspect of POTS is that the person's heart rate increases when the person stands. According to Dr. Gibbons, "For individuals age 12-19 years, the requirement is at least 40 beats/minute." Exhibit A at 7, quoting exhibit A-1 (Freeman et al., Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome). [25] Based largely upon this definition, Dr. Gibbons stated that Mr. Jossart's "autonomic testing from 2013 has a normal heart rate response to tilt table testing, with no evidence of POTS." Id. at 10, citing Exhibit 62 at 9-12. Dr. Gibbons continued: "The notes in the medical records of 'borderline POTS' do not represent a true diagnosis. The term 'borderline' is used to describe a vague

[25] The full citations to the medical articles are found in the bibliography in the appendix.

problem where a patient may report symptoms with a condition, but testing does not necessarily support a particular diagnosis." Id.

Rather than POTS, Dr. Gibbons thought that other conditions might explain Mr. Jossart's symptoms. These included anxiety, hyperventilation, and somatization disorder. Id. at 12.

Finally, Dr. Gibbons challenged the assertion that an HPV vaccination can cause POTS. In this regard, he relied primarily upon epidemiologic studies. Id. at 11.

The Secretary's other expert, Dr. Whitton, also discussed epidemiologic studies in his first report. At the time of his first report, Dr. Whitton was a professor at the Scripps Research Institute. Exhibit C at 2. Although Dr. Whitton attended medical school in the United Kingdom, he does not have a license to practice medicine in the United States. Id. at 3. Thus, when Dr. Whitton was invited to provide an opinion in this case, he relied on respondent's other expert to accurately address Mr. Jossart's POTS diagnosis. Id. at 3.

As opposed to diagnosis, Dr. Whitton focused on causation. He stated that he is "not aware of any convincing data to show that POTS can be triggered by any vaccine." Id. at 3. To support this assertion, Dr. Whitton cited various epidemiologic studies. Id. at 3-5.

In addition to relying upon epidemiologic studies, Dr. Whitton critiqued how Dr. Steinman used molecular mimicry. Dr. Whitton asserted that the homologies that Dr. Steinman found using computer searches were "predictable" and not shown to be immunologically relevant. Exhibit C at 7-10. Dr. Whitton also briefly questioned Dr. Steinman's opinion with respect to timing. Id. at 10-11.

Because the Secretary had presented reports from two people, Mr. Jossart was offered the same opportunity. Order, issued Nov. 1, 2018. Mr. Jossart, however, declined. Pet'r's Status Rep., filed April 5, 2019.

Accordingly, Dr. Steinman's next report responded to both Dr. Gibbons and Dr. Whitton. For diagnosis, Dr. Steinman stood by his earlier assertion that Mr. Jossart suffered from POTS based upon the diagnosis of "borderline POTS" from Dr. Chelimsky. Exhibit 83 at 1-2. Otherwise, Dr. Steinman "really [had] nothing further to add on this matter of whether POTS is an accurate and correct diagnosis." Id. at 2.

Before causation, Dr. Steinman added additional information about BLAST searches, including citing a paper by Robert Root-Bernstein. Id. at 4-8. Dr. Steinman also filtered his result through the immune epitope database. Id. at 6-9.

On November 29, 2019, the Secretary filed responses from Dr. Gibbons and Dr. Whitton. Dr. Gibbons stated that Mr. Jossart "was not actually diagnosed with POTS until January 3, 2017 – nearly 4 years after his last HPV vaccination. He carried notes of 'POTS' in his medical records for many years, but actually never came close to meeting criteria for this until 4 years later." Exhibit E at 3. Dr. Gibbons also continued to maintain that epidemiologic studies have not identified any relationship between the HPV vaccine and POTS. Id. Dr. Gibbons cited the study from the American Autonomic Society.

Dr. Whitton continued to disagree with Dr. Steinman's use of molecular mimicry. Dr. Whitton stated that Dr. Steinman was not using BLAST searches properly. Exhibit F at 5-9. In this regard, Dr. Whitton said that Dr. Root-Bernstein made "catastrophic mistakes" in the paper Dr. Steinman cited. Id. at 8. Dr. Whitton also criticized how Dr. Steinman used the immune epitope database. Id. at 9-11.

The Secretary's presentation of these two reports appeared to complete the expert report stage. Thus, the parties were directed to present briefs and other materials regarding entitlement to compensation. Order, issued May 28, 2020.[26]

Mr. Jossart filed his primary pre-hearing brief on August 31, 2020. In connection with that brief, he supplied additional articles. Exhibits 95-98. He filed a pre-hearing reply on February 25, 2021. In between those submissions, the Secretary filed his pre-hearing brief on January 13, 2021, and filed additional medical articles.

Upon review of this material, the undersigned determined that a hearing was appropriate. Due to commitments, a mutually convenient time for a three-day hearing was delayed until March 2022. Order, issued May 11, 2021. During the pretrial process, the parties agreed to divide the amount of time available over the course of three days. To avoid unnecessary duplication, the experts' reports were accepted as the experts' direct testimony.

[26] Before the briefing stage, the parties were referred for alternative dispute resolution. Because the parties could not settle this case, it returned to the litigation track.

The hearing began with testimony from Mr. Jossart and then his mother, Kristeen Jossart. Mr. Jossart, who resides in Japan, explained that the symptoms he associates with POTS occur very infrequently for him. Mr. Jossart also recounted his health going back to middle school. Likewise, Ms. Jossart testified about her son's health and activities from middle school through college. Generally, the oral testimony of Mr. Jossart and Ms. Jossart about Mr. Jossart's health matched the information presented in the medical records created contemporaneously with the events the medical records were describing.

After these two percipient witnesses completed their testimony, the parties called their expert witnesses. Dr. Steinman, Dr. Gibbons, and Dr. Whitton generally testified in accord with the opinions they had previously disclosed in their written reports, which are summarized above and further analyzed below.

The experts' demeanor in testifying varied. Dr. Steinman appeared, at times, contentious and unnecessarily fenced with the Secretary's attorney during cross-examination. During rebuttal, Dr. Steinman argued with the attorney for Mr. Jossart. At times, Dr. Whitton also engaged with the attorney for Mr. Jossart, who was cross-examining him. However, Dr. Whitton's questioning of a question seemed to be intended to provide specific and accurate information. While the line separating an overly hostile witness from an exacting witness may be difficult to discern, Dr. Whitton's demeanor was more positively received than Dr. Steinman's. Finally, the demeanor of Dr. Gibbons was fine. Dr. Gibbons responded to questions posed to him by the attorney for the Secretary, the attorney for Mr. Jossart on cross-examination, and the undersigned appropriately.

The parties completed the presentation of oral testimony in approximately 2½ days, meaning that the time restrictions did not prevent either party from submitting evidence. After the hearing concluded, the evidentiary record closed. The parties answered specific questions posed after the hearing. With the filing of Mr. Jossart's post-hearing reply, the case is ready for adjudication.

IV. 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).

As noted in this decision's introduction, the outcome derives from two independent findings. The first reason for denying compensation is that Mr. Jossart has not established that he suffered from POTS before or shortly after he was vaccinated. The second reason for denying compensation is that Mr. Jossart has not established that the HPV vaccination harmed him.

V. Analysis First Reason: Diagnosis

A. Law regarding Diagnosis

In Broekelschen v. Sec'y of Health and Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the Althen test." This principle also means that petitioners must establish that the vaccinee suffers the injury allegedly linked to the vaccination. Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353-54 (Fed. Cir. 2011).

B. Whether Mr. Jossart Suffered from POTS

In the present case, Mr. Jossart claims that he suffered from POTS before the HPV vaccination and that the vaccination worsened his pre-existing POTS. The Secretary takes a different view. To the Secretary, Mr. Jossart did not suffer from POTS around the time of the HPV vaccinations. This broad dispute encompasses several discrete issues. One issue is the value of published diagnostic criteria. A second issue is how pieces of evidence preponderate. A third issue is the legal significance of Mr. Jossart's lack of success on proving POTS.

1. Diagnostic Criteria for POTS

The basic criteria for diagnosing POTS are not disputed. They are:

> 1. Heart rate increase≥30 bpm within 10 min of upright posture in adults. Heart rate increase of ≥40 bpm within 10 min is required in adolescents age 12–19 years.
>
> 2. Absence of orthostatic hypotension defined as a sustained drop in blood pressure≥20/10mmHg within 3 min of upright posture.
>
> 3. Symptoms of orthostatic intolerance for ≥6 months.
>
> 4. Absence of overt causes for sinus tachycardia such as acute physiological stimuli, dietary influences, other medical conditions and medications.

Exhibit A-5 (Arnold et al., Postural tachycardia syndrome – Diagnosis, physiology and prognosis) at 2; see also Pet'r's Prehear'g Br. at 4-6 (setting forth these criteria).

Mr. Jossart argues that diagnostic criteria cannot replace a clinician's judgment. Pet'r's Posthear'g Br. at 4, citing Singer et al., Postural Tachycardia in Children and Adolescents – What Is Abnormal, Exhibit A-2, at 6. However, the Secretary has persuasively shown the value of tilt table tasting in diagnosing POTS in adolescents. Resp't's Posthear'g Br. at 8. A series of articles discuss tilt table testing:

Articles regarding Tilt Table Testing in POTS			
Year	Exhibit	Author	Notes
2011	A-1	Freeman	Discussed at Tr. 222-24, 405
2012	A-2	Singer	Authors established a normative range. No testimony.
2014	44	Kizilbash	Need to give teens a diagnosis. Page 19; Tr. 492
2015	E-3	Canadian	No testimony.

Articles regarding Tilt Table Testing in POTS			
2018	A-5	Arnold	Dr. Steinman relied upon this group for sub-types of POTS. Tr. 321. This article lists tilt table testing disjunctively ("or").

Mr. Jossart's and Dr. Steinman's attempts to lessen the diagnostic rigor were generally unpersuasive. In his reports, Dr. Steinman portrayed the diagnostic criteria as "flexible." Exhibit 32 at 9; accord Exhibit 51 at 12. Likewise, in Dr. Steinman's oral testimony, he characterized the consensus criteria as "useful. . . But they [consensus committee] don't inform clinical practice." Tr. 222. When he was cross-examined about the criteria, Dr. Steinman's testimony was neither good nor credible. Tr. 242-46.

Dr. Steinman testified that Dr. G. Chelimsky mentioned that an elevated heart rate is not required to diagnose an individual with POTS. Tr. 222. The basis for this statement is not apparent as the Secretary argued. See Resp't's Posthear'g Br. at 11. Given an opportunity to substantiate Dr. Steinman's testimony, Mr. Jossart did not. See Pet'r's Posthear'g Reply.[27]

Given this testimony, the August 30, 2022 Order asked: "Is an elevation of at least 40 beats per minute on a tilt table test required to find, more likely than not, that an adolescent suffered from POTS?" The parties differed.

Mr. Jossart argued: "The criteria is a consensus criteria for medical professional and is not strictly required for this Court to find an adolescent suffered POTS, nor was it required for Dr. Gisela Chelimsky to diagnose and treat Petitioner for POTS." Pet'r's Posthear'g Br. at 4. Mr. Jossart did not cite any cases supporting his position.

In response, the Secretary argues that a diagnosis of POTS "must" be supported by a tilt-table test. Resp't's Posthear'g Br. at 8. Mr. Jossart did not directly engage with the Secretary's argument regarding "must." Instead, Mr. Jossart reasserted the position of Dr. G. Chelimsky. Pet'r's Posthear'g Reply at 3.

[27] In his emails with Dr. Chelimsky, Dr. Steinman preferred to communicate through voiced conversations. Exhibit 59. There is no record of what Dr. Chelimsky spoke. In the November 28, 2016 status conference, the undersigned explained that better evidence would come from Dr. Chelimsky directly.

Taken as a whole, the evidence does not support a finding that a positive tilt table test is an absolute requirement to diagnose POTS in all cases. Exhibit A-5 (Arnold et al., Postural tachycardia syndrome – Diagnosis, physiology and prognosis); Tr. 404. With the caveat that doctors do not always administer tilt table tests, tilt table testing creates valuable information into determining whether a person suffers from POTS. Looking at the results of tilt table tests as part of the process of determining whether a person suffered from POTS is in accord with the literature and non-binding opinions from special masters. See, e.g., Drummond v. Sec'y of Health & Hum. Servs., No. 16-702V, 2023 WL 3035072, at * 30 (Fed. Cl. Spec. Mstr. Apr. 21, 2023); Specks v. Sec'y of Health & Hum. Servs., No. 15-491V, 2023 WL 2947619, at * 42 (Fed. Cl. Spec. Mstr. Apr. 14, 2023); C.F. v. Sec'y of Health & Hum. Servs., No. 15-731V, 2023 WL 2198809, at * 38 (Fed. Cl. Spec. Mstr. Jan. 20, 2023); L.P. v. Sec'y of Health & Hum. Servs., No. 16-1278V, 2021 WL 2373863 at *24 (Fed. Cl. Spec. Mstr. Apr. 26, 2021); Balasco v. Sec'y of Health & Hum. Servs., No. 17-215V, 2020 WL 1240917 at *19 (Fed. Cl. Spec. Mstr. Feb. 14, 2020); Yalacki v. Sec'y of Health & Hum. Servs., No. 14-278V, 2019 WL 1061429 at *35 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), mot. for rev. denied, 146 Fed. Cl. 80 (2019).

2. Evidence regarding Mr. Jossart's Health in 2012-2013

Multiple pieces of evidence contribute to determining whether, on a more likely than not basis, Mr. Jossart suffered from POTS in late 2012 through early 2013. These include (a) the results of the tilt table test, (b) orthostatic testing, (c) Dr. G. Chelimisky's work as a treating doctor, (d) the opinions of Dr. Steinman and Dr. Gibbons, (e) the result of tilt table testing in 2017, and (f) potential alternative explanations for Mr. Jossart's symptoms. These are taken up in sequence.

a) Tilt Table Test

When Mr. Jossart underwent a tilt table test, his heart rate increased as expected. The amount of increase did not exceed the threshold of normal. Exhibit 62 at 36 (Jan. 3, 2013). Dr. Steinman agreed that Mr. Jossart did not qualify for POTS based upon the tilt table testing. Tr. 235, 246.

b) Orthostatic Testing

Because Arnold et al. proposed orthostatic testing as an alternative to tilt table testing, exhibit A-5 at 3, the parties were directed to discuss any orthostatic testing in Mr. Jossart. Order, issued August 19, 2022, ¶ 2.d.

Mr. Jossart identified a few instances of orthostatic testing. Pet'r's Posthear'g Br. at 8-9. Mr. Jossart did not argue that this testing showed any abnormality. Instead, Mr. Jossart "maintains Dr. Gisela Chelimsky's clinical diagnosis of POTS is sufficient." Id. at 9.

In contrast, the Secretary asserts that orthostatic vital signs do not "'support a diagnosis of POTS.'" Resp't's Posthear'g Br. at 19, quoting Tr. 393 (Dr. Gibbons). The basis for this opinion is a series of tests.

Mr. Jossart's Orthostatic Tests From Date of Vaccination (November 26, 2012) through end of 2013		
Date	Increase in beats per minute	Cite
12/18/2012	16	Exhibit 7 at 190
2/5/2013	15	Exhibit 31.05 at 489
4/3/2013	1	Exhibit 7 at 89
6/18/2013	22	Exhibit 31.15 at 1962
10/15/2013	36	Exhibit 31.19 at 2514; Exhibit 10 at 29 (duplicate)
12/31/2013	28	Exhibit 31.23 at 3091; Exhibit 10 at 162 (duplicate)

As the Secretary argued, Mr. Jossart "never demonstrated a heart rate increase of 40 BPM at any point in 2012 or 2013." Resp't's Poshear'g Br. at 19. These measurements underlie Dr. Gibbon's assessment that Mr. Jossart's heart rate "was not remotely approaching POTS." Tr. 393.

c) Dr. G. Chelimsky's Opinion

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). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See

McCulloch v. Sec'y of Health & Hum. Servs., No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26. 2016).

Dr. G. Chelimsky is a leading authority on POTS. Exhibit 106-08; Tr. 313. Dr. Gibbons endorsed her work. Tr. 425.

Under these circumstances, shouldn't her diagnosis of POTS carry the day? The answer is "no" for two reasons.

First, Dr. G. Chelimsky did not diagnose Mr. Jossart as having POTS. In early January 2013, Dr. G. Chelimsky recognized that the results of the tilt table testing did not meet the diagnostic criteria. Exhibit 62 at 38 (Jan. 3, 2013). Following an evaluation of him, Dr. Chelimsky stated that he had "borderline POTS." Exhibit 31.4 at 364 (Jan. 17, 2013).

According to Dr. Gibbons, "borderline POTS is not widely used in the medical literature." Tr. 405. Dr. Steinman did not rebut this statement and no articles have been located in this case's record with that term.

So, then why did Dr. G. Chelimsky put forward "borderline POTS"? A direct inquiry to Dr. G. Chelimsky might have been useful. See Tr. 405. But, in the absence of a statement from Dr. G. Chelimsky about her treatment of Mr. Jossart, some information can be gained from a 2014 article that she co-wrote. Tr. 492.

Dr. G. Chelimsky and her co-authors wrote a guide to help clinicians treat adolescents with POTS. They saw a need for this information because, in part, "[w]ithout accurate and timely diagnosis, education, and motivation to incorporate new healthy living practices into their lives to remediate their symptoms, affected adolescents are at heightened risk for academic decline. . . ." Exhibit 44 (Kizilbash et al., Adolescent Fatigue, POTS, and Recovery: A Guide for Clinicians) at 109. These authors explained that as part of the recovery process, "[t]eens and families first need a diagnosis to hold onto to begin learning about how to recover."

Exhibit 44 at 127. Thus, it appears that Dr. G. Chelimsky may have assigned Mr. Jossart the diagnosis of "borderline POTS" as a way to initiate his recovery.[28]

Coincidentally, Mr. Jossart appears to have responded in the way the Kizilbash article predicted. He informed a child psychiatrist, Dr. Long, that he was "beginning to think he was 'crazy' because none of the doctors he met with could diagnose or identify a specific medical concern until he met with Dr. Chelimsky." Exhibit 31.10 at 1213 (Apr. 4, 2013). Mr. Jossart's account to Dr. Long tends to corroborate Dr. G. Chelimsky's idea that receiving a diagnosis helps the patient.

d) Opinions of Other Doctors in 2013 and 2014

Some medical records memorialize a history in which a treating doctor wrote that Mr. Jossart suffered from POTS. See, e.g., Exhibit 31.12 at 1424 (neurologist's record on April 11, 2013: "officially [diagnosed] [with POTS] on 2/2012, tilt table/qsart."), Exhibit 13 at 14 (cardiologist's record from March 11, 2014 that Mr. Jossart carries a diagnosis of POTS but noting that the cardiologist had not reviewed the tilt table test). Whether these doctors were reaching a diagnosis independently or simply repeating what was told to them appeared unclear. See J.S. v. Sec'y of Health & Hum. Servs., 164 Fed. Cl. 314, 336-40 (2023) (ruling that the chief special master was not arbitrary in rejecting a diagnosis from a treater who obtained inaccurate history from the petitioner and did not have all objective tests), appeal docketed, No. 2023-1644 (Fed. Cir. Mar. 22, 2023); Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 220 (2012) (a history is not the same as a diagnosis); Rothenberger v. Sec'y of Health & Hum. Servs., No. 15-696V, 2018 WL 2731639, at *16 (Fed. Cl. Spec. Mstr. Apr. 19, 2018) (distinguishing what a petitioner told a doctor from a diagnosis reached by the doctor). Given this lack of clarity, the parties were directed to comment on diagnoses in medical records from doctors other than Dr. G. Chelimsky. See Order, issued Aug. 19, 2022, ¶ 2.b.

The parties differed. Mr. Jossart argued that except from the February 5, 2013 records from Dr. Husain, evaluating the role of Dr. G. Chelimsky's diagnosis would require "speculation." Pet'r's Posthear'g Br. at 5. The Secretary contended

[28] Mr. Jossart argues that Dr. G. Chelimsky could not have created a diagnosis for Mr. Jossart because a discrepancy about diagnosing and billing would be unethical. Pet'r's Posthear'g Br. at 3. This argument carries little weight because there is a lack of testimony about the ethics of doctors' diagnosing and billing.

that doctors associated Mr. Jossart's fainting with hyperventilation. Resp't's Posthear'g Br. at 18.

Overall, the collection of medical records created in 2013 and 2014 tends not to offer persuasive support for the proposition that Mr. Jossart suffered from POTS. Other doctors stated that his tilt table testing did not meet the criteria for POTS. See Exhibit 31.14 at 1684 (April 30, 2013 report of pain management doctors that Mr. Jossart's "history of POTS is somewhat unusual in the fact that his autonomic testing was not consistent with POTS"), Exhibit 31.19 at 2509 (October 15, 2013 report from APNP Banda that he did not meet the diagnostic criteria for POTS), Exhibit 13 at 5 (June 2, 2014 report from a cardiologist that the January 3, 2023 testing did not meet the heart rate criteria for POTS).

e) Positive Tilt Table Test in 2017

Mr. Jossart underwent a second tilt table test when he was transitioning from the care of doctors who treated children and adolescents to the care of doctors who treated adults. The result of this second test fulfilled the diagnostic criteria for objective testing.

This second test does not shed much light on Mr. Jossart's health approximately four years earlier. Due to the passage of time, a 2017 test provides little useful information about a person's condition in 2013. See J.S. v. Sec'y of Health & Hum. Servs., No. 16-1083V, 2022 WL 20213038, at *23 (Fed. Cl. Spec. Mstr. July 15, 2022) (declining to give much weight to tests showing petitioner had anti-adrenergic antibodies when test was conducted almost five years after vaccination), mot. for rev. denied, 164 Fed. Cl. 314, 339-41(2023) ; E.M. v. Sec'y of Health & Hum. Servs., No. 14-753V, 2021 WL 3477837, at *33-34 (Fed. Cl. Spec. Mstr. July 9, 2021) (declining to give much weight to skin biopsy performed four years later). But, see, Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760 at *27 (Fed. Cl. Mar. 23, 2018) (finding that several years of medical records were mostly supportive of a diagnosis but the overall record did not have preponderant evidence that the HPV vaccine caused petitioner's POTS).

In addition to the passage of time, Dr. Gibbons questioned the reliability of the results of the 2017 test because medications may have affected the accuracy of the result. Exhibit A at 9; Tr. 422-23, 434-36. Resolution of this discrete issue is not required.

f) Dr. Steinman vs. Dr. Gibbons

The previous four points addresses information largely created during the doctors' treatment of Mr. Jossart. Another type of evidence is information generated in the context of litigation. See 42 U.S.C. § 300aa–13(a) (allowing special masters to make findings based upon "medical records" or "medical opinion"). As mentioned earlier, the parties retained doctors to present various opinions.

The two doctors who opined about whether Mr. Jossart suffered from POTS in late 2012 through early 2013 are Dr. Steinman and Dr. Gibbons. Dr. Steinman stated that Mr. Jossart had POTS. Exhibit 51 at 6-11 (summarizing medical records). Dr. Gibbons disagreed. Exhibit A at 8-9.

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

On the topic of the diagnosis of POTS, Dr. Gibbons was much more qualified than Dr. Steinman. Dr. Steinman does not normally treat adolescents with POTS. Tr. 232. Dr. Gibbons spends most of his time studying the autonomic nervous system. Tr. 336. He has written articles on the autonomic nervous system, including POTS. Tr. 340. Dr. Gibbons has seen thousands of patients with POTS. Tr. 342-43.

Thus, on the question as to whether a person suffers from POTS, Dr. Gibbon's opinion is more valuable than the opinion of Dr. Steinman.

g) Other Conditions in 2012-13

A petitioner bears the burden of establishing that he (or she) suffers from the condition a vaccine allegedly caused. Lombardi, 656 F.3d 1343. For the reasons explained above, Mr. Jossart has not met his burden.

However, the Secretary put forward other conditions that could have caused Mr. Jossart to have symptoms in the later part of 2012 and continuing into 2013. In Dr. Gibbons's first report, he proposed hyperventilation and anxiety. Exhibit A at 12. In his second report, Dr. Gibbons suggested a psychological or somatic

symptom disorder. Exhibit E at 3. The Secretary argued that a basis for Mr. Jossart's health trouble could be vasovagal syncope or hyperventilation. Resp't's Prehear'g Br. at 36-43; see also Pet'r's Prehear'g Reply at 8-9.

In Dr. Gibbons's oral testimony, he expanded his opinion, asserting how various medications could have side effects. For a summary, see Resp't's Posthear'g Br. at 20-24. Although Mr. Jossart might have objected to this testimony about the side effects of medications (See Simanksi v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1382 (Fed. Cir. 2012)), Mr. Jossart did not. Without a pre-hearing disclosure of opinions regarding the side effects of medications, Mr. Jossart's ability to respond seems hampered as he has cited internet searches, rather than evidence. See Pet'r's Posthear'g Reply at 6-7.

Further evaluation is not required. As discussed, an element of a petitioner's case is to prove diagnosis by a preponderance of the evidence. As explained in paragraphs a-f, Mr. Jossart has not met his burden. Moreover, the presence of some symptoms such as anxiety is compatible with a diagnosis of POTS because anxiety can be a co-morbidity with POTS. Tr. 426.

h) Summary

When considered as a whole, the evidence does not preponderate in favor of finding that Mr. Jossart suffered from POTS within a few months of his November 26, 2012 vaccination. The primary way doctors determine whether a person's heart rate increases excessively is a tilt table test and Mr. Jossart's tilt table test did not detect any abnormality. An alternative to tilt table testing is the measurement of orthostatic vital signs. These were consistently within the normal range for Mr. Jossart. When the objective testing does not meet the diagnostic criteria for the disease, a statement from a treating doctor that Mr. Jossart had "borderline POTS" is not persuasive. The more persuasive opinion comes from Dr. Gibbons, who is also an authority in POTS and who declared that Mr. Jossart did not have POTS in the relevant time. Exhibit A at 13.

3. Legal Significance for a Lack of Proof of POTS

The next question concerns the consequence of finding that Mr. Jossart did not suffer POTS in 2012-2013. The parties differ. Mr. Jossart contends: "If the Court finds he did not suffer from the formal diagnosis of POTS, Petitioner's worsening dysautonomia remains and his expert's Althen evidence remains useful in elucidating the etiology of Petitioner's dysautonomia." Pet'r's Posthear'g Reply at 3-4. On the other hand, the Secretary argues that a lack of preponderant proof of

POTS is "fatal" to Mr. Jossart's claim. Resp't's Posthear'g Br. at 7. In a footnote, the Secretary addressed Mr. Jossart's reliance on "dysautonomia." Resp't's Posthear'g Br. at 10 n.7. Mr. Jossart did not reinforce the claim that dysautonomia is a defined and recognized injury. See Pet'r's Posthear'g Reply.

Relatively few cases have explored whether a condition satisfies the requirement of an injury. One case is in which this issue arose was Lasnetski v. Sec'y of Health & Hum. Servs., 128 Fed. Cl. 242 (2016), aff'd in non-precedential op., 696 Fed. App'x 497 (Fed. Cir. 2017).[29] There, Ms. Lasnetski alleged that an HPV vaccine caused multiple problems, including "sensory dysesthesia." Id. at 245. "Dysesthesia" means "the distortion of any sense, especially of that of touch." Dorland's at 570. A doctor whom the Secretary retained, Thomas Leist, opined that "'sensory dysesthesia' and 'idiosyncratic severe reaction' did not amount to medical diagnoses." Lasnetski, 128 Fed. Cl. at 251. Dr. Leist further opined that "sensory dysesthesia could be a symptom consistent with many different diagnoses, none of her treating doctors actually assessed her with any of those conditions." Id. The special master found that Ms. Lasnetski was not entitled to compensation because "'she has failed to identify the underlying injury from which all of her alleged symptoms arise.'" Id. at 252, quoting special master's decision.

After Ms. Lasnetski filed a motion for review, the Court of Federal Claims addressed petitioner's obligation to put forward a "defined and recognized injury," which originated in Lombardi, 656 F.3d at 1352. Lasnetski, 128 Fed. Cl. at 260-63. The Court stated that the special master "chose to adopt Dr. Leist's opinion that the petitioner's diagnoses of sensory dysesthesias and idiosyncratic severe reaction to vaccination were 'merely a symptom or manifestation of an unknown injury.'" Id. at 263. The Court further ruled that the special master's determination "was based upon sufficient evidence and was not arbitrary or capricious." Id.

Ms. Lasnetski appealed the denial of compensation. Like the Court of Federal Claims, the Federal Circuit ruled that the special master's finding "was a reasonable inference drawn from the record evidence." 696 Fed. App'x at 505. Thus, the Federal Circuit affirmed the denial of compensation.

[29] The special master's April 29, 2016 decision is not available publicly. Thus, this decision relies upon the presentation of facts as part of the opinion denying the motion for review.

A lesson to be drawn from the two non-binding appellate opinions in Lasnetski is that the determination of whether a condition constitutes a defined and recognized injury should be based upon the evidence, including the testimony of experts.

Here, there was some evidence about whether "dysautonomia" is a defined and recognized condition. Dr. Gibbons stated "dysautonomia" is "nonspecific." Tr. 448. He continued, "dysautonomia for some people means symptoms." Id. As for Dr. Steinman, the Secretary argued "Dr. Steinman never explained [what] that term [dysautonomia] meant." Resp't's Posthear'g Br. at 10 n.7. Mr. Jossart did not correct this statement. See Pet'r's Posthear'g Reply.

The evidence, therefore, preponderates in favor of a finding that "dysautonomia" is not a defined and recognized injury as required under Lombardi and progeny. See J.S., 2022 WL 20213038, at *22 (suggesting that transient symptoms of "inappropriate tachycardia" do not constitute a condition cognizable in the Vaccine Program), mot. for rev. denied, 164 Fed. Cl. at 337-40. Thus, an analysis of whether the HPV vaccination caused any harmful consequences is not required.

VI. Analysis Second Reason: Significant Aggravation

Assuming Mr. Jossart established he suffered from POTS, he would also be required to establish that the HPV vaccine can significantly aggravate POTS.

A. Law regarding Significant Aggravation

As confirmed in W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013), the elements of an off-Table significant aggravation case were stated in Loving. There, the Court blended the test from Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005), which defines off-Table causation cases, with a test from Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resulting test has six components. These are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened

> condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving v. Sec'y of Health & Hum. Servs., 86 Fed. Cl. 135, 144 (2009).

Special masters may focus on the last three elements in Loving, which correspond to the framework for causation-in-fact cases. Hennessey v. Sec'y of Health & Hum. Servs., No. 01-190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), mot. for rev. denied, 91 Fed. Cl. 126 (2010); Martin v. Sec'y of Health & Hum. Servs., No. 13-486V, 2020 WL 6865931, at *10 (Fed. Cl. Spec. Mstr. Oct. 27, 2020).

B. Loving Prong 4/Althen Prong 1: Theory

Relevant to determining whether an HPV vaccine can aggravate (or cause) POTS are two types of evidence. The first type of evidence is the set of studies in which researchers looked to see whether vaccinations increased the incidence of POTS among people receiving the vaccinations. These epidemiologic studies are discussed in section B.1 below. The second type of evidence is the set of opinions presented by doctors retained in the litigation. This opinion evidence is discussed in sectionB.2 below.[30]

1. Studies on Vaccination and POTS

a) Law regarding usefulness of epidemiology

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).

[30] Arguably, a third type of evidence consists of case reports, such as an article by Brinith, which was filed as Exhibit 37. See Pet'r's Prehear'g Br. at 30. Although these case reports have been considered, they carry almost no weight. See Cottingham v. Sec'y of Health & Hum. Servs., No. 15-1291V, 2021 WL 6881248, at *43 (Fed. Cl. Spec. Mstr. Sept. 27, 2021), mot. for rev. denied, 159 Fed. Cl. 328 (2022), aff'd without op., No. 2022-1737, 2023 WL 7545047 (Fed. Cir. Nov. 14, 2023).

b) Studies Exploring Whether Vaccines Can Cause POTS

By way of background, the media reported that some young women developed health problems after receiving a vaccination to protect against human papillomavirus. Many of these reports originated in Denmark. See Exhibit A-17 (Arana et al., Reports of Postural Orthostatic Tachycardia Syndrome After Human Papillomavirus Vaccination in the Vaccine Adverse Event Reporting System) at 582, Exhibit E-6 (Skufca et al., The association of adverse events with bivalent human papilloma virus vaccination: A nationwide register-based cohort study in Finland) at 5926, exhibit E-7 (Ward et al., A cluster analysis of serious adverse event reports after human papillomavirus (HPV) vaccination in Danish girls and young women, September 2009 to August 2017) at 2-3. These reports appear to have inspired further investigation. Determining whether the vaccination contributed to the health problem or was simply coincidental to the development of the health problem is challenging because adolescents, especially adolescent young women, can have troubles in their health regardless of receiving a vaccination. Exhibit A-13 at 3, Exhibit E-7 at 8. Another complication is the difficulty in diagnosing POTS. Exhibit A-17 at 582, Exhibit E-6 at 5930, Exhibit A-13 at 7.

The Secretary advanced several studies in which researchers investigated whether vaccination caused POTS. See Resp't's Posthear'g Br. at 28.

Epidemiologic Studies Investigating Vaccinations and POTS				
Year	Lead Author's Last Name	Exhibit	Population Studied	Notes
2015	European Medical Agency, Pharmacovigilance Risk Management Committee	A-13	63 million doses of Gardasil worldwide	Information came from marketing authorization holders. "Taking into account the totality of the available information the PRAC concluded that the evidence does not support that HPV vaccines . . . cause . . . POTS."
2017	Skufca	A-15	Finland, girls aged 11-15	No increase in POTS detected

Epidemiologic Studies Investigating Vaccinations and POTS				
2017	Arana	A-17	VAERS from June 2006 to August 2015	Denominator came from doses distributed according to the manufacturer.
2017	Ward	E-7	Follow up in Denmark	Cluster analysis
2018	Skufca	E-6	240,606 Finnish girls who received Cervarix, aged 11-15	Adjusted hazard ratio was 0.99 with a 95% confidence interval of 0.46-2.11

Each of these studies have various strengths and weaknesses. Some points were further developed on cross-examination. Tr. 407-09 (Dr. Gibbons), 436-47 (Dr. Gibbons), 535-38 (Dr. Whitton); See also Pet'r's Prehear'g Br. at 34-38; Pet'r's Prehear'g Reply at 12-15.

Some of these studies were referenced in a consensus statement from the American Autonomic Society. Exhibit E-5 (Barboi et al., Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society) (references 23, 29, 32, 43). Twenty-two people authored the report. The list of co-authors includes several prominent names, such as Dr. Gibbons. Dr. Gibbons disclosed his work in the Vaccine Program on behalf of the Government. Two other authors, HK and PAL, also disclosed this connection. Id. at PDF 4; See also Tr. 410. Other authors were Gisela Chelimsky and Thomas Chelimsky, the doctors who treated Mr. Jossart.

Dr. Gibbons testified about the origins of this paper. Dr. Gibbons stated that many patients were asking questions to their doctors about the safety of the HPV vaccine. Tr. 411, 473; See also exhibit E-5 at 3 (discussing how anecdotal reports affect how medical providers communicate with patients). According to Dr. Gibbons, members of the clinical affairs committee, members of the board of directors, and anyone else who wanted to participate joined this group. Tr. 474. Members of the group searched for relevant materials and distributed the articles.

Members also reviewed and summarized data. Id.; Tr. 341. The group discussed the findings and eventually wrote its analysis. Tr. 474.

The authors of the consensus statement wrote: "the American Autonomic Society finds that there are no data to support a causal relationship between HPV vaccination and . . . postural tachycardia syndrome." Exhibit E-5 at PDF 1; accord Tr. 341, 409. According to Dr. Gibbons, Dr. G. Chelimsky and Dr. T. Chelimsky agreed with the conclusions of this paper that lists them as co-authors. Tr. 474.

The consensus statement carries significant weight against the proposition that the HPV vaccine causes POTS. The authors have expertise in POTS. They persuasively explained why better and stronger data have not shown recipients of a vaccination have an increased susceptibility to POTS. The participation of two doctors who treated Mr. Jossart further enhances its value.

Given the strength of the epidemiology, Mr. Jossart has an uphill climb to establish with preponderant evidence that the HPV vaccination harmed him. However, as the Secretary's expert recognized, epidemiology cannot prove a negative. Tr. 407, 523-24, 540; see also Crutchfield v. Sec'y of Health & Hum. Servs., No. 09-0039V, 2014 WL 1665227, at *16 (Fed. Cl. Spec. Mstr. Apr. 7, 2014), mot. for rev. denied, 125 Fed. Cl. 251, 263 (2014). Thus, Mr. Jossart's theory is considered.

2. Molecular Mimicry

Dr. Steinman has proposed molecular mimicry as a theory by which the HPV vaccine could have harmed Mr. Jossart. The analysis begins with a review of non-binding appellate precedents on this topic. Then, the details of Dr. Steinman's opinion are set out.

a) Appellate Precedents on Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role of reviewing opinions. In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd sub nom., 463 F. App'x 932 (Fed. Cir. 2012). Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to

be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately three years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.[31] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159, 169 (2021) (finding that a special master

[31] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." *Dorland's* at 868.

erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

Very recently, the Court of Federal Claims explained why petitioners must present some evidence to show the persuasiveness of molecular mimicry as a theory in their cases. Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023), appeal docketed, No. 2024-1214 (Fed. Cir. Dec. 1, 2023). There, Ms. Dennington alleged that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine caused her to develop GBS. Id. at 644. She supported her claim with two reports from a neurologist, Carlo Tornatore, who put forward molecular mimicry. Id. at 647-49. The chief special master denied entitlement. Id. at 656.

In an opinion made available to the public on October 6, 2023, the Court of Federal Claims denied a motion for review because the chief special master did not commit any error in evaluating Ms. Dennington's prong one evidence. The Court emphasized the lack of evidence supporting Dr. Tornatore's opinion:

- "While Petitioner and Dr. Tornatore put forth the well-established medical theory of molecular mimicry as the mechanism through which the Tdap vaccine could cause GBS, nowhere in Dr. Tornatore's expert reports, nor in Petitioner's briefs, do they specifically tie the Tdap vaccine to GBS through molecular mimicry." Id. at 653.

- "Dr. Tornatore never actually explains how molecular mimicry might occur from the Tdap vaccine specifically, nor does he elaborate on how molecular mimicry could cause the specific autoimmune system reaction that could cause GBS." Id.

- "There is nothing in Dr. Tornatore's report that explains or even alludes to what antigens or structures in the Tdap vaccine could share homology with possible host antigens and how these antigens could react in the manner GBS is believed to progress." Id. at 654.

- "The literature upon which he relies make no mention of any causal connection between GBS and the Tdap vaccine." Id.

Based upon these observations, the Court criticized the lack of specificity in Dr. Tornatore's opinions:

> In fact, because Dr. Tornatore does not offer any specific explanation as to the distinct connection between Tdap,

> molecular mimicry, and GBS, one could take Dr. Tornatore's causation theory and substitute any table vaccine (e.g., the measles vaccine) and any autoimmune disorder (e.g., autoimmune encephalitis) and Dr. Tornatore's expert report's discussion of molecular mimicry would require absolutely no changes. That is how general his molecular mimicry theory is—it does not matter which vaccine and which autoimmune disorder are plugged in. But *Althen* prong one requires more.

Id.

These opinions guide the following assessment of Dr. Steinman's opinion regarding molecular mimicry.

b) Dr. Steinman's Opinion as to Molecular Mimicry

Under an assumption that Mr. Jossart has POTS, Dr. Steinman proposed a method by which the HPV vaccine can cause (or aggravate) POTS. Dr. Steinman's proposal is known as molecular mimicry and contains several steps.

Dr. Steinman identified the components of the HPV vaccine by referencing the package insert. See Exhibit 32 at 13, quoting reference 16, Exhibit 51 at 16. The Secretary did not dispute this aspect.

Dr. Steinman also identified a portion of human tissues potentially involved in the development of POTS, adrenergic receptors. Exhibit 32 at 4, 11-12, 16, Exhibit 51 at 5, 14-15, Exhibit 83 at 3; Tr. 256; see also Pet'r's Prehear'g Br. at 27. An adrenergic receptor is "a site on an effector organ innervated by postganglionic adrenergic fibers of the sympathetic nervous system, classified as either α-adrenergic or β-adrenergic according to its reaction to norepinephrine and epinephrine, as well as to certain blocking and stimulating agents." Dorland's at 1579; accord Dorland's at 33 (defining "adrenergic" as "activated by, characteristic of, or secreting epinephrine or related substances, particularly referring to the sympathetic nerve fibers that liberate norepinephrine at a synapse when a nerve impulse passes").[32]

[32] Dr. Whitton explained that "there are at least five different types of adrenergic receptor and, in some of the types, there are several subtypes . . . multiple different proteins fall under the umbrella term 'adrenergic receptor.'" Exhibit C at 5.

With a foundation of these substances, Dr. Steinman used a computer to determine the degree to which the sequences of amino acids are similar. The program is known as the Basic Local Alignment Search Tool, more commonly known by its acronym, BLAST. A key feature of BLAST searches is known as the "expect value" or E value. Essentially, an E value reflects the degree to which any similarity could be due to chance. Exhibit F at 7; see also exhibit F-4 (Silvanovich et al., The use of *E*-scores to determine the quality of protein alignments).

Consistent with reports he authored in other cases, Dr. Steinman maintained a homology of 5 amino acids out of 12 could be biologically significant. Exhibit 32 at 14, Exhibit 51 at 17, Exhibit 83 at 5. Some results of Dr. Steinman's BLAST searches exceeded this cut-off. Exhibit 32 at 14-15, Exhibit 51 at 16-18; See also Pet'r's Prehear'g Br. at 28-29. In a supplemental report, Dr. Steinman entered particular sequences of amino acids into the immune epitope database. Exhibit 83 at 6-12. Dr. Steinman declared his methodology was followed by another researcher, Robert Root-Bernstein. Id. at 8.

Through his experts, the Secretary generally challenges Dr. Steinman's use of molecular mimicry as a theory to explain how the HPV vaccine can cause or aggravate POTS. See Resp't's Prehear'g Br. at 42-54; Exhibit A (Dr. Gibbons) at 9-12 (relying primarily on epidemiology), Exhibit E (Dr. Gibbons) at 3 (again relying primarily on epidemiology), exhibit G (Dr. Gibbons) at 3-4 (discussing Li and Gunning), exhibit C (Dr. Whitton) at 3-11, exhibit F (Dr. Whitton), and exhibit H (Dr. Whitton addressing Li).

Two aspects of the parties' various disputes merit detailed analysis. The first concerns adrenergic receptors and the second concerns the 5/12 cut-off.

(1) Adrenergic Receptors

In the BLAST searches, Dr. Steinman compared portions of the HPV vaccine to adrenergic receptors. Exhibit 51 at 16. Dr. Steinman selected adrenergic receptors because of a paper by Benaroch. Exhibit 51 at 14, Exhibit 83 at 3; see also Exhibit 36 (Benaroch et al., Postural Tachycardia Syndrome: A Heterogenous and Multifactorial Disorder). As Mr. Jossart later argued, the HPV vaccine induced the production of antibodies that "target and caused dysfunction with Petitioner's alpha-1 and beta adrenergic receptors." Pet'r's Prehear'g Br. at

26. Dr. Gibbons accepted a "theory that disorders that damage the autonomic nervous system can cause a postural tachycardia." Exhibit A at 10.[33]

As part of the pre-hearing briefing, Dr. Steinman identified two other articles regarding autoantibodies to adrenergic receptors causing POTS. Exhibit 95, citing Li and Gunning. A fair amount of testimony was devoted to these two articles. See Tr. 256-63 (Dr. Steinman), 494 (Dr. Gibbons), 557-67 (Dr. Whitton), 577-87 (Dr. Steinman's rebuttal).

Overall, the evidence substantiates that some cases of POTS may have an autoimmune origin. Although the autoimmune POTS cases are likely a minority of all POTS cases, it seems likely that at least some POTS could be autoimmune. See Specks v. Sec'y of Health & Hum. Servs., No. 15-491V, 2023 WL 2947619, at *36-37 (Fed. Cl. Spec. Mstr. Apr. 14, 2023) and A.F. v. Sec'y of Health & Hum. Servs., No. 19-446V, 2023 WL 251948, at *23 (Fed. Cl. Spec. Mstr. Jan. 18, 2023).

(2) Five out of Twelve Amino Acids

The experts disputed the value of finding five identical amino acids out of a string of twelve amino acids. As support for his opinion regarding the biological significance for homology at a level of 5 out of 12 amino acids, Dr. Steinman relied upon two Gautum articles and, in his supplemental report, an article by Root-Bernstein. Exhibit 51 at 17, Exhibit 83 at 5, 8.

In response to Dr. Steinman's reliance on Gautum, Dr. Whitton did not address those articles specifically. Instead, Dr. Whitton made a more general point that "when comparing to proteins, short homologies are not remarkable - they are predictable." Exhibit C at 7. Dr. Whitton came to this conclusion by presenting a mathematical model, which Dr. Steinman did not contest. See Exhibit 83 (responding to Dr. Whitton's report). Dr. Whitton also relied upon an article by Silvanovich and colleges. They concluded "searches for short amino acid sequence matches of eight amino acids or fewer to identify proteins ... is a product of chance and adds little value to allergy assessments for newly expressed proteins." Exhibit C-11 (Silvanovich et al., The Value of Short Animo Acid Sequence Matches for Prediction of Protein Allergenicity) at 252.

[33] This aspect seems to contradict Dr. Whitton's assertion that "there is no evidence that these imaginary, hypothetically cross-reactive responses can cause any disease." Exhibit C at 6; exhibit F at 11.

After Dr. Steinman pointed to Root-Bernstein as an example in which a researcher used a "similar search scheme," (Exhibit 83 at 8), Dr. Whitton aggressively criticized the paper. Dr. Whitton wrote that the Root-Bernstein "paper is replete with egregious errors." Exhibit F at 3. A critical aspect concerns the E value. To restate, lower E values are more meaningful. However, Root-Bernstein wrote "E values greater than 60 are generally rare and usually indicate lengthy and statistically significant regions of similarity." Exhibit 85 (Root-Bernstein) at 3 (caption to Table 1). Dr. Whitton's commentary was pithy: "This is nonsense." Exhibit F at 8.

Following the disclosure of written reports, the parties advocated. Mr. Jossart supported Dr. Steinman's opinion with Root-Bernstein. Pet'r's Prehear'g Br. at 28. The Secretary challenged its usefulness. Resp't's Prehear'g Br. at 45 n.33. Mr. Jossart did not otherwise defend the Root-Bernstein paper. See Pet'r's Prehear'g Reply.

In oral testimony, Dr. Steinman conceded that the way Root-Bernstein used E values was "wrong." Tr. 301. Root-Bernstein was analyzing E values completely backwards. Thus, Dr. Whitton's strong criticism was accurate. See Tr. 551-53. Dr. Steinman's reliance on Root-Bernstein constitutes an error on Dr. Steinman's part. If Root Bernstein is the best support Dr. Steinman can identify as supporting the significance of 5/12, then the Root-Bernstein article practically undermines the entire edifice.

Dr. Steinman's assertion (5/12) does rest upon more than the Root-Bernstein article. He also supported this aspect of his opinion with the Gautum articles. Exhibit 51 at 17. A problem, however, is that Dr. Whitton has described the identification of homologies at this level as "ten a penny." Tr. 545. "These homologies are commonplace. They are random, and they are of no proven biological significance." Id. Although Dr. Steinman testified in rebuttal, he did not counter this point. See Tr. 572-87.

Dr. Whitton reinforced his point about the commonness of short stretches of amino acid homologies by discussing two different sequences of amino acids found in the HPV vaccine. Exhibit F at 4. These two sequences are the L1 protein from HPV6 and the L1 protein from HPV11. According to Dr. Whitton, a BLAST search identified 487 instances in which 5 out of 12 amino acids were the same. Id. Dr. Whitton then explained that pursuant to Dr. Steinman's logic in which homology at a 5/12 level produces a reaction, "we would need to include only one of the viral proteins in the vaccine, because that protein would be sufficient to induce immune responses that would protect against both viruses." Id. The real

world, as Dr. Whitton pointed out, does not match what Dr. Steinman is saying. "In reality, the L1 proteins from four different strains of HPV are included in the vaccine because – despite the very large number of shared homologies – the immune response triggered by the L1 protein from one virus does not 'meaningfully' cross-react with, or protect against, the other viruses." Id. Although Dr. Whitton disclosed this point before the hearing, Dr. Steinman did not rebut it.

Crediting Dr. Steinman's opinion that using BLAST to identify homology at a level of 5/12 amino acids leads to molecular mimicry is difficult, even at a level below scientific certainty. See Sparrow v. Sec'y of Health & Hum. Servs., No. 18-295V, 2024 WL 1599165, at *24 (Fed. Cl. Mar. 19, 2024), mot. for rev. filed (Apr. 18, 2024). It would seem that if Dr. Steinman's method were generally accepted, other scientists would follow Dr. Steinman's lead, these scientists would write papers consistent with Dr. Steinman's method, and Dr. Steinman would cite them. While it is conceivable another paper exists in the literature that Dr. Steinman has not submitted into evidence,[34] the proffer of the erroneous Root-Bernstein article as supporting reduces the value of Dr. Steinman's opinion.

In sum, Dr. Steinman has not presented a persuasive theory to explain how an HPV vaccine can aggravate (or cause) POTS. Dr. Steinman has identified some portions of the human anatomy that might be involved in a small subset of POTS cases, adrenergic receptors. However, his attempt to link adrenergic receptors to the HPV vaccine falls short. Under the relevant appellate cases, simply identifying some homology is not sufficient. See J.S., 164 Fed. Cl. at 340 (ruling that special master was rational in rejecting Dr. Steinman's opinion that HPV vaccine can cross-react with adrenergic receptors to cause POTS).

3. Other Cases

The determination that Mr. Jossart failed to carry his burden rests upon the evidence as discussed above. See 42 U.S.C. § 300aa–13(a) (requiring special masters decide cases based upon "the record as a whole"). The outcome is consistent with the outcomes in other cases in which petitioner's alleged the HPV vaccine caused him to develop some form of autonomic neuropathy. See, e.g., A.F. v. Sec'y of Health & Hum. Servs., No. 19-446V, 2023 WL 251948 (Fed. Cl.

[34] A more recent paper regarding the Epstein Barr virus and multiple sclerosis did not describe BLAST searches. See Exhibit 103 (Lanz et al., Clonally Expanded B Cells in Multiple Sclerosis Bind EBV EBNA1 and GlialCAM), Tr. 567.

Spec. Mstr. Jan. 18, 2023), Hughes v. Sec'y of Health & Hum. Servs., No. 16-930V, 2021 WL 839092 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. July 15, 2019), Dingle v. Sec'y of Health & Hum. Servs., No. 08-579V, 2013 WL 4083220 (Fed. Cl. Spec. Mstr. July 23, 2013).

C. Loving Prong 6/Althen Prong 3: Timing

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).

Dr. Steinman initially had trouble presenting an opinion that minimally fulfilled a petitioner's burden to identify the "timeframe for which it is medically acceptable to infer causation." His first report stated that the frequency of Mr. Jossart's syncopal episodes intensified in the first four months following the HPV vaccinations. Exhibit 32 at 16, citing Exhibit 4 at 7 (a record from the April 2013 hospitalization). However, this report did not explain when the adverse reaction to the HPV vaccination would be anticipated. See id. Thus, Dr. Steinman was directed to explain his position. Order, issued Nov. 28, 2016. Dr. Steinman's next report did not provide additional information. See Exhibit 58. Thus, he was again ordered to expand his opinion. Order, issued April 7, 2017.

Dr. Steinman's June 5, 2017 report did engage with the two sub-issues regarding timing. First, as to the expected interval for any adverse reaction, Dr. Steinman made two points. He stated that recipients of the vaccine show evidence of seroconversion two years after receiving an HPV vaccine. Exhibit 67 at 4 (citing MacIntrye and Reisinger). Next, Dr. Steinman asserted that an adverse reaction between 7-38 days would be appropriate. Dr. Steinman did not cite any literature as the basis for this opinion.

Second, as to the time when Mr. Jossart's (asserted) POTS worsened, Dr. Steinman also made two points. As an initial matter, Dr. Steinman stated "POTS does not have a sudden, acute onset that one can note on one day on a calendar." Exhibit 67 at 1. Then, after reviewing the medical records, Dr. Steinman asserted that the intensification of Mr. Jossart's syncopal episodes occurred between December 3, 2012 and January 3, 2013. Id. at 3. Based upon the November 26, 2012 date of vaccination, the period of aggravation ranged from 7 to 38 days after the vaccination. Id.

After Dr. Steinman succeeded in presenting a minimally competent opinion on timing, the Secretary's response was relatively limited. On the question of the interval during which an adverse reaction could be expected, Dr. Whitton challenged Dr. Steinman's point that a harmful response to the HPV vaccine could last for up to two years. Exhibit C at 10-11; see also Resp't's Prehear'g Br. at 52-53. Dr. Whitton is correct that the purpose of immunizations is to create a persistent and prolonged response. Thus, Dr. Steinman's invocation of a time extending for years is misleading and not relevant. See Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1244 (Fed. Cir. 2014) (ruling that the special master was not arbitrary in rejecting that a theory based in cytokines could cause an adverse reaction seven months later); Hennessey v. Sec'y of Health & Hum. Servs., 91 Fed. Cl. 126, 142 (2010) (the expert's "overly broad" opinion on timing effectively "renders Althen's third prong a nullity"). On the other hand, Dr. Whitton did not comment upon Dr. Steinman's more narrow proposal of 7-38 days. Because this evidence is not challenged, Mr. Jossart meets his burden to demonstrate with persuasive evidence the timeframe in which an adverse reaction could be expected. See Order, issued March 11, 2022, at 2 (summarizing discussions at the pre-trial conference).

As to the question of whether Mr. Jossart's syncopal episodes worsened within about one month of the HPV vaccination, there was more controversy. In Dr. Gibbons's view, Mr. Jossart did not have POTS in 2012-2013. As found in section V.B. above, Dr. Gibbons is persuasive that Mr. Jossart did not have POTS then. Thus, assessing whether a disease from which Mr. Jossart did not suffer worsened would be an entirely hypothetical. Additionally, instances of syncope are not diagnostic for POTS. Dr. G. Chelimsky found that syncope occurs in approximately equal frequency in people who have POTS in people who do not have POTS. Exhibit 50 (Chelimsky et al., Comorbid Conditions Do Not Differ in Children and Young Adults with Functional Disorders with or without Postural Tachycardia Syndrome) at 3, cited by Resp't's Prehear'g Br. at 36. Dr. Gibbons further opined that episodes of syncope are not consistent with Dr. Steinman's theory that a cross-reaction to the HPV vaccine damaged Mr. Jossart's autonomic nervous system. Exhibit A at 9, cited by Resp't's Prehear'g Br. at 37; Tr. 381, 454. Moreover, the worst of Mr. Jossart's health problems appear to have occurred around April 2013, when he was hospitalized twice. See Exhibit 31.09 at 1055 (Dr. G. Chelimsky's March 27, 2013 stating that she was considering admitting Mr. Jossart to the hospital for a therapy to treat his headaches). If, for argument's sake, it were assumed that Mr. Jossart worsened on April 3, 2013, the date on which he was hospitalized, then the latency between this decline and the first dose of the HPV vaccination, which was November 26, 2012, would be 128 days.

Under these circumstances, a finding regarding when, if at all, as a hypothetical matter Mr. Jossart's POTS worsened after vaccination is not prudent. Mr. Jossart's case can be and is resolved based upon (1) a lack of persuasive proof regarding diagnosis and (2) a lack of persuasive proof regarding a theory. Any finding in Mr. Jossart's favor on timing would not entitle him to compensation. Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact.").

D. Loving Prong 5/Althen Prong 2: Logical Sequence

The remaining Althen prong, which corresponds to the fifth prong in Loving, is "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation."

A lack of a finding that Mr. Jossart's episodes of syncope in late 2012 and early 2013 constitute an aggravation of POTS complicates any analysis of whether there is a logical sequence of cause and effect. In arguing that he met his burden, Mr. Jossart focused on his condition during this period. See Pet'r's Prehear'g Br. at 44. An onset (or aggravation) of problems in a relevant time is not necessarily dispositive for Althen prong 2 / Loving prong 5. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1323 (Fed. Cir. 2010) ("neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation").

Another important factor is the view of doctors who treated a vaccinee. Here, although the May 27, 2020 Order requested this information, Mr. Jossart did not identify any doctors who stated that the HPV vaccine harmed him. See Pet'r's Prehear'g Br. This absence is notable because the doctor who diagnosed Mr. Jossart as suffering from "borderline POTS," Dr. G. Chelimsky, co-authored the consensus statement that found "no data to support a causal relationship between HPV vaccination and . . . postural tachycardia syndrome." Exhibit E-5 at PDF 1. As a matter of logic, it would seem that Dr. Chelimsky would opine that Mr. Jossart's HPV vaccine did not harm him.

Based upon this record, the evidence does not preponderate in favor of finding a logical sequence of cause and effect regarding the HPV vaccination and any decline in Mr. Jossart's health in late 2012 or early 2013.[35]

VII. Conclusion

Mr. Jossart has a lengthy history of various health problems, which fortunately seem to have abated after his post-college move to Japan. The evidence, however, fails to preponderate in favor of finding that he suffered POTS in 2012-2013. Thus, he cannot prevail on his claim that an HPV vaccine worsened his POTS. In addition, even if his diagnosis of POTS were assumed, Mr. Jossart failed to show how HPV vaccines can aggravate (or cause) POTS. These independent reasons mean that Mr. Jossart cannot be awarded compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

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

[35] The parties dispute whether the lack of testing of Mr. Jossart's blood for potentially relevant antibodies affects this analysis. See Howard v. United States, No. 16-1592V, 2023 WL 4117370, at *7 (Fed. Cl. May 18, 2023) (discussing lack of testing for antibodies).

Medical Literature Appendix

(listed alphabetically by lead author's last name) [36]

1. Arana et al., Reports of Postural Orthostatic Tachycardia Syndrome After Human Papillomavirus Vaccination in the Vaccine Adverse Event Reporting System, 61 JOURNAL OF ADOLESCENT HEALTH 577 (2017); filed as Exhibit A-17.

2. Arnold et al., Postural tachycardia syndrome – Diagnosis, physiology and prognosis, 215 AUTON NEUROSCI 1 (2018); filed as Exhibit A-5.

3. Barboi et al., Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society, 30 CLINICAL AUTONOMIC RESEARCH 13 (2019); filed as Exhibit E-5.

4. Bennarroch, Eduardo E., Postural Tachycardia Syndrome: A Heterogenous and Multifactorial Disorder, 87 MAYO CLIN PROC. 1214 (2012); filed as Exhibit 36.

5. Chelimsky et al., Comorbid Conditions Do Not Differ in Children and Young Adults with Functional Disorders with or without Postural Tachycardia Syndrome; 167 J. PEDIATR. 120 (2015); filed as Exhibit 50.

6. Freeman et al., Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome, 21 CLIN AUTON RES 69 (2011); filed as Exhibit A-1.

7. Gautum et al., A Viral Peptide with Limited Homology to a Self Peptide Can Induce Clinical Signs of Experimental Autoimmune Encephalomyelitis, 161 J. IMMUNOL 60 (1998); filed as Exhibit 42.

8. Gautum et al., Minimum structural requirements for peptide presentation by major histocompatibility complex class II molecules: Implications in

[36] This appendix provides bibliographic information about articles cited in the decision. Although the decision discusses some (not all) articles, all articles have been reviewed.

induction of autoimmunity, 91 PROC. NATL. ACAD. SCI. 767 (1994); filed as Exhibit 41.

9. Gibbons et. al., The recommendations of a consensus panel for the screening,
diagnosis, and treatment of neurogenic orthostatic hypotension and associated supine hypertension, 264 J. NEUROL 1567 (2017); filed as Exhibit A-7.

10. Gunning et al., Postural Orthostatic Tachycardia Syndrome Is Associated With Elevated G-Protein Coupled Receptor Autoantibodies, 8 J. AM. HEART ASSOC. 1 (2019); filed as Exhibit 98.

11. Kizilbash et al., Adolescent Fatigue, POTS, and Recovery: A Guide for Clinicians, 44 CURR PROBL PEDIATR ADOLESC HEALTH CARE 108 (2014); filed as Exhibit 44.

12. Lanz et al., Clonally Expanded B Cells in Multiple Sclerosis Bind EBV EBNA1 and GlialCAM, 603 NATURE 321 (2022); filed as Exhibit 103.

13. Li et al., Clinical Experience of Seropositive Ganglionic Acetylcholine Receptor Antibody In A Tertiary Neurology Referral Center, 52 MUSCLE NERVE 386 (2015); filed as Exhibit A-9.

14. MacIntrye et al., Immunogenicity and persistence of immunity of a quadrivalent Human Papillomavirus (HPV) vaccine in immunocompromised children, 34 VACCINE 4343 (2016); filed as Exhibit 68.

15. Pharmacovigilance Risk Assessment Committee, EUROPEAN MEDICINES AGENCY, Assessment Report: Review under Article 20 of Regulation (EC) No 726/2004 1 (2015), filed as Exhibit A-13.

16. Reisinger et al., Safety and Persistent Immunogenicity of a Quadrivalent Human Papillomavirus Types 6, 11, 16, 18 L1 Virus-Like Particle Vaccine in Preadolescents and Adolescents; 26 THE PEDIATRIC INFECTIOUS DISEASE JOURNAL 201 (2007); filed as Exhibit 69.

17. Root-Bernstein, Robert, Rethinking molecular mimicry in rheumatic heart disease and autoimmune myocarditis: laminin, collagen IV, CAR, and B1AR as initial targets of disease, 85 FRONT PEDIATR. 1 (2014); filed as Exhibit 85.

18. Silvanovich et al., The use of *E*-scores to determine the quality of protein alignments, 54 REGULATORY TOXICOLOGY AND PHARMACOLOGY S26 (2009); filed as Exhibit F-4.

19. Silvanovich et al., The Value of Short Animo Acid Sequence Matches for Prediction of Protein Allergenicity, 90 TOXICOLOGICAL SCIENCES 252 (2006); filed as Exhibit C-11.

20. Singer et al., Postural Tachycardia in Children and Adolescents – What Is Abnormal, 160 J. PEDIATR. 222 (2011); filed as Exhibit A-2.

21. Skufca et al., The association of adverse events with bivalent human papilloma virus vaccination: A nationwide register-based cohort study in Finland, 36 VACCINE 5926 (2018); filed as Exhibit E-6.

22. Ward et al., A cluster analysis of serious adverse event reports after human papillomavirus (HPV) vaccination in Danish girls and young women, September 2009 to August 2017, 24 EURO SURVEILL 1800380 (2019); filed as Exhibit E-7.