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

OMARY ROCHA, Executor for the Estate of NESTOR ROCHA,	*	No. 16-241V
	*	Special Master Christian J. Moran
Petitioner,	*	
v.	*	
	*	Filed: February 1, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner;
Kimberly Shubert Davey, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Omary Rocha is the executor of the estate of her husband, Nestor Rocha. She alleges that an influenza ("flu") vaccine caused Mr. Rocha to suffer from vasculitis, leading to his death. The Secretary disputes this claim. In support of her claim, petitioner submitted expert reports and medical literature from pathologist Dr. Steven Rostad and neurologist Dr. Lawrence Steinman. The Secretary countered with reports and literature from pathologist Dr. Barbara

[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.

Ducatman and rheumatologist Dr. Mehrdad Matloubian. The parties also developed their arguments through briefs, and a hearing was held December 1 through December 3, 2021.

As explained below, Ms. Rocha is not entitled to compensation. Ms. Rocha has not established by a preponderance of the evidence that the flu vaccine caused or worsened vasculitis in Mr. Rocha or contributed to his death.

The experts retained by Ms. Rocha disagreed with the Secretary's experts, and with one another, over Mr. Rocha's diagnosis. The opinion begins with an overview of proposed diagnoses. Section II provides Mr. Rocha's background and medical history, and Section III provides the procedural history of the case. Section IV goes over the qualifications of the parties' experts, and Section V follows with analysis of their dispute over Mr. Rocha's diagnosis. The opinion concludes with a brief consideration of significant aggravation in Section VI and an analysis of causation-in-fact in Section VII.

I. Conditions

Although Mr. Rocha suffered from multiple illnesses, an extensive discussion can be limited to three topics. They are vasculitis, cryoglobulinemia, and cryoglobulinemic vasculitis.

A. Vasculitis

Vasculitis means there is "inflammation of a blood or lymph vessel." Dorland's Med. Dict. at 2026 (33rd ed.). Vasculitis can be classified into different types, often depending upon the size of the affected blood vessel. Tr. 111, 148, 219, 422.[2] Vasculitis can be diagnosed by clinical and/or lab findings, although "classification criteria and diagnostic criteria do not necessarily require

[2] Although Dr. Rostad asserted that Mr. Rocha may have suffered from "postvaccine autoimmune vasculitis," Exhibit 55 at 12, he conceded on cross-examination that he could not point to any literature using this terminology. Tr. 263; see also Tr. 456-57 (Dr. Ducatman's testimony that she had never heard the terms "post vaccine autoimmune vasculitis or PAV" prior to this case).

microscopic confirmation of a pathologic process that is a defining feature of a disease." Jennette at 2.[3]

The process of reaching a diagnosis of vasculitis can take a long time. Tr. 147. Some tests, such as a test for sedimentation rate or "sed rate", can detect inflammation but inflammation does not necessarily indicate vasculitis. See Tr. 46-47, 128, 463, 555. Other tests, such as a magnetic resonance angiography or angiogram, screen more specifically for vasculitis. Tr. 116, 198.

Vasculitis can occur in the blood vessels found in different organs. Tr. 148, 596. Among the different organs, the gastrointestinal track tends to be a rare location for vasculitis. Tr. 210, 512, 618. A clinician might order a biopsy of an affected organ to look for evidence of vasculitis. Tr. 420. A biopsy, however, can come back negative if the sample is obtained from an area without lesions. Tr. 113, 147. Doctors, including pathologists, attempt to determine the type of vasculitis, although further subtyping is not always possible. Tr. 151, 219, 422-23, 597-98.

An accurate diagnosis of vasculitis can affect a person's treatment. Tr. 221. For example, because the manifestations of vasculitis can resemble the signs and symptoms of a viral infection, doctors want to rule out infectious causes. Tr. 104, 147. When doctors suspect vasculitis, the doctors will prescribe medications to suppress the immune system. Tr. 104, 118 (discussing use of rituximab), 152, 221. The doctors want to suppress the immune system because the immune system is believed to be acting aberrantly. Tr. 154.

Although the immune system is involved in the pathogenesis of vasculitis, details about how most vasculitides originate are not known. Tr. 151. Some proposed mechanisms involve (1) a T cell driven process, (2) immune complexes, and (3) autoantibodies. Tr. 153-54 (Dr. Rostad's discussion of Guillevin & Dörner[4]); see Tr. 426 (Dr. Ducatman's discussion of an autobody mediated vasculitis), 460 (Dr. Ducatman's testimony that some vasculitides are autoimmune in origin). This three-part list is consistent with the testimony that some, but not all, vasculitides involve immune complexes. See Tr. 200, 225. Some types of

[3] J.C. Jennette et al., Special Article - 2012 Revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides, 65 ARTHRITIS & RHEUMATISM 1 (2012); filed as Exhibit 57 and Exhibit II.

[4] Loic Guillevin & Thomas Dörner, Vasculitis: mechanisms involved and clinical manifestations, 9 ARTHRITIS RES. & THER. Suppl. 2 (2007); filed as Exhibit 80.

vasculitides are associated with infections such as a hepatitis C and a hepatitis B infection. Tr. 166, 285-86. Another virus associated with vasculitis is the varicella virus. Tr. 328, 504 (Dr. Matloubian's testimony that varicella zoster vasculitis is a "rare" entity).

B. Cryoglobulinemia

Cryoglobulins are "immunoglobulins, not present in normal serum, that undergo reversible precipitation as serum cools." Dorland's at 433 (33rd ed. 2020); accord Exhibit A (Dr. Matloubian Report) at 11, Tr. 130 (Dr. Rostad), Tr. 410 (Dr. Ducatman). "Cryoglobulinemia," in turn means "the presence of cryoglobulin in the blood, associated with a variety of clinical manifestations, including Raynaud phenomenon, vascular purpura, . . . vasculitis, . . . neurologic manifestations, . . . and glomerulonephritis." Dorland's at 433; accord Tr. 279-80.

The experts distinguished between having cryoglobulinemia and having symptoms of cryoglobulinemia. (Another condition called cryoglobulinemic vasculitis is discussed below). Strictly speaking, the term "cryoglobulinemia" refers to the presence of cryoglobulins in the serum. Tr. 279-82 (Dr. Rostad), 469 (Dr. Ducatman), 545-56 (Dr. Matloubian). A person could have cryoglobulins in his blood for a long time and not necessarily experience any health problems. Tr. 196, 280 (Dr. Rostad: cryoglobulins are "a lab artifact"), 546 (Dr. Matloubian). Cryoglobulins might become manifest if a person goes out in the cold and the cold causes the cryoglobulins to precipitate, turning his hands blue. Tr. 469; see also Tr. 176-78. However, cold insensitivity occurs in conditions other than cryoglobulinemia. Tr. 589.

When a person with cryoglobulinemia develops symptoms, a different term could be used. Dr. Ducatman prefers the term "cryoglobulinemic syndrome" to the term "vasculitis." Tr. 469. Dr. Rostad recognized that other people might say "cryoglobulinemia" when a more precise term would be "cryoglobulinemic syndrome." Tr. 282. Another manifestation of cryoglobulinemic syndrome can be having a rash (purpura). Tr. 413.

C. Cryoglobulinemic Vasculitis

A person with both vasculitis and cryoglobulinemia suffers from cryoglobulinemic vasculitis. "Between 2% and 15% of cryoglobulin positive

patients are considered to develop cryoglobulinemic vasculitis." Braun at 89.[5] "Cryoglobulinemic vasculitis" means a person has "vasculitis in small vessels with cryoglobulin immune deposits." Dorland's at 1996. Again, from the point of view of a self-described "picky and pedantic pathologist," vasculitis means "inflammation in the wall of a blood vessel." Tr. 469 (Dr. Ducatman).

Dr. Matloubian opined that certain types of cryoglobulin can be associated with chronic infections, such as hepatitis B. Exhibit A (Matloubian Report) at 10. Dr. Ducatman's expert report also noted that cryoglobulinemia can be associated with hepatitis B. Exhibit CC (Ducatman Report) at 8.

Petitioner's experts disagreed. Dr. Rostad challenged Dr. Ducatman's argument that cryoglobulinemia is associated with hepatitis B, suggesting instead that such science has not been confirmed and that it is primarily associated with hepatitis C. Exhibit 84 at 4; Tr. 166, 186; see also Cacoub (giving support for cryoglobulinemia for hepatitis C, *not* hepatitis B).[6]

Preponderant evidence supports a finding that a hepatitis B infection can cause cryoglobulinemic vasculitis. Exhibit A (Dr. Matloubian Report) at 10, Exhibit CC (Dr. Ducatman Report) at 8, Tr. 283-86 (Dr. Steinman), Exhibit 46 at 7 (Dr. Steinman Report), Tr. 502 (Dr. Matloubian).

A person with cryoglobulinemic vasculitis may have a variety of signs and symptoms. Renal problems are frequent. Braun at 91; Tr. 444, 547. Other problems include "palpable purpura that usually occurs in the lower extremities." Braun at 89. The course of cryoglobulinemic vasculitis may wax and wane. Tr. 612.

II. Events in Mr. Rocha's Life

Mr. Rocha's life is divided into eight different periods, starting with the time before he received the allegedly causal vaccination. Other periods generally conform to treatment at different facilities.

[5] Gerald S. Braun et al., Cryoglobulinemic vasculitis: classification and clinical and therapeutic aspects, 83 POSTGRAD MED. J. 87 (2007); filed as Exhibit 82.

[6] Patrice Cacoub et al., Cryoglobulinemia Vasculitis, 128 AM. J. OF MED. 950 (2015); filed as Exhibit O.

A. Before Vaccination

Mr. Rocha's pre-vaccination medical history is complex. The medical records, affidavits, and testimony about his health are summarized within section II.A.1 below. To understand the significance of Mr. Rocha's health, the opinions from the parties' four experts are discussed in section II.A.2, below. Then, various assessments are made.

1. Summary of Evidence

Nestor H. Rocha was born in Uruguay on July 13, 1943. Exhibit 2 at 1. He moved to the United States in 1969, and roughly six months after meeting his future wife in the summer of 1971, they married. Tr. 10. Mr. Rocha and his wife had two children, a son and daughter. Tr. 18.

According to a history given in 2014, following a 2001 trip to South America, Mr. Rocha developed red lesions on his leg, though it was uncertain from where these lesions came. Exhibit 10 at 227. Although the lesions subsequently healed, hypopigmentation remained on both of his legs. Id.

In May 2006, Mr. Rocha underwent a uropathy testing, which showed "[d]ysmorphic erythrocytes indicating mild glomerular and/or renal tubular bleeding." Exhibit 6 at 25. He also underwent a CT scan of the abdomen and pelvis. Id. at 22. The results showed Mr. Rocha's

> kidneys function symmetrically and are normal in size, configuration and axis. There is slight fullness of the left renal collecting system. There are no obvious renal masses or calculi. There is no evidence of radiopaque ureteral or bladder calculi. The urinary bladder and prostate gland are normal. There is no free fluid in the abdomen or pelvis.

Exhibit 6 at 22.

On November 1, 2010, Mr. Rocha sought care from Dr. Ramon Ledon based on a referral for a colorectal cancer screen. Exhibit 7 at 7. Dr. Ledon also addressed Mr. Rocha's "gastroesophageal reflux disease and Hepatitis B." Id. At the appointment, Mr. Rocha presented as normal, with no jaundice, ulcers, lesions, or rashes, and his gait was normal. Dr. Ledon's assessment of Mr. Rocha found that he had "Chronic Persistan[t] Hep B not C[hr]onic Active." Id. at 9. Dr. Ledon ordered blood tests and stated he would observe Mr. Rocha given that the "anti virals offered side effects." Id. His blood results from these tests showed low red blood cell, hemoglobin, hematocrit, and platelet counts (4.2, 13.0, 39.6, and 126,

respectively) and high creatinine and nitrogen levels (3.0, 62, respectfully). Id.at 27-28.

On November 17, 2010, Mr. Rocha underwent a colonoscopy, which revealed severe chronic gastritis, mildly active and focal mild activity in his stomach. Exhibit 7 at 16.

Mr. Rocha returned to Dr. Ledon for care on November 23, 2010, where he was treated for duodenitis, gastritis, and an H. pylori infection. Exhibit 7 at 18. Mr. Rocha was prescribed Carafate. Id. at 19. Roughly one week later, Mr. Rocha underwent another blood test, which showed low red blood cell, hematocrit, and platelet counts (3.96, 37.8, and 117 respectively), and high levels of creatinine and nitrogen (1.85 and 46, respectively). Exhibit 15 at 5-6.

In February 2011, Mr. Rocha sought care from Dr. Ledon for a follow-up regarding his gastritis and H. pylori infection. Dr. Ledon ordered Mr. Rocha to stop taking the Carafate and planned to wean him off proton pump inhibitors. Exhibit 7 at 22.

In February 2012, Mr. Rocha sought care from Dr. Alan P. Krieger for his lower urinary tract problems. Exhibit 6 at 9. Outside of exhibiting symptoms regarding nocturia, Mr. Rocha presented as normal. Id. Dr. Krieger ordered a blood test. Id. at 10.

On July 19, 2012, Mr. Rocha underwent a blood test at the direction of Dr. Fernandez. The results showed high BUN and creatinine levels (47 and 1.66) and low platelet levels (122). Exhibit 4 at 28. He also showed abnormalities regarding his occult blood and red blood cell counts. Id. at 29.

Mr. Rocha saw nephrologist James Agresti on August 20, 2012. Mr. Rocha reported a significant past history of hypertension and rheumatoid arthritis, and that he was at one time on methotrexate. Exhibit 4 at 18. He gave no other history of renal disease. Dr. Agresti wrote, "I suspect that [Mr. Rocha] has chronic kidney disease probably secondary to age related changes along with hypertension." Id.

A neurologist, Victor Hugo Pareja, evaluated Mr. Rocha on September 5, 2012. Mr. Rocha stated that he was "experiencing numbness, tingling and cramps in [both] lower extremities." Exhibit 20 at 2. Dr. Pareja also stated that Mr. Rocha has "a history of a right foot drop 7 years ago with some residual weakness." Id. Dr. Pareja performed a nerve conduction study and electromyogram. These tests revealed "evidence of a moderate sensorimotor predominantly demyelinating polyneuropathy affecting the lower extremities." Id. at 3.

In February 2013, Mr. Rocha conducted a yearly follow-up with Dr. Krieger. During the visit, Mr. Rocha presented as normal. Exhibit 6 at 2. His medical history included hypertension, enlarged prostate, previous tuberculosis, and varicose veins. At the time, the only medication he listed as taking was Flomax. However, Mr. Rocha's wife's affidavit states he was also on "a small dose of antihypertensive medication for slightly elevated blood." Exhibit 54 at 1; see also Exhibit 6 at 9 (noting Mr. Rocha was taking Avapro on February 7, 2012).

Mr. Rocha was described as "extremely energetic, lively, active, and charismatic" prior to October 18, 2013. Exhibit 54 (affidavit from Omary Rocha, filed June 19, 2018) at 1. Mr. Rocha performed various "labor intensive" jobs for employment, such as working in restaurants, construction, mechanics, as well as working as an independent trucker. Tr. 10; see also Exhibit 9 at 11 (noting Mr. Rocha was "previously employed as a driver"). Mr. Rocha began working very early, starting his days at 4:00 AM. Tr. 10. Family described Mr. Rocha as being "one of the hardest workers and healthiest men" they had met. Exhibit 53 at 1 (affidavit from Carmen Bucco, filed June 19, 2018). Despite retiring in 2008, Mr. Rocha continued working construction jobs with his cousin roughly two-to-three times a week, building decks, bathrooms, kitchens, and even breaking cement to build patios. Tr. 13. He also performed typical handyman tasks for neighbors and friends. Id. at 14. For example, in 2012, Mr. Rocha's daughter, Sandra Rocha, purchased a property, where Mr. Rocha helped reconstruct the basement. Tr. 14; see also Exhibit 53 at 1. This included "breaking down brick walls and ripping up concrete." Exhibit 53 at 1.

Mr. Rocha and his wife were also "avid ballroom dancers." Tr. 15. Mr. Rocha's daughter testified that in the summer of 2013—the summer right before Mr. Rocha received his influenza vaccine—Mr. Rocha and his wife "put on [a] show for their friends and . . . just danced the night away." Id.

2. Expert Commentary

Dr. Rostad noted that Mr. Rocha's erythrocyte sedimentation rate in 2012 was very low. Tr. 46-47. Dr. Rostad explained that sedimentation is a surrogate marker for inflammation or an inflammatory marker. Id. at 48. He stated, "a patient who might have vasculitis might have much higher values because of the increased number of inflammatory markers or proteins that accelerate that sedimentation rate." Id. at 47. He also noted that the antinuclear antibody was recorded as negative, which would be another negative measure of autoimmunity. Id. at 48.

Overall, Dr. Rostad found "very little wrong with Mr. Rocha's health" prior to vaccination. Tr. 49. He stated that it was exactly what he would expect from a "vibrant, very active, physically active individual" such as Mr. Rocha's daughter had described. Id. at 50. Dr. Rostad noted how much Mr. Rocha moved in his daily activities and opined that "if [Mr. Rocha] had a peripheral neuropathy, it certainly wasn't present in the activities that were described . . . at this point, his neuropathy was not a significant problem for him." Id. Dr. Rostad agreed that Mr. Rocha had gastritis prior to vaccination and tested positive for the H. Pylori infection. Tr. 209.

Dr. Steinman stated that Mr. Rocha "had kidney abnormalities beforehand" and had "hepatitis B positive serology." Tr. 340. Dr. Steinman opined that Mr. Rocha had cryoglobulinemic vasculitis prior to his vaccination. Id. at 341.

Dr. Ducatman testified that Mr. Rocha had longstanding, chronic, and stable cryoglobulinemia prior to his October 18, 2013 vaccination. Tr. 410. Dr. Ducatman explained that Mr. Rocha had evidence of cryoglobulin (a protein circulating in the blood that precipitates out below body temperature) prior to the vaccination. Id. Dr. Ducatman noted that Mr. Rocha had a positive rheumatoid factor twice during his illness in 2013-2014, and stated that the rheumatoid factor is generally stable over time. Id. at 411. Further, Mr. Rocha was treated with methotrexate, which is "a fairly toxic drug" that would not be given to a patient who "just had some arthralgia on the off chance." Id. With this, Dr. Ducatman opined that it was "a very reasonable assumption, much more likely than not, that [Mr. Rocha] had a preexisting rheumatoid factor," i.e., cryoglobulin. Id. at 411-12.

Additionally, clinical symptoms of cryoglobulinemia – rash, neuropathy, cold fingers, white and blue discoloration, and Raynaud's phenomenon – were present prior to his flu vaccination. See Exhibit 3 at 54-57; Tr. 413-14. Dr. Ducatman noted Mr. Rocha's chronic renal failure and explained that cryoglobulinemia is associated with renal disease. Tr. 414. She opined that Mr. Rocha's history of chronic hepatitis B, which pre-existed the vaccination, could "certainly . . . lead to the development of cryoglobulinemia." Id. at 414-15; see also Exhibit CC at 8.

Dr. Matloubian also stated that Mr. Rocha's positive rheumatoid factor and kidney findings were consistent with cryoglobulinemia, and further explained that the association between hepatitis B and cryoglobulinemia is well-established. Tr. 501-02; see also Exhibit A at 10. He opined that, to a reasonable degree of medical probability, Mr. Rocha had cryoglobulinemic vasculitis prior to his vaccination. Tr. 504.

3. Assessment

Dr. Rostad, Dr. Steinman, Dr. Ducatman, and Dr. Matloubian agreed that before the vaccination, Mr. Rocha suffered from a hepatitis B infection. Tr. 284 (Dr. Rostad), 329 (Dr. Steinman), 415 (Dr. Ducatman), 502 (Dr. Matloubian); see also Exhibit 12 at 392 (lab results from December 11, 2013, showing Mr. Rocha was reactive to hepatitis B antigens and antibodies). They also agreed that before the vaccination, Mr. Rocha had problems with his kidneys, manifesting as abnormalities in his urine. Tr. 171-72 (Dr. Rostad), 335-36 (Dr. Steinman), 497-98 (Dr. Ducatman), 510 (Dr. Matloubian).

Dr. Rostad parts company from Dr. Steinman as well as from Dr. Ducatman and Dr. Matloubian as to whether Mr. Rocha suffered from cryoglobulinemia and/or cryoglobulinemic vasculitis. Tr. 176. However, ample evidence supports a finding that, on a more likely than not basis, Mr. Rocha suffered from cryoglobulinemic vasculitis. A key piece of evidence on this point is that Ms. Rocha's other expert, Dr. Steinman, stated that Mr. Rocha had cryoglobulinemic vasculitis. Dr. Steinman's oral testimony could hardly be clearer:

> Q. Is it your opinion that Mr. Rocha had cryoglobulinemic vasculitis prior to his influenza vaccination on October 18 of 2013?
>
> A. Yes.

Tr. 340-41. Dr. Steinman further indicated that Mr. Rocha had lived with the cryoglobulinemic vasculitis for "decades," although this disease, in Dr. Steinman's view, did not cause Mr. Rocha much hardship. Tr. 345.

The opinions from Dr. Ducatman and Dr. Matloubian corroborate Dr. Steinman's opinion that Mr. Rocha suffered from cryoglobulinemic vasculitis. Tr. 447-48 (Dr. Ducatman), 491, 504 (Dr. Matloubian). Under the circumstances in which three of four retained experts agree with a diagnosis, it is easy to find the evidence preponderates in favor of finding that the diagnosis is correct.

A finding that Mr. Rocha had cryoglobulinemic vasculitis before the vaccination carries some limited consequences for the remainder of the case. First, this finding enhances the credibility of Dr. Matloubian, who first proposed the diagnosis of cryoglobulinemic vasculitis. See Exhibit A at 11. Second and correspondingly, this finding reduces the credibility of Dr. Rostad, whose opinion was not joined by Dr. Steinman, an expert also retained by Ms. Rocha.

On the other hand, a finding that Mr. Rocha had cryoglobulinemic vasculitis before the vaccination does not prevent Ms. Rocha from prevailing upon a claim that the flu vaccination caused Mr. Rocha's death. Dr. Steinman proposed that the flu vaccine, via reactivation of a latent varicella zoster virus, caused Mr. Rocha to develop a second vasculitis, a varicella zoster virus vasculitis:

Q. And then is it your opinion that [Mr. Rocha] developed a subsequent vasculitis, a varicella zoster virus vasculitis after the vaccination?

A. Yes.

Q. So he had two types.

A. Something very bad happened after that vaccination. Yes.

Tr. 341. Furthermore, Dr. Matloubian and Dr. Ducatman have not opined that the cryoglobulinemic vasculitis caused Mr. Rocha's death. Tr. 455-56 (Dr. Ducatman), 507 (Dr. Matloubian).

B. Date of Vaccination: October 18, 2013

Mr. Rocha visited his doctor, Jacqueline Fernandez, for a well adult patient visit on October 18, 2013. Exhibit 3 at 2. At the visit, Dr. Fernandez recorded that Mr. Rocha had generally normal vitals and presentation. Id.; see also id. at 1 (noting no skin lesions or discoloration). However, Mr. Rocha's medical records noted that Mr. Rocha had "benign prostatic hyperplasia, chronic kidney disease, chronic progressive renal failure, impotence, unspecific idiopathic peripheral neuropathy, peripheral nerve disease, platelet count below reference range, and other nonspecific findings on examination of blood." Id.; see also id. at 10. During his visit with Dr. Fernandez, Mr. Rocha also received a fluvirin ("flu") vaccine. Exhibit 19 at 3. Dr. Fernandez ordered several labs and a chest x-ray as a follow-up plan for Mr. Rocha. Exhibit 3 at 10-13.

Dr. Rostad described Mr. Rocha's issues as "ongoing" as of the date of his vaccination. Tr. 38-39. He noted a normal specific gravity measurement in the urinalysis, indicating that Mr. Rocha was not dehydrated. Tr. 40-41. Dr. Rostad opined that "a variety of conditions" could produce the small amount of blood in Mr. Rocha's urine, including benign prostatic hyperplasia. Tr. 42.

Dr. Steinman opined that Mr. Rocha had a preexisting vasculitis, but that "it didn't seem to have many severe consequences at all" and "didn't seem to bother him in any major way" until the flu shot on October 18, 2013. Tr. 331, 346.

C. Ear Treatments (November 12, 2013 – December 3, 2013)

Approximately four weeks after Mr. Rocha received the flu vaccine, Mr. Rocha sought care from an ear, nose, and throat doctor at the office of Dr. Diego Saporta on November 12, 2013. He was treated by Robert D. Huang. Exhibit 5 at 4. The November 12, 2013 visit was the first of a series of visits in November 2013 for ear pain. Tr. 250-51.[7] Mr. Rocha complained of having a "sensation of clogged ear" and "ear ache[s] in the right ear . . . [that] started 4 days ago." Exhibit 5 at 4. Dr. Huang diagnosed Mr. Rocha with "Chronic Serous Otitis Media" and prescribed him "Augmentin 875-125 mg," "Allegra-D 12 Hour 60-120 mg," and "Nasonex 50mcg/actuation." Id.; accord Tr. 51. Augmentin is antibiotic and Dr. Huang's prescription of an antibiotic could mean that Mr. Rocha suffered from a bacterial infection, although no culture was taken. Tr. 238.

On November 18, 2013, Mr. Rocha returned to Dr. Saporta's office but saw a different doctor---Dr. Saporta. The reason for the appointment was a continuation of pain despite taking Augmentin. Exhibit 5 at 5. Upon an examination of Mr. Rocha's ears, Dr. Saporta observed that Mr. Rocha's "right auricle is erythematous . . . drum is dull and slightly retracted . . . Tympanogram at right is Type B." Id. Dr. Saporta diagnosed Mr. Rocha as suffering from "Acute External Otitis." Id. Dr. Saporta prescribed Medrol 4 mg and ordered Mr. Rocha to contact him the next day. Id.; see also Tr. 51.

Medrol is a powerful steroid, which suppresses the immune system. Tr. 250. Dr. Rostad opined that Medrol "could have easily influenced any immune complement or any inflammatory conditions and calmed the inflammatory condition as well." Tr. 291. Dr. Rostad further explained that Medrol would have suppressed the immune response of vasculitis, ameliorating the harmful consequences. Tr. 302-03.

The experts the parties retained in this litigation differed in their interpretation of these first two visits to an ENT doctor. On cross-examination, Dr. Rostad seemed to indicate that Mr. Rocha was prescribed Medrol before Mr. Rocha developed shingles. Tr. 254. Dr. Matloubian shared this interpretation. Tr. 529. On the other hand, Dr. Steinman attributed the beginning of Mr. Rocha's

[7] Ear problems, however, were not entirely unprecedented for Mr. Rocha. His January 23, 2012 visit with Dr. Saporta noted a history of bilateral serous otitis media, bilateral myringotomy, and tubes in his ears. Exhibit 5 at 3.

Ramsay Hunt syndrome to the start of Mr. Rocha's ear pain because Ramsay Hunt syndrome can cause ear pain. Tr. 311-12.[8]

Mr. Rocha returned to Dr. Saporta two days later on November 20, 2013. Exhibit 5 at 6. During the visit, Dr. Saporta noted Mr. Rocha was "not getting better, rather pain is worse" despite being on Augmentin. Id. In examining Mr. Rocha's ears, Dr. Saporta noted that there were "no major changes," and again indicated that Mr. Rocha's "right auricle [wa]s erythematous." Id. In addition to examining Mr. Rocha's ears, Dr. Saporta examined Mr. Rocha's nose and neck. Dr. Saporta did not indicate a rash was present. Id.; see also Tr. 253. Dr. Saporta prescribed ciprofloxacin and noted that if Mr. Rocha's condition did not improve, he would consider consulting Dr. Jyung. Exhibit 5 at 6; see also Tr. 52, 239.

The next day, on November 21, 2013, Mr. Rocha returned to Dr. Saporta's office after Mr. Rocha's wife "noticed some vesicles." Exhibit 5 at 7. On examination, Dr. Saporta recognized vesicles "in the immediate preauricular area and in the concha . . . [and] also in the right temporal area." Id. Vesicles are manifestations of shingles. Tr. 240. Dr. Rostad stated that the presence of vesicles is "highly suggestive or highly consistent with a varicella zoster or herpes zoster infection." Tr. 53.

During the exam, Dr. Saporta noted Mr. Rocha was walking "ataxic." Dr. Saporta diagnosed Mr. Rocha with two conditions. First, Dr. Saporta continued the previous diagnosis of "acute otitis media." Second, Dr. Saporta added a diagnosis of Ramsay Hunt syndrome. Exhibit 5 at 7. He prescribed Valtrex 500 mg and suggested that Mr. Rocha discontinue taking Cipro. Mr. Rocha, however wanted to continue on Cipro. Dr. Saporta's report stated he would speak to Mr. Rocha the next day if his condition worsened. Id.

Mr. Rocha's development of Ramsay Hunt syndrome is one link in the chain of events constructed by Dr. Steinman to explain how the flu vaccine harmed Mr. Rocha. Exhibit 21 at 6. Additional details about Dr. Steinman's theory are set out in sections III.B.1 and VII.B.2 below.

Dr. Saporta continued to care for Mr. Rocha. On November 26, 2013, Mr. Rocha returned to Dr. Saporta for care, explaining that he "has no pain" but

[8] Dr. Steinman's testimony is ambiguous as to whether he is referring to the appointment with Dr. Huang, who prescribed Augmentin or the appointment with Dr. Saporta. Whether Dr. Steinman was referencing the November 12 or the November 18 visit does not affect the analysis.

"continues to be dizzy." Exhibit 5 at 8. Dr. Saporta described the results of his examination for different parts of Mr. Rocha's body. For the right ear, the "erythema [was] resolved. There are vesicles that are now dry." Id. Mr. Rocha had "clear fluid in the right middle ear." Id. For the facial exam, Dr. Saporta recognized "Incipient right facial paresis." Id. The development of facial nerve problems is consistent with a diagnosis of Ramsay Hunt syndrome. Tr. 53. Dr. Saporta's two diagnoses were: "Chronic Serous Otitis Media" and "Ramsay-Hunt syndrome (Herpes Zoster Oticus)." Exhibit 5 at 8. Mr. Rocha was prescribed prednisone and Dr. Saporta stated he would perform surgery on Mr. Rocha to place tubes in his ears to relieve his pressure and inflammation. Exhibit 5 at 8; Tr. 54.

D. Hospitalization at Trinitas (November 27, 2013 to December 2, 2013).

Mr. Rocha's stay in Trinitas concerned two different problems---his ear trouble for which he was initially admitted, and kidney problems that were discovered during his admission. For the sake of simplicity, these are discussed separately.

1. Ear Problems

Mr. Rocha was admitted at Trinitas Regional Medical Center on November 27, 2013, when he underwent an operation in which the doctor placed tubes both his ears. Exhibit 9 at 188; see also Tr. 240, 312, 366. The doctor performing the procedure, which is known as a myringotomy, was Dr. Huang. Exhibit 9 at 9. Dr. Huang's preoperative and postoperative diagnoses were "Bilateral otitis media, acute." Id.

Dr. Huang's diagnosis of "bilateral otitis media, acute" raised a small, and ultimately inconsequential, issue during the hearing. The Secretary's questions to Dr. Steinman on cross-examination seemed to suggest that Dr. Huang implicitly rejected the diagnosis of Ramsay Hunt syndrome. See Tr. 369-71. Dr. Matloubian developed this point briefly. Tr. 514-16. After the hearing, the Secretary referred to the potential conflicts in diagnoses. Resp't's Posthearing Br., filed May 2, 2022, at 36-37.

Doctors maintained Mr. Rocha's diagnosis of Ramsay Hunt syndrome after the myringotomy. In the report discharging Mr. Rocha from Trinitas, one of his final diagnoses was "Ramsay Hunt syndrome status post myringotomy tube placement." Exhibit 9 at 22. Furthermore, in a follow up appointment that occurred on December 3, 2013, the day after Mr. Rocha's discharge, Dr. Saporta

included as diagnoses both "Acute otitis media" and "Ramsay-Hunt syndrome (Herpes Zoster Oticus)." Exhibit 5 at 9; accord Tr. 67.

Thus, preponderant evidence supports a finding that Mr. Rocha suffered from Ramsay Hunt syndrome. As to whether the flu vaccine contributed to Mr. Rocha's Ramsay Hunt syndrome, that question is deferred until section VIII.B.3 below.

2. Kidney Troubles

After Dr. Huang operated on Mr. Rocha, labs revealed that Mr. Rocha had elevated levels of creatinine (3.0) and urea nitrogen (BUN) (62). Exhibit 9 at 14, 209. Although it appears that the labs results came back after the operation, the blood was drawn at 7:30 AM, a time before the operation. See Exhibit 9 at 209 (listing time of blood draw), at 188 (listing time Dr. Huang dictated the operative report); see also Tr. 55 (discussing morning labs).

Due to the laboratory values, Dr. Agresti was consulted at approximately 4:30 PM on November 27, 2013. Exhibit 9 at 10. Dr. Agresti described Mr. Rocha as "known to me and was seen by me in August 2012." Id. Dr. Agresti obtained a history in which Mr. Rocha recounted that his "problems started approximately 2 weeks ago when he developed apparently shingles involving the right ear." Id. When Mr. Rocha was taking amoxicillin, he developed "some nausea and vomiting." Id. Mr. Rocha informed Dr. Agresti that he "has not been eating or drinking well." Id. Mr. Rocha's more distant medical history included "chronic kidney disease" and "a history of rheumatoid arthritis." Id. at 11.

Dr. Agresti's impressions included "Acute kidney injury, which I suspect is most likely secondary to dehydration." Exhibit 9 at 12. Dr. Agresti admitted Mr. Rocha to the hospital for IV fluids and ordered additional labs. Id. at 13; see also Tr. 55.

During his stay at Trinitas, Mr. Rocha experienced gastrointestinal issues, abdominal pain, dizziness associated with his Ramsay Hunt syndrome, and was placed on IV fluids. Exhibit 9 at 14-18. He was seen by several doctors and had various tests and studies. Id.

Mr. Rocha's urine was analyzed after he provided a sample on November 29, 2013. One aspect showed the specific gravity for his urine was within the normal range. Exhibit 9 at 215. According to Dr. Rostad, a normal finding is not expected for someone suffering from dehydration. Tr. 61. Dr. Rostad recognized

that the normal specific gravity could reflect treatment (hydration) after being admitted to the hospital on November 27, 2013. Tr. 64-65.

By December 2, 2013, Mr. Rocha's "nausea, vomiting, [and] diarrhea [had] improved. His laboratory results have also improved." Exhibit 9 at 23. The doctors, therefore, discharged him. His final diagnoses included "Acute renal insufficiency," "Dehydration," and "Chronic kidney disease." Id. at 22. He was instructed to follow up with Dr. Saporta, Dr. Fernandez, and Dr. Agresti. Id. at 24. As discussed above, the follow up appointment with Dr. Saporta did occur on December 3, 2013. The other appointments did not occur as planned due to intervening health problems.

3. Additional Expert Commentary

Without discussing the material from Trinitas specifically, Dr. Matloubian opined that he did not see any medical records documenting Mr. Rocha manifested signs and symptoms consistent with varicella zoster virus vasculitis. Tr. 506-07. Although Dr. Steinman testified in rebuttal, he did not address this aspect of Dr. Matloubian's opinion.

E. Mr. Rocha's 1st Emergency Room Visit - Barnabas Medical Center (December 4-14, 2013)

As previously mentioned, on December 3, 2013, Mr. Rocha saw Dr. Saporta. Exhibit 5 at 9. Later that evening, Mr. Rocha began having "night fevers and pain in his stomach which continued, as well as weakness, vomiting and diarrhea." Exhibit 1 (affidavit of Sandra Rocha Bucco) at 1.

On the evening of December 4, 2013, Mr. Rocha went to Barnabas Medical Center's emergency room. Exhibit 1 at 2; Exhibit 12 at 9-10. He remained at Barnabas for roughly ten days. Exhibit 12 at 22 (discharge summary). During this admission, he was seen by a variety of specialists.[9]

1. Emergency Department

Mr. Rocha recounted his recent health problems starting with the ear pain approximately two weeks earlier. Exhibit 12 at 59; see also Tr. 69-70. He had

[9] The organization by specialty largely tracks the Secretary's presentation of events in Barnabas Medical Center. See Resp't's Posthearing Br. at 5-7. Although Ms. Rocha's posthearing brief does not contain much information about Barnabas, Ms. Rocha set forth some material earlier. See Pet'r's Prehearing Br., filed Oct. 22, 2020, at 5-7.

been having "diarrhea, vomiting, and abdominal pain." He was admitted to the hospital.

One of the earlier tests performed on Mr. Rocha was a CT scan of his abdomen and pelvis. Mr. Rocha had ascites around the liver, spleen, and pelvis, and inflammation. Exhibit 12 at 378-79; 381; see also Tr. 551-52. Ascites lead to intravascular volume depletion and interfere with the ability of the kidneys to filter. Tr. 551; see also Dorlands's at 160.

2. Nephrology

A nephrologist, Naga Komati, saw Mr. Rocha on December 5, 2013. Exhibit 12 at 167; see also Tr. 72-74. Based upon the history, laboratory studies, the results of an abdominal CT scan, Dr. Komati assessed Mr. Rocha as having an "Acute kidney injury, most likely acute tubular injury." Exhibit 12 at 168. Dr. Komati also proposed that Mr. Rocha could suffer from acute interstitial nephritis.

By December 8, 2013, a different nephrologist (Nita Shah) indicated that Mr. Rocha's rise in creatinine was "hemodynamic", and Mr. Rocha required "supportive care only." Exhibit 12 at 113; accord Tr. 88. Dr. Shah carried that opinion forward in her next reports. Exhibit 12 at 126 (Dec. 10, 2013), at 137 (Dec. 11, 2013), 150 (Dec. 12, 2013), and 159 (Dec. 13, 2013). After quoting one of these reports, Dr. Matloubian wrote, "the rise in creatinine was attributed to dehydration and not an autoimmune process." Exhibit A at 5; accord Resp't's Posthearing Br. at 6 (asserting without citing any evidence that "hemodynamic" meant "due to dehydration").

In Dr. Rostad's view, either an acute tubular injury or an acute interstitial nephritis could have been caused by vasculitis or inflammation. Tr. 88. Dr. Rostad was not asked to comment upon a potential hemodynamic reason for any decline in kidney functioning.

Respondent's expert, Dr. Matloubian, opined that the changes in Mr. Rocha's kidney function during this time were due to dehydration, not Mr. Rocha's worsening of his cryoglobulinemic kidney disease, given that his renal issues were corrected with hydration. Exhibit A (Matloubian Report) at 4, 9.

3. Gastroenterology

On December 5, 2013, the day after being admitted to St. Barnabas, Mr. Rocha was seen by a gastroenterologist, Robert Schuman. Exhibit 12 at 102 (identifying Dr. Schuman as the doctor consulting on gastrointestinal issues), at

170-71 (consultation report). Dr. Schuman stated that "the etiology seems to be infectious in nature," although other possibilities remained. Id. at 171; see also Tr. 75-78.

An upper endoscopy was performed, and four samples were tested. The results ruled out neoplasm, lymphoma and H. pylori. Exhibit 12 at 364; see also Tr. 80-84. Dr. Rostad stated that these tests are unlikely to detect vasculitis. Tr. 84. Gastric vasculitis is "extraordinarily unusual or rare." Id.

The doctors retained in this case could not clarify why Mr. Rocha had problems in his gastrointestinal system. According to Dr. Ducatman, Mr. Rocha's GI symptoms were "never adequately explained." Tr. 430. Dr. Matloubian stated, "no one ever got a satisfactory answer [with] what was going on in his GI tract." Tr. 511. Dr. Rostad also testified that Mr. Rocha's "gastrointestinal issues . . . have not been fully explained." Tr. 77.

4. Discharge

Mr. Rocha was discharged from Barnabas Medical Center on December 14, 2013. Exhibit 12 at 22-25. The report is particularly detailed in summarizing Mr. Rocha's course while hospitalized at St. Barnabas. The list of diagnoses at discharge consisted of 11 items: nausea and vomiting, severe bipedal edema, ascites, acute renal failure on chronic kidney disease, hypertension, recent shingles to the right ear post status treatment, hepatitis, acute thrombocytopenia, chronic protein malnutrition, low grade fevers with cough, and diastolic disfunction. Exhibit 12 at 22. He was taking the following medications: amlodipine, carvedilol, guaifenesin, hydrochlorothiazide, nystatin, and omeprazole. Id. at 25.

The doctors' follow-up care plan included Mr. Rocha undergoing a CT scan in approximately one month and to follow up with his primary care physician next week. Exhibit 12 at 23. He was also instructed to see some of the doctors who had seen him in the hospital including, Dr. Shah, Dr. Khot, and Dr. Schuman. Id. at 25.

5. Additional Expert Commentary

In his oral testimony, Dr. Rostad reviewed the detailed discharge report. Tr. 89-96. In this portion, Dr. Rostad emphasized that compared with his appointment with Dr. Fernandez when he received the flu vaccine, Mr. Rocha developed new symptoms. As example of new problems, Dr. Rostad pointed to abdominal symptoms, such as "nausea, vomiting, diarrhea, [and] abdominal pain." Tr. 91. Dr. Rostad opined that these problems were unlikely to be derived from Mr. Rocha's chronic gastritis because (a) the Augmentin and Cipro would have treated

an infection with H. pylori and (b) the biopsies did not detect H. pylori. However, in this portion of his testimony, Dr. Rostad did not explain why information presented in the discharge summary supported a diagnosis of vasculitis.

During the hearing, Dr. Matloubian stated Mr. Rocha's CT results, particularly the nonspecific findings, would not prompt him to consider Mr. Rocha as suffering from vasculitis. Tr. at 552. Moreover, according to Dr. Matloubian, the medical records from St. Barnabas, which exceed 600 pages, do not mention vasculitis. Id. at 521.

F. Follow-Up Care (December 23–28, 2013)

On December 23, 2013, Mr. Rocha sought care from the nephrologist who previously treated him at Trinitas, Dr. Agresti. Mr. Rocha complained about persistent abdominal discomfort and gastrointestinal distress. Exhibit 4 at 5; see also Tr. 97-98. Dr. Agresti's assessment notes showed Mr. Rocha's chronic kidney disease was stage 3 but stable, his hypertension was stable, but his edema was worsening. Exhibit 4 at 6. Mr. Rocha was ordered to take Lasix and stop use of Norvasc. Id.

Four days later, Mr. Rocha saw the hematologist / oncologist who treated him in St. Barnabas, Dr. Khot, for a diagnosis of anemia. Exhibit 3 at 50-52; see also Tr. 99-100. Mr. Rocha complained of weakness, fatigue, weight loss, and a 101º Fahrenheit fever roughly every night. Exhibit 3 at 50. Additionally, Mr. Rocha was still suffering from leg swelling and could hardly move around. Id. Mr. Rocha underwent a complete blood count test, which showed that his hemoglobulin and platelet levels had worsened (8.6 and 299 respectively). Id. at 52. However, Mr. Rocha's shingles appeared to have resolved. Id. at 51. Dr. Khot's impression included "anemia of chronic DZ and inflammation." Id. Dr. Khot planned to have Mr. Rocha undergo another CT in a few weeks due to his inflammation and edema. Mr. Rocha was ordered to stop taking Ferrex and Procrit, and to follow-up with Dr. Khot in one week. Id. at 52.

G. Mr. Rocha Second Emergency Room Visit – Overlook Hospital (December 29, 2013 – January 14, 2014)[10]

In the evening of December 29, 2013, Mr. Rocha sought care at the Overlook Hospital emergency room after experiencing abdominal pain, nausea,

[10] The medical records from Overlook exceed 1,300 pages. Thus, this decision focuses upon the medical records the experts discussed in their testimony and the parties cited in their briefs. Among the testifying experts, Dr. Steinman discussed Mr. Rocha's medical records from

and vomiting. Exhibit 10 at 24. Mr. Rocha remained in Overlook until January 14, 2014, when he was transferred to another hospital. As Dr. Rostad stated, Mr. Rocha's health during this time in January reflected a "very complicated hospital stay." Tr. 126.

Upon admission, Mr. Rocha underwent a series of tests. A test did not detect the presence of influenza A or influenza B antigen. Exhibit 10 at 39 (Dec. 30, 2013). A chest x-ray showed evidence of infiltrates, and Mr. Rocha was admitted with pneumonia. Id. at 214. He was given heparin, starting on December 30, 2013. Id. at 236. Heparin has "potent anticoagulant properties." Dorland's at 834.

In the early days of his hospitalization at Overlook, Mr. Rocha saw a variety of specialists. For example, Mr. Rocha saw the hematologist/oncologist who had treated him previously (Dr. Khot). He also saw a specialist in infectious diseases, a pulmonologist, and a gastroenterologist. For more details about these consultations, see Pet'r's Posthearing Br. at 6-8 and Resp't's Posthearing Br. at 8-10. For purposes of resolving Mr. Rocha's claim, the more important consultations, and the ones that received much more attention from the experts, are the consultations with a nephrologist and a rheumatologist.

The nephrologist who saw Mr. Rocha at Overlook on December 30, 2013 was Dr. Agresti. Exhibit 10 at 214-16. Dr. Agresti noted that Mr. Rocha "is well known to me." Id. at 214. Dr. Agresti discussed Mr. Rocha's recent problems that "started several months ago when he developed acute herpes zoster involving his ear." Id. Dr. Agresti briefly summarized treatment at Trinitas and St. Barnabas.

As part of Dr. Agresti's review of systems, Dr. Agresti indicated that Mr. Rocha's "appetite has been quite poor. He has had persistent nausea and vomiting. He has not been eating well." Exhibit 10 at 215. One of the laboratory studies on admission showed that his serum creatinine was 2.4. Id. at 214. Dr. Agresti's impression was: "1. Acute kidney injury, most likely secondary to dehydration. 2. Chronic kidney disease secondary to age and nephrosclerosis. [and] 3. Pulmonary infiltrates, possible pneumonia." Id. at 215. He recommended continuing IV hydration, adjusting all medications for renal failure, and following up with hematology/oncology. Id.

Overlook the least. Consequently, this decision often cites testimony from Dr. Rostad, Dr. Matloubian, and Dr. Ducatman.

The hematologist/oncologist, Dr. Khot, examined Mr. Rocha the next day and diagnosed him as suffering from anemia, severe gastritis, elevated alkaline phosphates, leg edema, possible pneumonia, acute renal insufficiency on chronic renal insufficient, [and] chronic creatinine "around 1.4 to 1.8." Exhibit 10 at 222.

Several other doctors saw Mr. Rocha between December 30-31, 2013. Dr. Nicholas Maglaras's notes show he thought Mr. Rocha's fever was either caused by infection, rheumatology, or a malignancy. Exhibit 10 at 213. Dr. Kunal Grover's notes suggested that Mr. Rocha's ongoing nausea and vomiting might have been due to "medication reaction given the acuity, as his LFTs were normal approximately 1 month ago." Id. at 220. Dr. Grover discontinued Mr. Rocha's use of "Reglan in favor of Zofran." Id. Dr. Khot recommended Mr. Rocha continue treatment for possible pneumonia and that he undergo QuantiFERON testing." Id. at 222. Dr. Juan Baez assessed Mr. Rocha for his fever and sepsis. Id. at 224. Dr. Baez's assessment was that:

> A multisystem etiology suggests a probabl[e] connective tissue disorder origin, questionable malignancy although so far workup is negative, questionable reactivation TB viral, question[able] HIV. . . . He apparently saw me about 5-6 years ago with a questionable positive HIV serology.

Exhibit 10 at 225.

Mr. Rocha's first of a series of appointments with rheumatologist Dr. Tanisha Mathur at Overlook occurred on January 1, 2014. Exhibit 10 at 227-29. Dr. Mathur obtained two pieces of information about Mr. Rocha's remote medical history, which did not feature prominently in histories gathered by other doctors. First, Mr. Rocha stated that in 2007, he "developed a footdrop on his right leg. [Mr. Rocha and his wife] report that at that time patient used to have a lot of leg cramps, and then, suddenly, after the severe leg cramp developed footdrop." Id. at 227. This report contributes to Dr. Ducatman's opinion that Mr. Rocha had cryoglobulinemia prior to his October 18, 2013 flu vaccination. Tr. 464, 494-95. Second, Mr. Rocha informed Dr. Mathur that he developed red lesions on his legs after going to South America in 2001. Exhibit 10 at 227. Although the lesions healed, he still had hypopigmentation on both lower extremities. Mr. Rocha also mentioned that "his fingers become blue and white on exposure to cold." Id.; accord Tr. 178.

Dr. Mathur examined Mr. Rocha. She observed, among other things, a "Hyperpigmented rash on lower extremities." Exhibit 10 at 228; accord Tr. 102, 176-77. Dr. Mathur indicated that she had reviewed his laboratory studies,

including a urine analysis, showing "more than 50 RBCs." Id. at 228. The sedimentation rate was 85. Id.; see also Exhibit 10 at 513; Tr. 103, 127-28.

Dr. Mathur's assessment and plan, which is found on page 229 of Exhibit 10, is relatively lengthy. She stated, "So far, based on labs and based on his symptoms, it seems that an autoimmune condition such as vasculitis is a possibility." Dr. Mathur mentioned other possible conditions affecting Mr. Rocha including: "medium vessel vasculitis like polyarteritis nodosa," and "small-vessel vasculitis such as granulomatosis with polyangiitis." Dr. Mathur endorsed studies that other doctors had ordered. To the list of laboratory tests, Dr. Mathur added a check on "serum cryoglobulin."

Dr. Mathur explained steps in the diagnostic process should involve additional testing. She wrote:

> Ideally to diagnosis vasculitis, would like to have a tissue biopsy from involved organs which could include a kidney biopsy given his renal insufficiency and evidence of glomerulonephritis, or if possible, a lung biopsy since it would be ideal to have tissue diagnosis if he were to receive strong immunosuppression for vasculitis. Also we can consider CT or MR angiogram of the abdominal vessels to evaluate vasculature and look for changes from vasculitis such as stenosis or narrowing in the abdominal vessels.

Exhibit 10 at 229.

A test regarding Mr. Rocha's serum cryoglobulin was performed by the Mayo Medical Laboratories in Rochester, Minnesota. Exhibit 10 at 599-600; see also Tr. 129. The parties refer to this test as the "January 1, 2014 test." The result was negative. Exhibit 10 at 599.

The two pathologists retained in this litigation differed over the accuracy of the January 1, 2014 test for cryoglobulins. Dr. Rostad pointed to this test as evidence that Mr. Rocha did not have cryoglobulins. Tr. 129, 217-18. In contrast, in light of a subsequent positive test for cryoglobulin, Dr. Ducatman characterized the January 1, 2014 result as a false negative. Dr. Ducatman explained that the test for cryoglobulins is "finicky" because the sample needs to be maintained at a certain (warm) temperature. Tr. 416. Dr. Ducatman suspected that the sample that

Overlook sent to the Mayo Clinic may not have stayed at the correct temperature. Tr. 416-18.

Another test that Dr. Mathur recommended was imaging Mr. Rocha's abdomen. Exhibit 10 at 229. This study was done on January 2, 2014, and found a small amount of ascites; no biliary dilation; and no common duct calculus. Exhibit 10 at 615-16.

It appears that starting around January 6, 2014, Mr. Rocha's condition appeared to improve. Exhibit 10 at 132. He was able to eat and to drink and to sit up in bed, but his legs remained swollen up to his knees. Id.

To explore the possibility of vasculitis, Dr. Mathur had recommended a biopsy of an affected organ, such as Mr. Rocha's kidneys. Exhibit 10 at 229; see also Tr. 111 (Dr. Rostad's testimony that a reason for the kidney biopsy is to rule out vasculitis). A renal biopsy was taken from Mr. Rocha on January 6, 2014 at 10:44 the morning. Exhibit 10 at 610. The results were interpreted by a physician associated with Columbia University Hospital, Glen Markowitz. Exhibit 10 at 455-59; see also Tr. 105.

Later on January 6, 2014, Dr. Mathur, the rheumatologist, followed up with Mr. Rocha. Exhibit 10 at 111-12; Tr. 104. This visit occurred at 12:45 P.M. Exhibit 10 at 111. The handwritten note begins: "[Patient] had just returned from kidney biopsy." Id. Dr. Mathur expressly wrote that she was "await[ing] renal pathology." Id. at 112. Mr. Rocha reported that yesterday he had "less abd pain, n, v ["n,v" probably being abbreviations for "nausea and vomiting"]." Dr. Mathur indicated that it was "possible" Mr. Rocha had "mononeuritis multiplex [because he] had foot drop in the last year." Id. Dr. Mathur noted that she had started Mr. Rocha on IV steroids on January 4 (two days earlier) "due to concerns for vasculitis, however [she was] still waiting for confirmation of diagnosis." For the diagnosis of vasculitis, Dr. Mathur remained interested in obtaining an MR angiogram to look for "changes suggestive of vasculitis." Id. "Currently, [Mr. Rocha is] unable to get [an] MR angiogram due to GFR."[11] Id. Dr. Mathur indicated "cyros pending." Id.

[11] "GFR" is an abbreviation for "glomerular filtration rate." Dorland's at 765. The glomerular filtration rate refers to kidneys clearing substances. Dorland's at 1570; see also Rupert v. Sec'y of Health & Hum. Servs., No. 15-841V, 2021 WL 1832909, at *27 n.102 (Fed. Cl. Spec. Mstr. May 1, 2021). Apparently, Dr. Mathur was concerned that Mr. Rocha's kidneys were not functioning well enough for him to have an MR angiogram.

Dr. Mathur saw Mr. Rocha again on January 8, 2014. Exhibit 10 at 119-20. Mr. Rocha was "able to eat [and] drink." He had "no nausea." Id. at 119. However, he "still" had "significant pedal edema." Id. at 120. Dr. Mathur was still waiting for the results regarding renal pathology. Without this information, Dr. Mathur was proposing that it was "possible" for Mr. Rocha to have "PAN vs. ANCA [negative] small vessel vasculitis." Id. Dr. Mathur repeated her interest in obtaining an MR angiogram to evaluate the vasculature in Mr. Rocha's abdomen. Id.; see also Tr. 116.

The renal biopsy showed Mr. Rocha was negative for antinuclear antibodies ("ANA"), antineutrophil cytoplasmic antibodies ("ANCA"), hepatitis c antibodies ("HCVAb"), and cryoglobulins. Exhibit 10 at 456. Dr. Markowitz indicated that the results "are diagnostic of proliferative glomerulonephritis but are insufficient to determine the degree of activity of chronicity." Id. He added that "Etiologic considerations for a proliferative glomerulonephritis in which the deposits stain most intensely for IgM include[] infections (i.e. HCV), cryoglobulinemic, autoimmune/collagen vascular (i.e. rheumatoid arthritis), dysprotein-associated, and idiopathic forms of disease." Id. Dr. Markowitz recommended repeating cryoglobulin studies. Id.; see also Tr. 105-11.

Dr. Rostad acknowledged that Dr. Markowitz's interpretation of the renal biopsy does not suggest that Mr. Rocha suffered from vasculitis. Tr. 112. Dr. Rostad, himself, reviewed the slides and Dr. Rostad, too, saw no evidence of vasculitis. Tr. 112-15. Dr. Rostad discussed why a biopsy on tissues that were apparently randomly collected might miss tissues containing evidence of vasculitis. Dr. Rostad also suggested that Mr. Rocha's January 6 renal biopsies indicated "an immune-complex mediated proliferative glomerulonephritis." Exhibit 55 at 9; Exhibit 10 at 456.

It appears that a doctor requested that the tests for cryoglobulins be repeated on January 9, 2014, but they were not received for several days. See Exhibit 10 at 576 (test results); see also id. at 141 (Dr. Mathur's Jan. 13, 2014, note indicating that tests for cryoglobulins were pending), 184 (Dr. Mathur's Jan. 20, 2014 note indicating that "serum cryoglobulins repeat on 1/9/2014 – Positive.").

Doctors noted the results of the January 6, 2014 renal biopsy. For example, the assessment from a hematologist / oncologist was "proliferative GN

[glomerulonephritis] [with] cyro vasculitis." Exhibit 10 at 137. This January 12, 2014 handwritten note also indicated that Mr. Rocha was "doing okay." Id. Other doctors, whose names and specialties are not readily apparent on these handwritten documents, also mentioned similar problems. See Exhibit 10 at 133 ("vasculitis / glomerulonephritis"), 135 (a hospitalist's Jan. 11, 2014 note stating "glomerulonephritis / vasculitis – on steroids").

By January 10, 2014, Mr. Rocha was being treated for vasculitis. Exhibit 10 at 133; see also id. at 137 (noting 01/12/14 treatment notes for "cryo vasculitis"). Mr. Rocha was ultimately placed on IV steroids and a CBC was ordered to test for anemia. Id. at 137-38.

An important record is a January 13, 2014 record by Dr. Mathur. Exhibit 10 at 140-41; see also Tr. 117-18. Dr. Mathur recorded that Mr. Rocha tolerated the infusion of Rituximab well. He was negative for abdominal pain, nausea, and vomiting. His pedal edema was improving. Exhibit 10 at 140. Dr. Mathur's assessment began with "proliferative GN [glomerulonephritis], likely cryoglobulinemic vasculitis." Id. at 141. She noted that repeat tests for "serum cyro" was pending. Dr. Mathur also wrote: "clinically looking better, renal function improving." Id.

With the benefit of hindsight, it appears that January 13, 2014 marked the date by which Mr. Rocha's health had most improved. As Ms. Rocha maintained, "Initially, there was improvement in Mr. Rocha's renal function and GI symptoms, but his condition deteriorated." Pet'r's Prehear'g Br. at 12, citing Exhibit 10 at 161.

Manifestations of a deterioration were observed on January 14, 2014, when a hospitalist memorialized that Mr. Rocha felt weak and had a fever and chills. Exhibit 10 at 143. On January 16, 2014, Mr. Rocha's temperature was 100.6 degrees, while the day before it was 98.4 degrees. Id. at 150. The author of the medical record, who is a specialist in metabolic medicine, wondered whether the fever was due to "sepsis vs. vasculitis." Id. A test from January 16, 2014 showed that Mr. Rocha was infected with influenza A. Exhibit 10 at 561.[12]

After the infection with influenza A was discovered, doctors noted this in their treatment records. For example, Dr. Mathur saw Mr. Rocha at 4 PM on January 16, 2014 and she memorialized that Mr. Rocha's wife was "very

[12] The flu vaccine is not 100 percent effective in preventing infection with a flu virus. Tr. 558 (Dr. Matloubian).

concerned about [Mr. Rocha's] fevers, cough and new diagnosis of flu." Exhibit 10 at 55. Dr. Mathur was concerned about the influenza A infection because Mr. Rocha was immunosuppressed. She prescribed Tamiflu. Id. An infectious disease doctor described the influenza infection as "likely just acquired." Exhibit 10 at 161 (Jan. 17, 2014).

At around 9:30 PM on January 16, 2014, a nurse called for a rapid response team to assist Mr. Rocha because of hypoxia. Exhibit 10 at 56. At this time, Mr. Rocha's "Chest Xray looks worse than yesterday." Id. Mr. Rocha was transferred to the intensive care unit.

The initial report from an ICU doctor began "Events of 1/16/14 noted. [Patient with] development of [Right] mid-lower lung filed consolidation much [changed] since 1/14/14." Exhibit 10 at 159. The doctor's impression was "Multisystem organ dysfunction likely vasculitis, [with] GN." Id. at 160. The doctor wrote about a long discussion with Mr. Rocha's wife because Mr. Rocha's prognosis was "guarded – poor." Id.

A critical care resident stated that Mr. Rocha was suffering from hypoxic failure "likely [secondary to] [respiratory] infection." Exhibit 10 at 164. This doctor also noted that Mr. Rocha had been diagnosed with vasculitis.

Over the next four days, a variety of doctors continued to treat Mr. Rocha for his health problems, including his infection with influenza A. See Tr. 431 (testimony of Dr. Ducatman that Mr. Rocha "suddenly developed flu, and everything that goes on after that is really relevant to his influenza infection, and its complications and sequelae."). Dr. Rostad touched upon medical records created during this time. Tr. 120-26. With a handful of exceptions, the details of this material do not affect Ms. Rocha's claim that the flu vaccine injured Mr. Rocha. See Pet'r's Prehear'g Br. at 12-13; Resp't's Posthear'g Br. at 12.

After Mr. Rocha had been transferred to the ICU due to respiratory problems, doctors received the results of the second test for cryoglobulins, which had been ordered on January 9, 2014. On January 20, 2014, Dr. Mathur reported that the test was positive. Exhibit 10 at 184; see also id. at 576. Unlike the earlier test, which was sent to the Mayo Clinic, the positive January 9, 2014 test was done at the Overlook Medical Center. Id. Again, the pathologists disputed the accuracy of the result.

Dr. Ducatman credited the positive January 9, 2014 test as accurate. She pointed out that the testing was done immediately and locally. Tr. 419. As such, there is less chance the sample was handled incorrectly.

Contrastingly, Dr. Rostad viewed the January 9, 2014 test as returning a false positive. His explanation, which he presented for the first time during the hearing, was that Mr. Rocha was taking heparin on January 8, 2014. Tr. 129, citing Exhibit 10 at 801. Dr. Rostad further asserted that heparin can complicate the process of testing for cryoglobulins. Tr. 130, 182.

Dr. Rostad's explanation lacks credibility. Mr. Rocha actually started heparin on December 30, 2013. Exhibit 10 at 236. This chronology appears to disrupt Dr. Rostad's thesis. See Tr. 218. Moreover, according to Dr. Ducatman, ingestion of heparin does not interfere with tests for cryoglobulin. Tr. 417.

Dr. Mathur's assessment of January 20, 2014 included "cryoglobulinemic vasculitis – [positive] serum cryoglobulins, [positive] kidney biopsy GN." Exhibit 10 at 184. She also listed "worsening [respiratory] failure – Infection ([positive] influenza) vs. vasculitis." Id. Dr. Mathur recommended plasma exchange because this procedure could help Mr. Rocha if his "worsening is related to circulating antibodies." Id. at 185.

A hematologist / oncologist followed up with Dr. Mathur's recommendation for plasma exchange on January 21, 2014 at 8:00 A.M. Exhibit 10 at 187; see also Tr. 518-19. This doctor wrote "unlikely [illegible, potentially "sudden"] vasculitis, favor more influenza but if rheum (Dr. Mathur) thinks it's vasculitis and wants [I] would arrange … plasma exchange." Exhibit 10 at 187-88.

By noon on January 21, 2014, Mr. Rocha was experiencing acute hypoxic respiratory failure. Exhibit 10 at 197. The family wanted to transfer his care to Newark Beth Israel Hospital, where he could receive extracorporeal membrane oxygenation ("ECMO") support. Id.

The report discharging Mr. Rocha from Overlook listed 13 diagnoses. The first was "Acute respiratory distress syndrome ["ARDS"] with multi-organ failure, likely secondary to proliferative glomerulonephritis, likely cryoglobulinemia vasculitis." Exhibit 10 at 17. A pulmonologist at Beth Israel accepted Mr. Rocha's transfer.

H. Hospital Stay -- Newark Beth Israel Medical Center (January 21, 2014 – March 12, 2014) (Mr. Rocha's Passing).

Mr. Rocha was hospitalized at Newark Beth Israel Medical Center for approximately six weeks, during which his health declined. He died on March 12, 2014.

Over ninety exhibits were filed pertaining to Mr. Rocha's various stays at Newark Beth Israel. See Exhibits 11.1-11.96. While the medical records created during Mr. Rocha's final hospitalization are voluminous, relatively few contribute to determining whether the flu vaccination harmed Mr. Rocha. See Pet'r's Prehearing Br. at 13-17; Resp't's Posthearing Br. at 12-15. The experts testified about the medical records they considered significant. Tr. 135-45 (Dr. Rostad), 436-48 (Dr. Ducatman), 517-26 (Dr. Matloubian).[13] The important events were presented in a two-paragraph discharge summary:

> History of Present Illness: This is a 70-year-old male with past medical history of diabetes, hypertension, chronic kidney disease, hepatitis B infection, history of tuberculosis during childhood, was recently diagnosed with cryoglobulinemia vasculitis. Patient was being treated with steroids and _____. [sic] His kidney biopsy showed proliferative glomerulonephritis. The patient developed respiratory failure requiring mechanical ventilation. He was transferred from Overlook Hospital for possible extracorporeal membrane oxygenation placement in view of progressive respiratory failure.
>
> Hospital Course: Patient was brought to our institution, underwent extracorporeal membrane oxygenation placement. Overall, his course has been protracted. This was followed by pneumo sepsis as well as pneumothorax episodes. He was eventually weaned off the extracorporeal membrane oxygenation and placed on a ventilator. His condition overall was poor. He eventually succumbed to recurrent sepsis and went into septic shock and eventually expired.

Exhibit 11 at 6.

Mr. Rocha's death certificate documented his cause of death as cardiopulmonary arrest from multi-organ failure, septic shock, and gram-negative bacterium, in addition to other "significant conditions" such as vasculitis, ARDS, and cryoglobulinemia. Exhibit 2 at 1. Respondent's experts appear to disagree

[13] Dr. Steinman did not testify about Mr. Rocha's health while at Beth Israel.

with Mr. Rocha's cause of death as presented on the death certificate. Dr. Matloubian opined that although vasculitis was listed as a contributing factor in Mr. Rocha's death, he "did not think it played a role." Exhibit BB at 2.

Dr. Ducatman commented that, in her opinion as a pathologist, the death certificate lacks precision. She stated Mr. Rocha's likely cause of death "[w]as gram negative septicemia (which implies both shock and bacteremia as well as multiorgan failure) due to ARDS due to Influenza infection (Influenza A 2009 H1N1) . . . . [and] list[ed] as other significant findings: erosive gastritis, cryoglobulinemia, and chronic renal failure. The last two findings were chronic and stable prior to other diseases and interventions." Exhibit CC (Ducatman Report) at 10. Moreover, Dr Ducatman pointed out that "[t]hree of the four of Mr. Rocha's admissions were not for cryoglobulinemia or cryoglobulinemic vasculitis, they were for gastrointestinal symptoms and dehydration." Id.

Petitioner's experts opined that Mr. Rocha's death was caused by vasculitis, which was in turn caused by the flu vaccine. Dr. Rostad stated: "I believe vaccine-induced vasculitis was indeed the cause of terminal medical course." Exhibit 55 at 1. He proposed a theory that the vaccine triggered an "immune complex reaction leading to vasculitis, renal involvement with immune complex proliferative glomerulonephritis (ICPGN) and ultimately, other organ involvement and eventual death." Id. at 11. He noted that "[m]ultiple scientific reports have raised the association between influenza vaccine and vasculitis," and stated that "vasculitis was the primary cause of death." Id. at 19.

Dr. Steinman noted that the death certificate listed vasculitis as one of the "other significant conditions contributing to death." Exhibit 46 at 7. He theorized that the flu vaccine triggered Ramsay Hunt in Mr. Rocha, which induced the vasculitis that contributed to his death. Id. at 27.

III. Procedural History

A. Development before Expert Reports

Represented by Attorney Carol Gallagher, Omary Rocha, on behalf of Mr. Rocha's estate, claimed that the flu vaccine Mr. Rocha received on October 18, 2013 caused him to suffer vasculitis that caused his death. Pet., filed Feb. 18, 2016. Petitioner filed various medical records and affidavits over the next six months. Exhibits 1-20.

The Secretary argued Ms. Rocha should not be entitled to compensation because she did not establish causation between the flu vaccine and his vasculitis. Resp't's Rep., filed Oct. 31, 2016, at 14.

B. Expert Reports

Following the Secretary's report, the undersigned provided guidance about the expected content of forthcoming expert reports. Order, issued Nov. 14, 2016; see also Order, issued Nov. 30, 2016 (finalizing draft expert report instructions). As discussed below, the parties eventually presented reports from a total of four people. This group consists, in some respects, two pairs.

1. Neurologist and Rheumatologist

Ms. Rocha's first expert report was prepared by Lawrence Steinman, a neurologist, and was filed February 23, 2021. Ex. 21. Following a status conference, petitioner filed a supplemental expert report from Dr Steinman. Exhibit 46; see Order, issued Mar. 7, 2017 (discussing additional topics for Dr. Steinmann to discuss in his report).

Dr. Steinman began his recitation of relevant medical events in Mr. Rocha's life with the October 18, 2013 flu vaccination. Exhibit 21 at 4. In other words, Dr. Steinman did not extensively discuss Mr. Rocha's pre-vaccination medical history. Dr. Steinman proposed that in November 2013 (about one month after the flu vaccination), Mr. Rocha suffered from Ramsay Hunt syndrome, also known as herpes zoster oticus. Exhibit 21 at 4. This Ramsay Hunt syndrome was the result of an immune response to the flu vaccine. Id. at 6. Dr. Steinman further indicated that the activation of the previously latent herpes zoster virus "triggers vasculitis which contributes to Nestor Rocha's untimely death." Id. at 26. Dr. Steinman recognized that an infection with the hepatitis B virus could have contributed to the Mr. Rocha's vasculitis. Id. In his second report, Dr. Steinman stated that the vasculitis "caused renal and cerebral damage, leading to imbalances in fluid and electrolytes ultimately leading to [Mr. Rocha's] demise." Exhibit 46 at 2.

The Secretary then filed an expert report by Mehrdad Matloubian, a rheumatologist, on October 23, 2017. Exhibit A. Dr. Matloubian supplemented his report on January 10, 2018. Exhibit BB.

In contrast to Dr. Steinman, Dr. Matloubian emphasized Mr. Rocha's health before the vaccination. Dr. Matloubian stated that "Mr. Rocha's medical history contained multiple clues that are indicative of pre-existing but undiagnosed

cryoglobulinemic syndrome affecting multiple organs including his skin, peripheral nervous system, and kidneys." Exhibit A at 9.

Although Dr. Matloubian (like Dr. Steinman) summarized events in Mr. Rocha's life after the vaccination, Dr. Matloubian identified a different cause of death. In the view of Dr. Matloubian, the "major contributor to Mr. Rocha's death was development of ARDS [acute respiratory distress syndrome] as the result of influenza A H1N1 2009 infection." Exhibit A at 13. Thus, Dr. Matloubian challenged the assertion that any form of vasculitis contributed to Mr. Rocha's death. Id. at 3.

In addition to disputing what happened to Mr. Rocha, Dr. Matloubian did not agree with the various causal mechanisms Dr. Steinman had offered to explain how the flu vaccine can activate a herpes zoster virus. See Exhibit A at 14-20.

Petitioner filed a responsive expert report by Dr. Steinman on April 10, 2018. Exhibit 49. This report is approximately four pages. Dr. Steinman primarily addressed cryoglobulinemia, the reactivation of a latent herpes zoster virus, and the temporal interval. He also maintained his opinion that Mr. Rocha suffered from vasculitis.

The reports from the experts were discussed in a status conference held on May 8, 2018. See Order, issued May 9, 2018. During the status conference, the parties agreed that "whether Mr. Rocha had vasculitis appears to be a central question in determining if the vaccination can be linked to Mr. Rocha's death." Id. at 1. The parties were, therefore, instructed to seek additional information from doctors who treated Mr. Rocha. In addition, Ms. Rocha was directed to obtain some clarifying information from Dr. Steinman, which Dr. Steinman provided in a report dated May 30, 2018. Exhibit 51.

The parties eventually determined that the process of soliciting information from doctors who treated Mr. Rocha was not likely to produce helpful evidence. See Order, issued Oct. 26, 2018. Ms. Rocha was interested in possibly obtaining a report from a pathologist, who might support the diagnosis of vasculitis. Id.

2. Pathologists

Ms. Rocha determined that she wanted to obtain a report from a pathologist and filed a report from Steven Rostad, who is board-certified in anatomic pathology and neuropathology. Exhibit 55 (dated May 29, 2019). Dr. Rostad summarized Mr. Rocha's medical records. Id. at 4-7. Dr. Rostad also personally reviewed biopsy slides. Id. at 7-9. Although the biopsy slides did not show

evidence of vasculitis, Dr. Rostad "still suspected" this diagnosis based upon the "pathology findings, in concert with the clinical, imaging and laboratory features." Id. at 9.

Although it may have seemed that Ms. Rocha planned to retain a pathologist to supplement Dr. Steinman's opinion that Mr. Rocha suffered from vasculitis only, Dr. Rostad went further. He also opined that a flu vaccination can cause vasculitis. Dr. Rostad's "main theory" was "based on the concept of molecular mimicry." Exhibit 55 at 12. In explaining how vasculitis caused Mr. Rocha's death, Dr. Rostad disagreed with Dr. Matloubian's suggestions that Mr. Rocha suffered from cryoglobulinemic vasculitis, and that Mr. Rocha died from ARDS. Id. at 18.

The introduction of a second expert led the Secretary to retain a second expert. See Order, issued July 5, 2019. The Secretary presented the report from Barbara Ducatman on October 10, 2019. Exhibit CC.[14] Dr. Ducatman is also a pathologist, board-certified in anatomic pathology and clinical pathology.

Like the other experts, Dr. Ducatman reviewed Mr. Rocha's extensive medical records. She opined that before the vaccination, Mr. Rocha had cryoglobulinemia associated with a chronic hepatitis B infection. Exhibit CC at 8. With respect to vasculitis, Dr. Ducatman opined that Mr. Rocha may have suffered from either cryoglobulinemia or cryoglobulinemic vasculitis. Id. at 9. But, either condition was long-standing, probably related to his hepatitis B vaccination, and not caused by the flu vaccination. Id. Dr. Ducatman indicated that a more precise way to describe the cause of Mr. Rocha's death was a death due to "gram negative septicemia (which implies both shock and bacteremia as well as multiorgan failure) due to ARDS to influenza infection." Id. at 10.

Following the submission of Dr. Ducatman's report, Ms. Rocha stated that she did not intend to obtain another expert report. Pet'r's Status Rep., filed Dec. 17, 2019. Thus, because the parties had completed the stage during which the experts disclose their opinions and the bases for their opinions, the parties were directed to file briefs in advance of a potential adjudication. Order, issued Dec. 20, 2019.

[14] The Secretary originally designated Dr. Ducatman's first report as Exhibit K. However, the Secretary had already filed material as Exhibit K. Thus, Dr. Ducatman was refiled as Exhibit CC. Order, issued Feb. 3, 2021.

The December 20, 2019 order allowed the parties a final opportunity to present reports from experts to ensure that all opinions had been disclosed. Thus, Ms. Rocha submitted a comprehensive supplemental report from Dr. Rostad on March 12, 2020. Exhibit 84. Dr. Rostad continued to disagree about the potential diagnoses, maintaining vasculitis and questioning cryoglobulinemia. Dr. Rostad indicated that the conclusion that Mr. Rocha died from ARDS to be "speculative without more definitive findings." Id. at 14. Dr. Rostad stated that the "gram-negative septicemia was secondary to systemic vasculitis, most likely due to interruption in the integrity of the gastrointestinal system due to local ischemia of the mucosa." Id.

After representing Ms. Rocha for approximately four years, Ms. Gallagher stopped representing her.[15] Attorney Richard Gage substituted as counsel of record on June 16, 2020.

Dr. Ducatman responded to the opinions from Dr. Rostad in supplemental report, which the Secretary filed on July 6, 2020.[16] Dr. Ducatman's report was relatively short (essentially two pages), and she maintained her previously expressed opinions. Exhibit PP.

In a July 8, 2020 status conference, Ms. Rocha's counsel, Mr. Gage, agreed that the experts were finished disclosing their opinions. Order, issued July 8, 2020. Thus, the order to present arguments through written briefs was reinstituted.

C. Pre-Hearing Briefs

Acting through Mr. Gage, Ms. Rocha submitted her first Pre-Hearing Brief on October 22, 2020. The brief began with a recitation of Mr. Rocha's medical history, divided into periods roughly corresponding to hospitalizations. With respect to Mr. Rocha's health before the vaccination, Ms. Rocha cited her own affidavit and the affidavit of the Rochas's son-in-law, Carmen Bucco. Pet'r's Prehear'g Br., filed Oct. 22, 2020, at 1-2, citing Exhibits 53-54. Ms. Rocha did not address the contention from Dr. Matloubian and Dr. Ducatman that Mr. Rocha suffered chronic problems from before the vaccination. See id.

[15] Ms. Rocha was awarded some compensation for costs Ms. Gallagher incurred. See 2019 WL 2406954 (April 30, 2019).

[16] Originally, this report was labeled as Exhibit X. However, due to a repetition in the letters, the report was later refiled as Exhibit PP. See Order, issued Feb. 3, 2021.

As for the elements of a petitioner's case, Ms. Rocha started with the diagnosis. She maintained that "It is medically probable that Mr. Rocha had a systemic vasculitis. Systemic vasculitis is the only diagnosis that offers a unifying diagnosis for all of Mr. Rocha's symptoms and untimely death." Pet'r's Prehear'g Br.at 17. Throughout this section, Ms. Rocha cited the reports from Dr. Rostad (Exhibits 55 and 84) as well as the articles he cited. Ms. Rocha did not cite reports from Dr. Steinman.

For the first prong of Althen, which requires a theory to explain how a vaccine harmed a person, Ms. Rocha advanced Dr. Rostad's theory of a vaccine triggering immune complexes. Pet'r's Prehear'g Br., filed Oct. 22, 2020, at 25. She also proposed the theory of molecular mimicry. Id. at 29. In the context of molecular mimicry, Ms. Rocha also relied upon Dr. Rostad, not Dr. Steinman. The same is true for the second and third prongs of Althen: Ms. Rocha cited material from Dr. Rostad, not Dr. Steinman. Id. at 32-35.

Ms. Rocha argued that the vaccine-induced vasculitis caused Mr. Rocha's death. She proposed two methods---either a direct method in which the vasculitis led to multi-system organ failure or an indirect method in which the immunosuppressive treatments for vasculitis increased Mr. Rocha's vulnerability to an infection. Pet'r's Prehear'g Br. at 35.

Ms. Rocha advocated for a hearing to receive testimony orally. For her witnesses, Ms. Rocha listed five people. Three people were percipient witnesses, knowledgeable about Mr. Rocha's health. The remaining two witnesses were Dr. Rostad and Dr. Steinman. Pet'r's Prehear'g Br. at 36.

Following review of Ms. Rocha's brief, the undersigned noted the omission of any reliance on Dr. Steinman's opinions. Order, issued Oct. 26, 2020. After a status conference, Ms. Rocha requested an opportunity to expand her brief. Order, issued Nov. 4, 2020.

In a supplemental brief, filed on November 20, 2020, Ms. Rocha cited more articles in her discussion of a theory. Ms. Rocha continued to focus upon the opinions from Dr. Rostad, not Dr. Steinman. Pet'r's Supp'l Br. at 4 n.1. As required by the December 20, 2019 order, Ms. Rocha listed the articles on which she was primarily relying.

Another status conference was held to discuss how Ms. Rocha was proceeding. When asked whether Ms. Rocha was going forward with Dr. Steinman, Ms. Rocha's attorney, Mr. Gage, stated that he was not withdrawing Dr.

Steinman's reports. Dr. Steinman, according to Mr. Gage's representations in the status conference, remained part of the petitioner's case-in-chief. Based upon this explanation, the Secretary's attorney, Kimberly Davey, stated that she could proceed. Order, issued Dec. 11, 2020.

The Secretary argued that Ms. Rocha was not entitled to compensation for Mr. Rocha's death via a Pre-Hearing Brief, filed Feb. 4, 2021. The Secretary organized his summary of events in Mr. Rocha's medical history around various hospitalizations. This summary started with the medical visit during which Mr. Rocha received his flu vaccination.

The Secretary addressed the elements of a petitioner's case. With respect to diagnosis, the Secretary raised three points: (1) Mr. Rocha did not suffer from systemic vasculitis, (2) Mr. Rocha likely suffered from cryoglobulinemia, and (3) regardless of which condition affected Mr. Rocha, Mr. Rocha suffered from it before the vaccination. Resp't's Prehear'g Br. at 17-21.

For the theory by which a vaccine might have harmed Mr. Rocha, the Secretary challenged Dr. Rostad's opinion and Dr. Steinman's opinion. Resp't's Prehear'g Br. at 22-31. The Secretary also contended that Ms. Rocha's evidence for Althen prong 2 and Althen prong 3 was insufficient. For timing (Althen prong 3), the Secretary maintained his position that Mr. Rocha's "condition was chronic, long-standing, and certainly pre-dated [his] vaccination." Id. at 34. The Secretary also argued that if Mr. Rocha's condition developed after the vaccination, then the latency exceeded the time for which an inference of causation is appropriate. Id.

The Secretary devoted two sections of his brief to the topic of sequella. First, for Dr. Steinman's theory involving Ramsay Hunt syndrome, the Secretary argued that Ms. Rocha had not established that varicella zoster virus leads to vasculitis. Resp't's Prehear'g Br. at 36-37. Second, the Secretary contended that an infection, not vasculitis, caused Mr. Rocha's death. Id. at 37-39. The Secretary did not identify articles supporting his position in this brief.

Ms. Rocha supported her claim in a four-page reply, filed on March 22, 2021. A primary theme of the reply was that the experts interpreted Mr. Rocha's medical records differently and a hearing should be held. One example concerned the testing for cryoglobulins. Pet'r's Prehear'g Reply at 2. Another example concerned the cause of Mr. Rocha's death. Id. at 3. Ms. Rocha did not reply to the Secretary's attacks on the theory (Althen prong 1).

Because the Secretary did not identify the primary articles on which he was relying, the Secretary was given a second opportunity. Order, issued April 20, 2021. The Secretary did in a Supplemental Prehearing Brief, filed May 28, 2021. This submission completed the parties' written arguments before the hearing.

D. Hearing

Due to the complexities of Mr. Rocha's medical history, the case was scheduled for a hearing to receive oral testimony. Order, issued April 20, 2021 (proposing three days of hearing in December 2021). In a May 18, 2021 status conference, the parties determined that December 1-3, 2021 was a mutually convenient time. Order, issued May 19, 2021.

The hearing was held, as scheduled, on December 1-3, 2021 via WebEx videoconferencing. Petitioner called Ms. Sandra Rocha Bucco, who is the daughter of Mr. and Ms. Rocha. Petitioner also called her experts, Dr. Steinman and Dr. Rostad. Respondent's witnesses were his experts, Dr. Matloubian and Dr. Ducatman. The experts' testimony was more or less in accord with their reports. Following the hearing, the parties were directed to file posthearing briefs, which the parties submitted. Order, issued Dec. 6, 2021.

E. Posthearing Briefs

Ms. Rocha contended that she was entitled to compensation. Pet'r's Posthear'g Br., filed Mar. 9, 2022. More than one-half of her 21-page brief was devoted to discussing Mr. Rocha's medical history as described in the testimony from Ms. Sandra Rocha Bucco and Dr. Rostad. Id. at 1-14.

Ms. Rocha's analysis of the theory from Dr. Rostad was set forth in two paragraphs, which mentioned both immune complexes and molecular mimicry. Ms. Rocha presentation was:

> As for *Althen* Prong One, a biologically plausible theory connecting the vaccine to the injury, Dr. Rostad testified in accordance with his reports and the medical literature. He testified his theory involves a vaccine triggered immune complex reaction leading to vasculitis. Tr., p. 241. Immune complex deposition is an important aspect of the pathogenesis of vasculitis. Tr., p. 153-154. The literature points to molecular mimicry as being the most likely mechanism for the onset of immune mediated vasculitis. Tr., p. 156, 157, 158. Dr. Rostad agrees with

> the literature and believes molecular mimicry is the most likely mechanism of autoimmunity in this case. Tr., p. 245, 300-301. The influenza vaccine has been reported as the most common vaccine associated with vasculitis. Tr., p. 162.
>
> Dr. Rostad explained:
>
> > vaccinations, like infections stimulate the immune system. That antibody reaction can obviously form immune complexes, and in certain circumstances, it can be to other antigens of the body that they weren't necessarily intended to, the so-called molecular mimicry hypothesis or theory. Those circulating complexes can injure lots of different organ systems, and that is the believed pathophysiology of that vaccine -- post-vaccine induced injury.
>
> Tr., p. 163-164.

Pet'r's Posthear'g Br. at 14. In this context, Ms. Rocha did not specify any medical articles that supported Dr. Rostad's theory by which a flu vaccine can cause vasculitis.

In another portion of her brief, Ms. Rocha presented Dr. Steinman's theory, which she described as being "a little more nuanced." Pet'r's Posthear'g Br. at 18. Her summary was longer, running approximately three pages. Ms. Rocha again did not cite any medical articles supporting Dr. Steinman's opinion.

With respect to the onset of a vaccine-induced injury, Ms. Rocha advanced slightly different times. Dr. Rostad maintained that Mr. Rocha displayed kidney and abdominal problems 39 days after vaccination. Pet'r's Posthear'g Br. at 17, quoting Tr. 164-65. Dr. Steinman, in contrast, linked Mr. Rocha's vaccine-induced problem to Mr. Rocha's development of Ramsay Hunt syndrome. Pet'r's Posthear'g Br. at 20. Ms. Rocha discussed Dr. Steinman's recognition that Mr. Rocha suffered from cryoglobulinemic vasculitis "for decades." Id., quoting Tr. 345-46. But Dr. Steinman blamed the vaccine-induced vasculitis, "not the cryoglobulinemic which had preexisted" as leading to his death. Id. Thus, Ms. Rocha stated in a footnote that "there is no evidence that any pre-existing condition (real or potential) contributed to Mr. Rocha's post-vaccination decline and death.

However, should the Special Master find otherwise, Dr. Steinman has presented a strong case for significant aggravation." Id. at 20 n.3.

The Secretary answered and continued to assert that Ms. Rocha was not entitled to compensation. Resp't's Posthear'g Br., filed May 2, 2022. The Secretary discussed Mr. Rocha's medical history for approximately 15 pages. In terms of analysis, the Secretary argued that the people he retained, Dr. Matloubian and Dr. Ducatman, are better qualified to offer opinions than the people Ms. Rocha retained, Dr. Steinman and Dr. Rostad. Id. at 19-21.

The Secretary's assessment of diagnosis echoed the arguments that the Secretary had presented in his February 4, 2021 Pre-Hearing Brief. The Secretary continued to assert that Mr. Rocha did not have systemic vasculitis or varicella zoster vasculitis. Instead, the better evidence, in the Secretary's view, was that Mr. Rocha suffered from cryoglobulinemia. In any event, the cryoglobulinemia or the cryoglobulinemic vasculitis started long before the vaccination.

For the Althen analysis, the Secretary challenged the theories that Dr. Rostad and Dr. Steinman offered. In this context, the Secretary commented upon various articles about which the experts had testified. See Resp't's Posthear'g Br. at 29-35. The Secretary also disputed Althen prongs two and three. Id. at 35-39. Finally, the Secretary contended that Mr. Rocha's death was not a sequella to any injury induced by the vaccination. Id. at 40-41.

Ms. Rocha defended her position in a Reply, filed June 8, 2022, which is essentially five pages. Ms. Rocha advanced three points. The first point was an appropriate diagnosis is "immune complex mediated vasculitis." Pet'r's Posthear'g Reply at 1. Second, the Secretary mistakenly elevated her burden with respect to Althen prong one. In this context, Ms. Rocha did not respond to the evidentiary challenges put forward in the Secretary's brief. Third, Ms. Rocha asserts that the Secretary has admitted that cryoglobulinemia is a distraction. Id. at 5.

Accordingly, the case is now ripe for adjudication.

F. Summary of Opinions regarding Mr. Rocha's Health

As often seen in Vaccine Program cases, the parties and their experts dispute whether a vaccine can cause a particular injury. However, this case is unusual in that the experts differ on many aspects of the vaccinee's health. The prominent topics of dispute are presented in the following chart:

	Dr. Steinman, neurologist	Dr. Rostad, pathologist	Dr. Matloubian, rheumatologist	Dr. Ducatman, pathologist
Mr. Rocha's pre-vaccine health problems	Cryoglobulinemia	None	Cryoglobulinemia, cryoglobulinemic vasculitis	Cryoglobulinemia
Consequence of any pre-vaccine health problem:	None	Not applicable because Dr. Rostad did not accept any pre-vaccination health problem.	History of purpura, foot drop, and positive rheumatoid factor but no acute symptoms in time period leading up to death.	Longstanding, fairly stable, mild chronic renal failure (Tr. 442, 448)
Role of Ramsay Hunt syndrome	Critical	Not discussed	Flu vaccine did not cause Ramsay Hunt syndrome; syndrome had resolved by November 27, 2013.	Played no role in death; very unlikely that flu vaccine caused Ramsay Hunt syndrome.
Cause of Mr. Rocha's death	Vasculitis	Vasculitis	ARDS	ARDS

IV. Standards for Adjudication

A petitioner is required to establish her 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).

This evidentiary standard is used to evaluate various issues, starting with the qualifications of the retained doctors. An assessment of the doctors' expertise underlies some of the analysis in weighing competing opinions regarding diagnosis, which is discussed in section VI, below. After diagnosis, two alternative means of recovery are discussed: significant aggravation in section VII and causation-in-fact in section VIII.

V. Qualifications of Retained Doctors

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).

A. Doctors Whom Ms. Rocha Retained

Ms. Rocha retained two doctors. She first retained Dr. Steinman. Then, she retained Dr. Rostad.

1. Lawrence Steinman

Dr. Steinman has often opined that a vaccine harmed a person through written reports and oral testimony. As such, he is well-known to special masters and an extensive amount of testimony about his qualifications was neither presented nor required. See Tr. 306-07.

In brief, Dr. Steinman graduated from Harvard University Medical School in 1973. Since 1973, he has been affiliated with Stanford University Hospital, attaining the rank of professor in 1991. He became board-certified in neurology in 1984. Exhibit 22 (curriculum vitae) at 1. A significant portion of Dr. Steinman's research involves how the immune system affects the neurologic system, such as in multiple sclerosis. Tr. 330; see also Exhibit 22. For nearly a decade, Dr. Steinman chaired Stanford University's program in immunology. Exhibit 22 at 1.

In Dr. Steinman's view, "Every patient with inflammatory demyelinating disease has a vasculitis." Exhibit 46 at 1; accord Tr. 330. He, therefore, estimated that when he wrote his second report in 2017, he had treated more than 100 patients with vasculitis in the last five years. Exhibit 46 at 1. Also, within the last five years, Dr. Steinman had treated seven patients with Ramsay Hunt syndrome. Id. at 2. Dr. Steinman recognized that rheumatologists and nephrologists, as opposed to neurologists, study cryoglobulins. Tr. 330.

Dr. Steinman was accepted as an expert in neuroimmunology. Tr. 307.

2. Steven Rostad

The second doctor whom Ms. Rocha retained, and the one on whom she more heavily relied, was Steven Rostad. Dr. Rostad has not previously testified before the undersigned and has worked on approximately five cases in the Vaccine Program. Tr. 32, 267. Thus, his qualifications are presented more fulsomely.

Dr. Rostad earned his medical degree from the University of Washington in 1983. Exhibit 56 (curriculum vitae) at 1. He spent one year as an intern in pathology at the University of Denver. Thereafter, the remainder of his career was affiliated with the University of Washington. After a fellowship in neuropathology, a term as a resident in anatomic pathology, a term as chief resident in anatomic pathology---all at the University of Washington--Dr. Rostad worked at CellNetix Pathology PLLC from 1988 to 2017. Exhibit 56 at 1; Tr. 32-33. Dr. Rostad served as a clinical associate professor of pathology at the University of Washington from 1990 to 2015. Exhibit 56 at 1; Tr. 34, 266. He became board-certified in anatomic pathology and neuropathology in 1988. Exhibit 56 at 2; see also Tr. 37.

His position at CellNetix Pathology overlapped with his role as an attending pathologist / neuropathologist at Swedish Medical Center in Seattle, Washington. Exhibit 56 at 1; Tr. 33-34, 269. In this role, Dr. Rostad examined tissue samples from "virtually all organ sites with regards to the question of vasculitis," including

the "skin, kidney, [and] lung." Tr. 35; accord Tr. 37. Like other pathologists, Dr. Rostad did not see patients clinically. Tr. 37.

Dr. Rostad explained that pathologists attempt to suggest a specific type of vasculitis to the treating doctors. Tr. 219-221. However, because there are more than 30 types of vasculitis and because stains provide little assistance in subtyping vasculitis, Dr. Rostad is not able to provide details often.

After Dr. Rostad's employment at CellNetix Pathology concluded at the end of 2017, Dr. Rostad has continued to participate in medico-legal matters. Tr. 266-67. He has presented opinions for both plaintiffs and defendants.

Dr. Rostad was recognized as an expert in pathology. Tr. 37.

B. Doctors Whom the Secretary Retained

Like Ms. Rocha, the Secretary also retained two doctors. The Secretary first retained Dr. Matloubian and then Dr. Ducatman.

1. Mehrdad Matloubian

Dr. Matloubian has participated in several cases in the Vaccine Program. He earned a Ph.D. in virology and a medical degree from the University of California, Los Angeles in 1996. Exhibit B (curriculum vitae) at 1; Tr. 487. After an internship and residency, Dr. Matloubian was a fellow in rheumatology for three years at the University of California, San Francisco and had a post-doctoral fellowship there. Exhibit B at 1.

In 2001, Dr. Matloubian began working as an assistant adjunct professor of medicine at the University of California, San Francisco. He was promoted and became an associate adjunct professor in 2013. Exhibit B at 2. He became board-certified in rheumatology in 2013. Id. There was no question that Dr. Matloubian was qualified as an expert in rheumatology. Tr. 486.

However, the Secretary proffered Dr. Matloubian as an expert in immunology as well. The Secretary, therefore, solicited information about Dr. Matloubian's background in immunology. Dr. Matloubian explained that his Ph.D. was in viral pathogenesis. Later, he studied lymphocytes, which are part of the immune system, and ran his own laboratory exploring the immune responses to chronic viral infections. Tr. 487. He also is the codirector of the immunology course for medical students at the University of California, San Francisco.

Collectively, these factors led to his recognition as an expert in immunology. Tr. 488.

Although Dr. Matloubian is knowledgeable about immunology, his practice focuses on rheumatology. Tr. 488. As a rheumatologist, he sees patients with vasculitis. Moreover, because the University of California, San Francisco hospital is a tertiary care center to which patients with difficult conditions are referred, Dr. Matloubian sees more patients with vasculitis. Tr. 489-90. His duties include participating in conferences with other rheumatologists in which doctors discuss vasculitis. Tr. 490, 557. In 2017, Dr. Matloubian estimated that within the last five years, he saw at least 50 patients with vasculitis. Exhibit A at 2.

As previously mentioned, Dr. Matloubian was recognized as an expert in rheumatology and immunology. See Farag v. Sec'y of Health & Hum. Servs., No. 17-714V, 2023 WL 7203034, at *6 (Fed. Cl. Sept. 29, 2023) (recognizing Dr. Matloubian as an expert in rheumatology and immunology); Braun v. Sec'y of Health & Hum. Servs., No. 16-1098V, 2018 WL 2375751, at *15 (Fed. Cl. Apr. 24, 2018) (quoting a report from a doctor a petitioner retained as saying Dr. Matloubian is "first and foremost a researcher with a sound background in immunology").

2. Barbara Ducatman

Dr. Ducatman's participation in this case was the second time she worked in the Vaccine Program. Exhibit CC at 1. When she has occasionally participated in other medico-legal work, she has donated any earnings to her employer to fund activities to teach residents. Id. at 1-2.

Dr. Ducatman earned her medical degree from Albany Medical College in 1979. She received additional training in anatomic pathology and clinical pathology at the Mayo Clinic from 1979 to 1983. Exhibit SS (updated curriculum vitae) at 4. In 1983, she became board-certified in anatomic and clinical pathology. Id.

A significant portion (1996-2017) of Dr. Ducatman's career was working in the pathology department at the West Virginia University School of Medicine. Exhibit SS at 5. She became a professor of pathology in 2017. Id. at 6. While at West Virginia, Dr. Ducatman taught subjects in the second-year pathology course, such as pulmonary pathology, head and neck pathology, and gynecologic pathology. Tr. 405.

From West Virginia University, Dr. Ducatman moved to Oakland University William Beaumont School of Medicine, where she is currently the assistant dean of clinical affairs. Exhibit SS at 5-6. She also serves as a professor of pathology in the same institution.

Dr. Ducatman has continued to act as a pathologist. She estimated that in the last five years, she reviewed 50 cases in which a pulmonary vasculitis was suspected. Exhibit CC at 1. She also reviewed approximately 5-10 cases in which vasculitis was suspected in other organs, such as the skin. Id.

Dr. Ducatman was recognized as an expert in the field of pathology. Tr. 409.

C. Comparison

Here, on the topic of diagnosing vasculitis, Dr. Matloubian was superior to Dr. Steinman. Dr. Steinman recognized that rheumatologists treat people suffering from cryoglobulinemia. Tr. 330. Dr. Matloubian also works in a hospital that receives people with complex cases of vasculitis. Tr. 489-90. On the other hand, Dr. Steinman's description of his experience with "vasculitis" seems overly broad in that Dr. Steinman included any patient with a demyelinating disease. Tr. 330.

Between the two pathologists, Dr. Ducatman was superior. Her knowledge about vasculitides was more advanced than Dr. Rostad's knowledge on this topic. She also made a favorable impression as someone who was primarily interested in conveying information, as opposed to presenting an opinion that would assist the party who had retained her in the litigation.

VI. 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." When petitioners do not establish that the vaccinee suffered the condition they allege a vaccine caused, the Althen analysis becomes superfluous. See Doe v. Sec'y of Dep't of Health & Hum. Servs., 94 Fed. Cl. 597, 624 (2010), aff'd sub nom. Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343 (Fed. Cir. 2011).

A. Procedural History regarding Disputes over Diagnosis

The parties and the four experts they retained do not agree about the conditions affecting Mr. Rocha. These disputes were initially disclosed in the reports from the experts. However, the parties' positions were "confusing." Order for Preadjudication Briefs, issued July 14, 2020, at 5 (summarizing expert reports).

Ms. Rocha asserted that Mr. Rocha suffered from "systemic vasculitis." Pet'r's Prehear'g Br. at 17. She further maintained that Mr. Rocha suffered manifestations of this vasculitis within approximately three weeks of his October 18, 2013 flu vaccination. Id. at 20. Ms. Rocha did not put forward a theory that Mr. Rocha experienced varicella zoster vasculitis.

The Secretary advanced three points regarding diagnosis. First, the Secretary argued that Mr. Rocha did not have vasculitis, but it was possible he had cryoglobulinemic vasculitis. Resp't's Prehear'g Br. at 17. Second, Mr. Rocha had cryoglobulinemia. Id. at 19-21. Third, either the cryoglobulinemia or the cryoglobulinemic vasculitis started before Mr. Rocha's vaccination. Id. at 21.

Ms. Rocha replied to the Secretary's arguments regarding diagnosis with a request for a hearing to receive oral testimony. Ms. Rocha argued that oral testimony about diagnosis was especially important due to the inconsistencies among the experts. Pet'r's Prehear'g Reply at 1-3.

The experts did testify at the hearing. Their testimony largely did not change the parties' positions. However, the pathologists discussed the scope and types of vasculitides.

Dr. Rostad stated that the etiology of most major types of vasculitis is unknown, but that they can be grouped based on their histologic appearance, the immune profile, and certain infections with which different types are associated.

Tr. 151. He testified that "it's difficult to classify all types of vasculitis." Id. at 199. Dr. Rostad would defer to a clinician as to whether the type of vasculitis would affect a person's treatment, but opined that the type can affect one's prognosis. Id. at 221-22. Dr. Rostad stated that the type of vasculitis Mr. Rocha had was immune complex mediated and acknowledged that cryoglobulinemic vasculitis is one of the many types of immune complex types. Id. at 226.

Dr. Ducatman disagreed with Dr. Rostad's statement that it is difficult to classify the different types of vasculitis. Tr. 423. She explained that, although there is "some overlap" between the types, they have different clinical symptoms, organs they affect, histologies, and treatments. Id. at 422. Dr. Ducatman testified that she "make[s] these diagnoses all the time," and she could not recall any recent cases in which she diagnosed vasculitis but was unable to specify the type. Id. at 423.

Dr. Ducatman explained that identifying the precise type of vasculitis affects treatment. Tr. 424-25. She also maintained that "systemic vasculitis" is not a type of vasculitis because the term systemic refers to the presence of vasculitis "throughout the body in different organs." Tr. 424. Dr. Ducatman explained that all types of vasculitis are potentially systemic; vasculitis may be organ-specific, or may affect multiple organs. Tr. 424-25. "Even though you may call it systemic – it's a systemic form . . . It may only affect one organ initially . . . and then go in another." Tr. 425. Dr. Ducatman also stated that it is "highly unlikely to have . . . multiple types of vasculitis in the same person." Tr. 446. To her recollection, she had never diagnosed a person with two types of vasculitis and had never seen such in any of the hundreds of autopsies and biopsies she has performed. Id. at 446, 450.

Dr. Steinman testified that varicella zoster, and no other vasculitides, accounted for Mr. Rocha's clinical presentation. Tr. 340. It was his opinion that Mr. Rocha had cryoglobulinemic vasculitis prior to his vaccine, and developed a varicella zoster virus vasculitis after the vaccination, with onset in January 2014. Id. at 340-41. Dr. Steinman also opined that Mr. Rocha's kidney and perhaps GI tract were affected by varicella zoster vasculitis. Id. at 343.

Dr. Matloubian disagreed with Dr. Steinman's proposal that Mr. Rocha had varicella zoster vasculitis. Tr. 504. He stated that if this had been the cause of vasculitis in the other organs, he would expect Mr. Rocha to have signs and symptoms of the varicella zoster vasculitis affecting his intracranial and cerebral arteries, and symptoms of a stroke or aneurysms and bleeding in his head. Id. at 505.

After the hearing, just as she had argued in her prehearing brief, Ms. Rocha contended that Mr. Rocha suffered from "systemic vasculitis" and that he experienced symptoms within three weeks of the vaccination. Pet'r's Posthear'g Br. at 11-12. She maintained: "Preponderant evidence supports a finding that Mr. Rocha developed vasculitis as a direct result of the flu vaccine." Id. at 16-17. Ms. Rocha stated that the flu vaccine caused an "immune complex reaction." Id. at 14, citing Tr. 241. Ms. Rocha did not discuss varicella zoster vasculitis.

In response, the Secretary added a new argument that Ms. Rocha's assertion of "vasculitis" without any description of the type of vasculitis did not satisfy petitioner's burden on Broekelschen. Resp't's Posthear'g Br. at 21-22. Otherwise, the Secretary largely reargued the same three points: Ms. Rocha had not established that Mr. Rocha suffered from systemic vasculitis or varicella zoster vasculitis; Mr. Rocha suffered from cryoglobulinemia; and regardless of whether Mr. Rocha had cryoglobulinemia or cryoglobulinemic vasculitis, his problem pre-dated the flu vaccination. Id. at 23-29.

Ms. Rocha replied. She characterized Mr. Rocha's condition as "immune complex mediated vasculitis." Pet'r's Posthear'g Reply at 1. She further argued that this degree of specificity is in accordance with Mager v. Sec'y of Health & Hum. Servs., 158 Fed. Cl. 136, 154 (2022), appeal dismissed, No. 2023-2382, 2023 WL 7318303 (Fed. Cir. Nov. 7, 2023). She maintained that the doctors' treatment for vasculitis proves that Mr. Rocha had vasculitis. Ms. Rocha also characterized whether Mr. Rocha suffered from cryoglobulinemia before vaccination as a "red herring." She again did not offer varicella zoster vasculitis.

B. Assessment of Diagnosis

The collection of briefs identified three issues within the topic of diagnosis: (1) whether a description of "systemic vasculitis" or "immune complex mediated vasculitis" satisfies Broekelschen's requirement; (2) whether Mr. Rocha suffered from any type of vasculitis and, if so, when the vasculitis began; and (3) whether Mr. Rocha suffered from varicella zoster vasculitis. These are taken up in turn.

1. Sufficiency of Proposed Diagnosis

The Secretary argues that Ms. Rocha has not presented preponderant evidence showing that Mr. Rocha suffered from "systemic vasculitis." Resp't's Posthear'g Br. at 21-22. This argument rests upon Dr. Ducatman's testimony that there are many different vasculitides. Id.; Tr. 422. Dorland's Medical Dictionary lists more than 20 types. Dorland's at 1996.

Ms. Rocha argues that, pursuant to Broekelschen, she does not need to identify a more specific injury if "the possible diagnoses for the injury are variants of the same disorder." Pet'r's Posthear'g Reply at 1. Here, she argues, "immune complex mediated vasculitis could have varied expressions, but the pathogenesis would be the same," and the "symptoms are all on the same spectrum of immune complex mediated vasculitis." Id. Further, Ms. Rocha argues that the case "is not about the type of immune complex mediated vasculitis Mr. Rocha had," but whether he had it at all. Id. at 2.

Pursuant to Broekelschen, a petitioner must demonstrate that a vaccinee suffered from the injury that a vaccine is alleged to have caused. 618 F.3d at 1346. Relatively few cases have wrestled with the question about whether a certain condition is sufficiently defined to satisfy the terminology used in Broekelschen.

In Mager, the parties agreed that the vaccinee suffered from an epileptic seizure disorder but disagreed as to the diagnosis; petitioner argued that it was autoimmune epilepsy, and respondent argued juvenile myoclonic epilepsy. 2021 WL 3737056 at *2 (Fed. Cl. Spec. Mstr. July 29, 2021). The (undersigned) special master found that petitioner had not met his burden to show that the vaccinee suffered from autoimmune epilepsy and denied compensation. Id. at 12. The decision was vacated and remanded. As the Court of Federal Claims explained, although the case "involve[d] competing diagnoses, they are only competing in the sense that the parties dispute them – not in the sense that they are mutually exclusive." 158 Fed. Cl. 136, 155 (2022). The parties agreed that the vaccinee suffered from a seizure disorder, and thus "the 'existence and nature of the injury' was not in dispute." Id. at 156 (quoting W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013)). These circumstances distinguished Mager from Lombardi and Broekelschen, where the identification and nature of the injury were in dispute, and "the question of causation turn[ed] on [the] injury." Id. at 155 (quoting Broekelschen, 618 F.3d at 1346).

Here, the conditions that Ms. Rocha proposes are too general. To repeat, at various points, she has maintained that Mr. Rocha suffered from "systemic vasculitis," Pet'r's Posthear'g Br. at 12; "vasculitis," Pet'r's Posthear'g Br. at 16-17, and "immune complex mediated vasculitis," Pet'r's Posthear'g Reply at 1. Any of these diagnoses is too broad to meet petitioner's burden under Broekelschen. As Dr. Ducatman explained, different types of vasculitis are distinguishable, and two types do not affect a single patient. Thus, Mr. Rocha's condition is distinguishable from the competing diagnoses in Mager, which were not mutually exclusive. See 158 Fed. Cl. at 155. Dr. Ducatman was adamant that "systemic vasculitis" is not a proper diagnosis and noted that different types of

vasculitis require different treatments. Dr. Rostad also acknowledged that different types are associated with different viruses and have different prognoses. Because the types of vasculitis are so distinct, a generalized injury of "system vasculitis" or "immune complex mediated vasculitis" is not specific enough. See E.M. v. Sec'y of Health & Hum. Servs., No. 14-753V, 2021 WL 3477837, at *35 (Fed. Cl. Spec. Mstr. July 9, 2021) (finding that petitioner failed to show by preponderant evidence that she suffered from "small vessel vasculitis," as this is "not a disease in and of itself, but rather is an umbrella diagnosis" encompassing several versions of small vessel vasculitis, which each have differential diagnostic criteria).

Regardless, as found below in section II.A.3, the evidence preponderates in favor of finding that Mr. Rocha suffered from a specific type of vasculitis – cryoglobulinemic vasculitis – before he received the flu vaccine. This finding is based upon all the evidence and is not simply an endorsement of the opinion from a single expert. Sword v. United States, 44 Fed. Cl. 183, 188–89 (1999). Mr. Rocha's cryoglobulinemic vasculitis is discussed more thoroughly below.

2. Vasculitis in Mr. Rocha

Ignoring Dr. Steinman's opinion that Mr. Rocha had longstanding cryoglobulinemic vasculitis (Tr. 340-45), Ms. Rocha argues that the flu vaccine caused Mr. Rocha to have vasculitis. Pet'r's Posthear'g Br. at 16-17. However, ample evidence supports a finding that Mr. Rocha had cryoglobulinemia for years before the vaccination. See Exhibit A at 3-9 (Dr. Matloubian's report summarizing medical records). Admittedly, the evidence that Mr. Rocha suffered cryoglobulinemic vasculitis (meaning that cryoglobulins were in Mr. Rocha's small vessels) is not quite as strong. Dr. Ducatman's assessment was "50/50." Tr. 441-42. However, the burden of proof for any factual issue is simply preponderance of the evidence. Here, other evidence, including most significantly Dr. Steinman's opinion, tips the proverbial evidentiary scales to favor a finding that Mr. Rocha suffer cryoglobulinemic vasculitis before the vaccination.

Ms. Rocha contends that before the vaccination, no doctor diagnosed Mr. Rocha as suffering from cryoglobulinemia or cryoglobulinemic vasculitis, but after the vaccination, doctors did diagnose Mr. Rocha with vasculitis. As a preliminary point, Ms. Rocha's contention is accurate on the facts. However, this simple reliance on the date of diagnosis is not persuasive.

Although the parties' experts disagreed as to the overall complexity in diagnosing vasculitis, they agreed that diagnosing vasculitis may be difficult in at least some cases. Tr. 219 (Dr. Rostad), 421, 423 (Dr. Ducatman). This challenge is

enhanced because Mr. Rocha was not being treated for his infection with hepatitis B virus, an infection that is associated with vasculitis.

The difficulty in detecting vasculitis is reflected in the events at Trinity and Barnabas. During these two hospitalizations, which totaled approximately 16 days, doctors did not diagnose Mr. Rocha with vasculitis. Exhibit 9 at 22 (Trinity discharge report); Exhibit 12 at 22 (Barnabas discharge report). This treatment occurred when, according to Ms. Rocha, Mr. Rocha was suffering from a vasculitis induced by his October 18, 2013 flu vaccination.

The doctor who first raised the possibility of vasculitis was the rheumatologist at Overlook, Dr. Mather. On January 1, 2014, she stated that "based on the labs and based on his symptoms, it seems that an autoimmune condition such as vasculitis is a possibility." Exhibit 10 at 229. Dr. Mather also documented how a diagnostic possibility of vasculitis could be confirmed via additional testing such as a kidney biopsy, lung biopsy, CT scan of the abdomen and/or an MR angiogram. Id.

In any event, after Dr. Mather received Dr. Markowitz's interpretation of the kidney biopsy and the result of the second test for cryoglobulins, Dr. Mather assessed Mr. Rocha was "cryoglobulinemic vasculitis." Exhibit 10 at 184. The Overlook discharge report stated that Mr. Rocha "likely [had] cryoglobulinemic vasculitis." Id. at 17.

As a matter of logic, a doctor's detection of a disease does not establish the date the disease began. Special masters have recognized that a person could be suffering from a disease for months or years before the disease is diagnosed, and multiple appellate opinions have upheld those findings. See, e.g., Milik v. Sec'y of Health & Hum. Servs., 822 F.3d 1367, 1380 (Fed. Cir. 2016) (special master was not arbitrary in determining that child-vaccinee had developmental delay before vaccination); W.C., 704 F.3d at 1358 (special master was not arbitrary in relying upon MRI lesions to find petitioner suffered from multiple sclerosis before vaccination); Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1254 (Fed. Cir. 2011) (special master was not arbitrary in finding that liver biopsy meant that petitioner had liver disease for many years before vaccination); Spahn v. Sec'y of Health & Hum. Servs., 133 Fed. Cl. 588, 599 (2017) (special master was not arbitrary in finding that child-vaccinee suffered from obsessive-compulsive disorder before vaccination); Hunt v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 509, 520-21 (2015) (special master did not err in finding child-vaccinee suffered from undiagnosed multiple sclerosis before vaccination); Crutchfield v. Sec'y of Health & Hum. Servs., 125 Fed. Cl. 251, 264 (2014) (special master was not

arbitrary in finding that results of A1c test for hemoglobin meant that petitioner's islet cell destruction began before vaccination); see also M.R. v. Sec'y of Health & Hum. Servs., No. 16-1024V, 2023 WL 4936727 at *34 (Fed. Cl. Spec. Mstr. June 30, 2023) (special master distinguished when a neuroma was discovered from when the neuroma began); Orm v. Sec'y of Health & Hum. Servs., No. 14-257V, 2023 WL 2984794 at *37 (Fed. Cl. Spec. Mstr. Mar. 24, 2023) (special master determined petitioner had celiac disease before vaccination because anemia takes long time to manifest); Specks v. Sec'y of Health & Hum. Servs., No. 15-491V, 2023 WL 2947619 at *42 (Fed. Cl. Spec. Mstr. Feb. 17, 2023) (special master found petitioner's POTS pre-existed vaccination and noting that the date of diagnosis did not control the date of onset).

Dr. Mather's diagnosis of cryoglobulinemic vasculitis returns the analysis in this decision to its start. The foundational point is that a preponderance of the evidence supports a finding that Mr. Rocha had cryoglobulinemic vasculitis of many decades' duration before the flu vaccination. Dr. Rostad's attempts to undermine Dr. Mather's conclusions were largely ineffective. In this regard, Dr. Rostad's inability to propose a type of vasculitis diminished his credibility. See Tr. 198, 201; see also Tr. 423 (Dr. Ducatman stating that she "make[s] these diagnoses all the time.").

For all these reasons, Ms. Rocha has not persuasively shown that Mr. Rocha developed vasculitis after the flu vaccine. Instead, the evidence persuasively shows that he had cryoglobulinemic vasculitis before the vaccination.

3. Varicella Zoster Vasculitis

Dr. Steinman's theory of the case involves the flu vaccine triggering a latent herpes virus and the zoster infection causing vasculitis. Exhibit 21 at 6. Dr. Steinman indicated that the first sign of the varicella zoster vasculitis was when Mr. Rocha had Ramsay Hunt. Tr. 341-43.

The other experts did not agree that Mr. Rocha suffered from varicella zoster vasculitis. On cross-examination, Dr. Rostad stated that Mr. Rocha did not have the signs of varicella zoster vasculitis listed in an article about varicella zoster vasculitis. Tr. 228. Dr. Matloubian maintained that he did not see any evidence that Mr. Rocha suffered from varicella zoster vasculitis. Tr. 504. This testimony was the basis for the Secretary's argument that Mr. Rocha did not suffer from varicella zoster vasculitis. Resp't's Posthear'g Br. at 24.

Ms. Rocha's failure to present any argument that Mr. Rocha suffered from varicella zoster vasculitis could constitute a forfeiture of a claim involving varicella zoster vasculitis. Vaccine Rule 8(f)(1). But resolving this issue based upon waiver or forfeiture is unnecessary, because the evidence does not preponderate in favor of finding that Mr. Rocha had varicella zoster vasculitis. See Tr. 504. This evidentiary finding resolves the issue against Ms. Rocha.

VII. Significant Aggravation

Theoretically, the finding that Mr. Rocha suffered from cryoglobulinemic vasculitis before the flu vaccination does not necessarily end his case because he could allege that the flu vaccination significantly aggravated his cryoglobulinemic vasculitis. However, as a practical matter, the finding that the cryoglobulinemic vasculitis existed before the flu vaccination means that Mr. Rocha's estate cannot receive compensation for two related reasons.

First, a claim for significant aggravation requires a showing that a vaccine experienced "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa–33(4). However, the evidence does not support a finding that Mr. Rocha's cryoglobulinemic vasculitis worsened within a reasonable amount of time proximate to the vaccination. After the flu vaccination, Mr. Rocha's first heath problem was in his ears, leading to a diagnosis of Ramsay Hunt syndrome. See Exhibit 5 at 7; see also section II.C, above. No persuasive evidence connects vasculitis to an ear problem. The treatment for the ear problem, the placement of tubes in Mr. Rocha's ears, led to a hospitalization during which renal troubles were detected as part of an apparently routine blood test. Exhibit 9 at 14, 209. The treating nephrologist, Dr. Agresti, indicated that the acute kidney injury is "most likely secondary to dehydration." Id. at 12. Dr. Matloubian concurred that that dehydration explained the temporary kidney problems. Tr. 510.

Dehydration was also the basis for reduced kidney function according to the nephrologist who treated Mr. Rocha during his hospitalization at Barnabas, Dr. Shah. Exhibit 12 at 113. Dr. Matloubian again concurred. Exhibit A at 4-5, 9.

Furthermore, Dr. Matloubian and Dr. Ducatman opined that during Mr. Rocha's hospitalizations at Overlook and Beth Israel, Mr. Rocha's cryoglobulinemia and cryoglobulinemic vasculitis were stable. Tr. 439, 445, 448, 561. Ms. Rocha has not identified any evidence that persuasively shows that Mr. Rocha's cryoglobulinemic vasculitis worsened during his hospitalization.

This leads to the second reason for not compensating Ms. Rocha based upon a theory that the flu vaccine significantly aggravated any pre-existing cryoglobulinemic vasculitis---Ms. Rocha has not advanced this claim. Ms. Rocha's briefs filed before the hearing do not claim significant aggravation. At best, after the hearing, Ms. Rocha mentioned this claim in a footnote. She argued:

> Petitioner has not presented this as a significant aggravation case because there is no evidence that any pre-existing condition (real or potential) contributed to Mr. Rocha's post-vaccination decline and death. However, should the Special Master find otherwise, Dr. Steinman has presented a strong case for significant aggravation under Loving v. Secretary of Health & Human Services, 86 Fed. Cl. 135, 144 (2009).

Pet'r's Posthear'g Br. at 20 n.3.

This two-sentence statement is not sufficiently developed to be persuasive. See SmithKline Beecham, Corp. v. Apotex Corp., 439 F.3d 1312, 1320 (Fed. Cir. 2006) (explaining an argument needs to be developed, not just in footnote). Ms. Rocha has not cited any evidence in which Dr. Steinman presented an opinion regarding significant aggravation. It appears that Dr. Steinman mentioned a potential "exacerbation" in responding to two questions on cross-examination. Tr. 345. Again, this evidence is too slight to constitute a persuasive basis for awarding compensation. The lack of evidence is particularly noticeable because the Secretary had argued before the hearing that Mr. Rocha's cryoglobulinemia or cryoglobulinemic vasculitis existed before the vaccination. Resp't's Prehear'g Br. at 21. Thus, any claim for significant aggravation is too late. See Hirmiz v. Sec'y of Health & Hum. Servs., 119 Fed. Cl. 209, 219-20 (2014) (declining to allow petitioner to amend a petition to allege significant aggravation as part of a motion for review), aff'd without op., 618 Fed. Appx. 1033 (Fed. Cir. 2015).

Accordingly, Ms. Rocha has not established with preponderant evidence that the condition she alleges the flu vaccine caused (vasculitis) actually worsened within a reasonable time after the vaccination. This finding is another sufficient reason to deny compensation. Moreover, even if Ms. Rocha had persuasively proven a sequence of events in which the flu vaccine preceded a worsening of the vasculitis, Ms. Rocha would be required to establish that the flu vaccine caused the worsening. As explained below, Ms. Rocha has not presented a persuasive theory explaining how the flu vaccine can cause (or worsen) cryoglobulinemic vasculitis. She therefore cannot prevail on a significant aggravation claim.

VIII. Causation-in-Fact

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

A. *Althen* Prongs 2 and 3

As discussed above, preponderant evidence supports a finding that Mr. Rocha had cryoglobulinemic vasculitis before he received the October 18, 2013 flu vaccine. A sequence of events in which the vaccination occurred after the onset of the disease means that the vaccination did not cause the disease. Thus, Ms. Rocha has not established "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278.

Likewise, that Mr. Rocha's vasculitis pre-dated his vaccine necessarily means that his symptoms did not arise within a "timeframe for which it is medically acceptable to infer causation." 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).

Accordingly, Ms. Rocha has not met her burden under Althen prong two or three. See Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("Given the Special Master's finding that the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness."). An analysis of the first Althen prong is therefore not necessary. Nevertheless, a brief analysis is provided.

B. *Althen* Prong 1

The first Althen prong requires a petitioner to present a reliable and persuasive medical theory. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citing Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). Ms. Rocha has advanced the theory of molecular mimicry. See Pet'r's Posthear'g Br. at 14.

1. Appellate Precedents regarding 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 opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C., 704 F.3d 1352, and Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd without op., 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 four 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.[17] 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.

[17] 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.

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., Dennington v. Sec'y of Health & Hum. Servs., 167 Fed. Cl. 640 (2023) (finding the special master did not err in rejecting molecular mimicry because the theory was too general), appeal docketed, No. 18-1303 (Fed. Cir. Dec. 1, 2023); 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 erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

Here, both Dr. Rostad and Dr. Steinman provided reports and literature to contribute to Ms. Rocha's molecular mimicry theory.[18] Dr. Ducatman and Dr. Matloubian opposed this theory. The experts' opinions are summarized.

2. Summary of the Evidence

Dr. Rostad's reports and Dr. Ducatman's responses focused primarily on Mr. Rocha's diagnosis. Their discussion of causation was limited. In his first report, Dr. Rostad explained that molecular mimicry "is generally accepted as a primary mechanism by which vaccines can lead to autoimmune disease." Exhibit 55 at 12. He stated that "Vaccines have been associated with autoimmune diseases in a number of conditions," and provided tables of various autoimmune diseases and manifestations related to several different vaccines. Id. at 13, 15. Dr. Rostad concluded: "The influenza vaccine initiated an autoimmune response towards antigens possibly present in the endothelium of blood vessels, through the mechanism of molecular mimicry." Id. at 19.

[18] Dr. Rostad also noted that other theories, such as epitope spreading, bystander activation, and polyclonal activation "may work in isolation or in concert with each other." Exhibit 55 at 12. However, he did not discuss these theories beyond listing them, and they are not included in the analysis here.

In response, Dr. Ducatman commented that "Dr. Rostad's hypotheses are not likely to represent the cause of [Mr. Rocha's] demise," and noted that "cryoglobulinemia is a very infrequent result of influenza vaccination with only two reported cases." Exhibit PP at 2.

Dr. Steinman and Dr. Matloubian dedicated more of their reports to causation. Dr. Steinman theorized that the flu vaccine activated an innate immune response in Mr. Rocha, leading to activation of a latent herpes zoster virus, culminating in Ramsay Hunt, which then triggered vasculitis. Exhibit 46 at 7. Dr. Steinman performed BLAST searches to identify homologies between the flu vaccine and the dorsal root ganglia, which is where the herpes zoster virus lies latent. Id. at 5, 9. He explained that his criterion for a "relevant molecular mimic" in his BLAST searches was based on the Gautam articles finding that homology between 5 of 12 and 4 of 11 non-consecutive amino acids was sufficient to trigger experimental encephalomyelitis. Id. at 13-15 (referencing the two Gautum articles and the Bao article).[19] Dr. Steinman stated that the nuclear factor kappa B-cell signaling (NF-κB) cell – "the master regulator of inflammation" – is activated by the flu vaccine and leads to the activation of zoster. Id. at 23; see also Tr. 325.

Dr. Matloubian disputed that an activated immune response could result in Ramsay Hunt, stating that it is "the opposite of the generally accepted principle that waning immunity or immunosuppression is the major cause of [varicella zoster virus] reactivation." Exhibit A at 16. He characterized the theory as "purely speculative" and without scientific support. Id. Dr. Matloubian noted that the studies cited by Dr. Steinman did not address whether the inactivated flu vaccine can activate NF-κB where varicella zoster virus lies dormant, nor did the studies show a long-lasting effect of the flu vaccine on the nervous system. Id. at 19. Further, the studies indicated that activation of NF-κB should inhibit – not activate – varicella zoster virus. Id. at 20.

Dr. Matloubian also commented on the BLAST searches, noting that none of the articles Dr. Steinman cited "show any association between a T cell mediated response to [the proteins he searched for] and development of an 'inflammatory

[19] Anand M. Gautum et al., A polyalanine peptide with only five native myelin basic protein residues induces autoimmune encephalomyelitis, 176 J. EXP. MED. 605 (1992); filed as Exhibit 34; Anand M. 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 35; Lan Bao, Trafficking regulates the subcellular distribution of voltage-gated sodium channels in primary sensory neurons, 11 MOL. PAIN 61 (2015); filed as Exhibit 36.

neuropathy.'" Exhibit A at 15-16. Additionally, many linear sequence homologies exist, and "the vast majority of these are not associated with biologically relevant autoimmune phenomena or actual human disease." Id. at 15 (quoting Institute of Medicine's Committee to Review Vaccine Adverse Effects of Vaccines). Because of this commonality, as well as the complexity by which T cells recognize foreign peptides or antigens, "sequence homology itself is not sufficient evidence to prove pathogenic molecular mimicry as agreed to by the [Institute of Medicine's] committee." Id. at 16. Dr. Matloubian criticized Dr. Steinman's reliance on the two Gautam articles, as their findings relate to how specific antigen peptides interact with specific mice, and do not mean that sequence homology implies antigenicity. Id. at 16-17.

In response, Dr. Steinman "strongly disagree[d]" with Dr. Matloubian's statement that varicella zoster virus infection is caused by immune suppression rather than activation. He explained that varicella zoster virus suppresses the NF-κB pathway by down-modulating the interferon beta pathway. The varicella zoster virus then goes into latency. However, the flu vaccine activates the interferon beta pathway and thereby directly opposes NF-κB suppression, activating the varicella zoster virus and resulting in Ramsay Hunt Syndrome. Exhibit 49 at 2-3. Dr. Steinman did not address Dr. Matloubian's critiques of his BLAST searches or reliance on Gautam. Dr. Matloubian maintained his opinions in his second report. Exhibit BB at 3.

At the hearing, when asked if his theory that NF-κB could trigger varicella zoster virus reactivation was accepted in the medical community, Dr. Steinman stated, "I believe it is, but that all depends on what you mean by accepted." Tr. 356-57. He noted that he provided medical literature, but the studies he referenced did not discuss NF-κB reactivating a latent varicella zoster virus. Tr. 358-61.

In contrast, Dr. Matloubian testified that the theory that NF-κB activation triggers varicella zoster virus reactivation is not generally accepted in the medical community, and he was unaware of any medical literature hypothesizing such. Tr. 527-28. Moreover, nothing in the literature supported the theory that the flu vaccine activates the interferon beta pathway and thus opposes NF-κB suppression. Tr. 532. He stated that nothing Dr. Steinman submitted persuaded him that NF-κB activation would be beneficial to varicella zoster virus in any way. Id. at 532-33. Dr. Matloubian explained that interferons are antiviral and interfere with virus replication. When interferon activates NF-κB, it inhibits varicella zoster virus replication. Id. Additionally, Dr. Matloubian stated that the literature Dr. Steinman submitted actually contradicts his own theory and shows that NF-κB inhibits varicella zoster virus replication. Id. at 535. Dr. Matloubian reiterated that

homology with amino acids is common and questioned the significance of Dr. Steinman's BLAST results. Id. at 562-63.

3. Analysis

Under Broekelschen, "a petitioner must provide a reputable medical or scientific explanation that pertains *specifically* to the petitioner's case." 618 F.3d at 1345 (emphasis added). Dr. Rostad's conclusion that "The influenza vaccine initiated an autoimmune response towards antigens possibly present in the endothelium of blood vessels, through the mechanism of molecular mimicry," Exhibit 55 at 19, is not supported by the medical literature Dr. Rostad cited. These articles largely discuss different vaccines, different types of vasculitis, or different diseases altogether. See Exhibit 55 at 13-15 (Dr. Rostad discussing various autoimmune diseases reported linked to several vaccines); see also Resp't's Posthear'g Br. at 31 (noting that Exhibits 60, 68, 73, 74, and 81 discuss different diseases and conditions); see also Tr. 257-64 (discussion of articles at hearing). Ms. Rocha did not address the Secretary's argument that the literature was irrelevant, beyond stating that the Secretary was attempting to raise the burden of proof. See Resp't's Posthear'g Reply at 3-4. Dr. Rostad's bare molecular mimicry theory, unaccompanied by literature linking the flu vaccine to cryoglobulinemic vasculitis, is not reliable or persuasive to meet Ms. Rocha's burden under first Althen prong. See Sullivan, 2015 WL 1404957, at *18 (finding that expert had "done no more than opine that it is intellectually conceivable that administration of [vaccine] could result in injury]" where petitioner advanced bare molecular mimicry theory and "offer[ed] a few alternative mechanisms, but they are incompletely sketched out at best.").

While Dr. Steinman was rather equivocal about whether his theory was accepted in the medical community, Dr. Matloubian was firm that it was not. Special masters may consider whether an opinion is generally accepted. Terran v. Sec'y of Health & Hum. Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). Furthermore, Dr. Steinman was not able to identify clear support for his theory in literature. Although Dr. Steinman identified homologies with his BLAST searches, "the finding of sequence homology does not necessarily mean the similarity has significance to the immune system." Tullio, 2019 WL 7580149, at *15. Dr. Steinman did not provide any evidence demonstrating that the homologies he identified were related to Mr. Rocha's injury. See Brayboy v. Sec'y of Health & Human Servs., No. 15-183V, 2021 WL 4453146, at *19 (Fed. Cl. Spec. Mstr. Aug. 30, 2021) ("It also cannot be enough that a medical expert can simply identify homologous peptides from a generic BLAST search that are not, in any way, linked to the biological process that is dysfunctional or has suffered

injury."). For these reasons, Dr. Steinman's theory is also not reliable or persuasive, and Ms. Rocha has not met her burden under Althen prong one.

IX. **Conclusion**

Mr. Rocha suffered from medical conditions before receiving a flu vaccination on October 18, 2013. Indisputably, he suffered from an infection with hepatitis B. He also, most likely, suffered from cryoglobulinemic vasculitis. Mr. Rocha also suffered from additional health problems after receiving the flu vaccination and the etiology of some of these health problems was elusive. This uncertainty regarding the cause of Mr. Rocha's decline and eventual death may have led Ms. Rocha to believe that the flu vaccine caused Mr. Rocha's health problems. Ms. Rocha merits sympathy for the death of her husband.

However, the evidence does not support a finding that the flu vaccine caused any adverse effect on Mr. Rocha's health. The flu vaccine did not worsen his cryoglobulinemic vasculitis, which existed before the vaccination.

Accordingly, Ms. Rocha is not entitled to compensation. The Clerk's Office is instructed to enter judgment in accordance 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, available through the Court's website.

IT IS SO ORDERED.

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