

been preponderantly shown that the flu vaccine can cause rhabdo (rendering moot questions about whether AMPS could be a sequela of it).

I. Fact Summary

Vaccination and Subsequent Rhabdo Diagnosis

A.C. was born on August 31, 2006, and was thus twelve years old on the date of vaccination. Ex. 1 at 2. On November 5, 2018 (a Monday), A.C. saw her then-primary care provider (“PCP”) for examination of a growth on her scalp and irritated skin on her right ear lobe. Ex. 4 at 34. A.C. was diagnosed with dermatitis on her ear lobe and referred to dermatology for evaluation of the scalp growth. *Id.* at 35. She received the flu vaccine at this doctor’s visit. *Id.*

That same week, A.C. began to experience post-vaccination symptoms, some of which occurred in the context of her school day. When A.C. returned home from school on Tuesday afternoon (November 6th – the day after the vaccination), she told Petitioner that she felt worn down and achy. *See* Affidavit of Jamie Myers, dated April 26, 2021, filed as Ex. 17 (ECF No. 8-6) (“Myers Aff.”). Assuming A.C. was experiencing a typical response to receiving the flu vaccine, Petitioner gave her some Motrin and sent her to bed. Myers Aff. at 2. By the next day, however, A.C. felt worse, complaining of weakness and whole body achiness. *Id.* She had trouble lifting a textbook, so Petitioner kept her home from school. *Id.* She did not feel any better on Thursday. *Id.*

On the Friday after vaccination (November 9, 2018), Petitioner took A.C. to the emergency department (“ED”) of Providence Sacred Heart Medical Center. Ex. 8 at 1. A.C. now complained of increasing pain and weakness that had begun the previous Tuesday (one day after vaccination), as well as an episode of diarrhea earlier that week. *Id.* at 2-3. An exam was unremarkable, and A.C. did not have a fever, but a comprehensive metabolic panel revealed a significantly elevated creatine kinase (“CK”) level of 29,376 U/L (with CK being a biomarker of rhabdo³) plus elevated liver enzymes. *Id.* at 3-6. Treeters determined A.C. was suffering from some unspecified myositis and proposed that she be admitted to pediatrics to receive intravenous fluids. *Id.* at 6.

A.C. was subsequently hospitalized for two days, through November 11, 2018. Ex. 8 at 8. The initial admission records noted that A.C. (who had played volleyball in gym class the same day as vaccination) had participated in weight training and calisthenics in her gym class the day after vaccination (November 6th). *Id.* at 15. That night, she developed upper body pain with “intermittent tingling and paresthesia in her arms” that resolved with rest. *Id.* She stayed home the next day, but her pain and weakness progressively worsened. *Id.* It was also noted that A.C.’s half-

³ CK level tests are commonly used to test for rhabdo. CK enters the bloodstream when muscle tissue is damaged, resulting in increased CK levels when rhabdo is present. *Signs and Symptoms of Rhabdomyolysis*, National Institute for Occupational Safety and Health, <https://www.cdc.gov/niosh/rhabdo/signs-symptoms/index.html> (last visited November 6, 2024).

brother had experienced rhabdo recently, after football practice. *Id.* Based on reported symptoms and testing results, treaters diagnosed A.C. with non-traumatic rhabdo “from unknown cause, likely multifactorial - flu shot, weightlifting.” *Id.*

While hospitalized, A.C. received rhabdo-specific treatments, and her CK levels began to drop toward normal levels (and although her liver enzymes remained high, her liver function was deemed normal). Ex. 8 at 13, 27. A.C. also received a respiratory PCR test,⁴ which yielded positive results for rhinovirus/enterovirus infection, but not for mycoplasma.⁵ *Id.* at 12. During this time, A.C. developed a fever and experienced a single episode of vomiting. *Id.* at 30. A.C. was discharged on November 11, 2018. In the discharge notes, a treating pediatrician noted that her rhabdo was likely “secondary to unclear etiology at this time, likely multifactorial secondary to recent weightlifting, viral illness, vs other.” *Id.* at 11.

In the days thereafter, A.C. continued to experience fatigue, staying home as a result. Ex. 4 at 32. At a visit to her PCP on November 13, 2018, it was noted that the actual cause of her rhabdo could not be definitively ascertained, although the treater expressed the view that the vaccine’s role was “very suspect due to when it was given.” Ex. 4 at 33. It was also noted that A.C. had never experienced an adverse reaction to the vaccine before, and that she had not participated in any sports activities strenuous enough to have likely contributed to her rhabdo. *Id.* (Indeed, at a treater visit later that month, A.C. specifically recalled that her initial symptoms started right after she began a new physical education section at school, but that she had only performed about “10 minutes of light reps on the [weight] machines.” Ex. 3 at 4).

For the remainder of November 2018, A.C. continued to experience some pain and leg weakness, often leading her to seek early release from school. *See, e.g.*, Ex. 4 at 27, 28. Additional CK testing performed that month revealed slightly elevated levels (but lower than while she had been hospitalized). *Id.* at 31. It was proposed that her persistent pain and weakness was associated with her rhabdo. *Id.* at 28.

On November 16, 2018, A.C. saw a pediatric sports medicine specialist, Ryan Baker, M.D., at Shriner’s Hospital for Children. Ex. 3 at 3. She now denied any pain, numbness, or tingling in her extremities, but stated that her abdomen and thighs were sore. *Id.* Dr. Baker noted that A.C.

⁴ “PCR (polymerase chain reaction) tests are a reliable and accurate way to diagnose certain infectious diseases, some types of cancer, and certain genetic changes.” *PCR Tests*, MedlinePlus, <https://medlineplus.gov/lab-tests/pcr-tests/> (last visited November 6, 2024).

⁵ *Mycoplasma pneumoniae* bacteria can cause respiratory tract infections that have a wide spectrum of clinical symptoms, including extrapulmonary manifestations. A *mycoplasma pneumoniae* infection is often referred to as “walking pneumonia.” *Mycoplasma Pneumoniae Infection*, CDC, <https://www.cdc.gov/mycoplasma/index.html> (last visited November 25, 2024).

had “a history of Klippel-Trenaunay syndrome,”⁶ and that testing performed at the time she was hospitalized for her rhabdo had revealed the presence of both a rhinovirus and enterovirus infection (with the latter being associated with rhabdo). *Id.* at 5. Blood testing performed at this visit revealed elevated liver enzymes and a slightly elevated CK level (but still progressing lower). *Id.* at 18. A.C. continued to experience fatigue thereafter, however, leading to another PCP visit on November 20th – but by this time additional testing showed her liver enzyme and CK levels had returned to normal. Ex. 3 at 16, Ex. 4 at 24-26.

At the end of November, A.C. again saw Dr. Baker, and she was still complaining of weakness and fatigue, plus dizziness, all of which led her to continue to stay home from school. Ex. 3 at 42. An exam revealed no notable issues, however, and Dr. Baker observed that A.C.’s CK levels were now normal (confirmed by yet more testing). *Id.* at 43, 76. Blood testing performed at this time also now revealed the presence of a mycoplasma infection (despite the negative PCR result earlier that month), plus parvovirus and streptococcus. *Id.* at 72-130. Dr. Baker noted that any relationship between the flu vaccine and A.C.’s rhabdo could simply be “serendipitous, [but] possibly causal[.]” *Id.* at 42. It was recommended that A.C. be tested for possible viral or autoimmune etiologies, that genetic counseling occur (given that A.C.’s sibling had also experienced rhabdo), and that a hematologist be consulted for evaluation of A.C.’s Klippel-Trenaunay syndrome. *Id.*

The next month, A.C. experienced additional symptoms, which led Petitioner to bring A.C. in for a visit with her PCP on December 7, 2018. Ex. 4 at 21-23. At this visit, the PCP noted that A.C. had been placed on antibiotics after testing positive for a mycoplasma infection back in November. *Id.* at 22. An ED visit in early December resulted in A.C.’s second hospital admission that fall. Ex. 8 at 119, 121, 123. But exams again were unremarkable (with CK levels confirmed to be normal – now *one month* post-vaccination), and A.C. was discharged not long thereafter. Ex. 8 at 125, 130, 136, 141-42. A treater who evaluated A.C. during this timeframe speculated that the symptoms A.C. was reporting might be post-infectious and associated with the mycoplasma infection that testing had revealed (and which additional testing revealed to exist at an elevated level). *Id.* at 125, 150.

For the remainder of December 2018, A.C. obtained additional physical therapy treatments for her weakness concerns. Ex. 3 at 81-83. She saw Dr. Baker again on December 17, 2018, and complained of muscle and feet/hands tingling. *Id.* at 101. Dr. Baker expressed doubt, however, that these symptoms were related to her prior rhabdo diagnosis, observing that (a) the rhabdo had begun “after serendipitously getting a flu vaccine,” (b) antibiotic treatment for the mycoplasma infection had not seemed to help, leading to the proposal of trying a different antibiotic, and (c)

⁶ “Klippel-Trenaunay syndrome” is a rare venous malformation disorder that affects how blood and lymph vessels develop in a baby before birth. *Klippel-Trenaunay syndrome*, Johns Hopkins Medicine, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/klippel-trenaunay-syndrome> (last visited November 6, 2024).

the rhabdo might be attributable to that infection. *Id.* at 101-02. A.C.'s CK levels were checked yet again at the end of December (in connection with an urgent care visit), but were found to be normal, which led treaters to conclude that the bout of rhabdo had *not* likely recurred. Ex. 6 at 3, 5, 6, 10.

Treatment in 2019 and Suspicion of AMPS

In 2019, A.C. had numerous medical treater visits aimed at addressing her ongoing complaints of weakness, pain, and fatigue (plus many nonspecific complaints). At no time did any treater ever propose that her rhabdo persisted. However, A.C.'s ongoing symptoms were alleged to be *related* to the rhabdo, and were best characterized as AMPS.

In early January 2019, A.C. received a neuromuscular evaluation. Ex. 2 at 2-3. Her prior positive test results for several infections (rhinovirus and enterovirus at the beginning of November 2018, mycoplasma at the end of that month) were noted, and the neurologist speculated that A.C.'s rhabdo had an infectious etiology, despite an absence of common infection-related symptoms. *Id.* at 5. The treater proposed myopathy as a diagnostic explanation for A.C.'s presentation and recommended genetic testing, more lab work, and an EMG. *Id.* at 5. A.C.'s symptoms that month also resulted in visits with her PCP (Ex. 4 at 19-20), and another ED event (Ex. 8 at 210, 213-14), but no clear explanation was provided (although it was recommended she receive another evaluation for her Klippel-Trenaunay Syndrome).

That February, A.C. was taken to see pediatrician Dr. Renata S. Moon. Ex. 1 at 3. Dr. Moon was informed both of A.C.'s ongoing symptoms and that A.C. had felt better before receipt of the flu vaccine in early November 2018 – an incident her family deemed responsible for what came after. *Id.* Dr. Moon opined that A.C.'s pain had an uncertain etiology, but she did take into account A.C.'s history of “non-traumatic rhabdomyolysis,” which could be attributed to the vaccine or a viral illness. *Id.* at 2. A physical exam revealed no concerns, and a subsequent MRI was similarly unhelpful, leading Dr. Moon to state at a family conference that there was “nothing today that could be causing [A.C.'s] neurological issues or pain with regard to the findings.” *Id.* at 11, 13. After the family conference, Dr. Moon had a face-to-face discussion with A.C. *Id.* at 14. During this discussion, A.C. reported that “the pain is much better” and she “just forget[s] about [the pain]” when she is with a close friend. *Id.* Petitioner also told Dr. Moon that one week earlier, A.C. had a short episode of sciatica-like pain that caused her to leave school early. *Id.* at 13. At the conclusion of this conversation, Dr. Moon offered an AMPS diagnosis for A.C. *Id.* at 14.

A.C. saw additional treaters in March 2019. *See, e.g.,* Ex. 5 at 30, 31-32 (outpatient physical therapy visit on March 5th); Ex. 1 at 24 (March 21st visit with internist pediatrician). The PT specialist noted no obvious evidence of specific pain, and proposed “some psychological overlay to [A.C.'s] physical symptoms[,]” and that A.C. “tends to feed off the power of suggestion from

[Petitioner] in regards to her pain and this may be limiting in her progress.” Ex. 5 at 32. Despite her reporting of ongoing and persistent weakness, A.C. showed tolerance to exertion at a subsequent PT encounter and exhibited no pain. *Id.* at 42. But the pediatrician did propose that some of the lingering complaints of pain could be AMPS-associated. *Id.* A.C. was also taken to a social worker on March 26, 2019, and diagnosed with “[a]djustment disorder with mixed anxiety and depressed mood[.]” Ex. 1 at 29, 35,37.

Dr. Moon saw A.C. again in April 2019 for an unrelated issue. Ex. 1 at 42. Dr. Moon indicated her willingness to write a letter in support of the position that the flu vaccine caused A.C.’s rhabdo, but added that A.C. had tested “positive for viruses at the same time, [and] there is no way to know for certain what caused her issues.” *Id.* at 43. That letter (dated April 26, 2019) sets forth Dr. Moon’s view that “the Influenza vaccination that [A.C.] received on 11/05/2018 was the likely trigger for [her] development of rhabdomyolysis and the subsequent medical issues,” and includes the recommendation that A.C. not again receive the vaccine. *Id.* at 93.

Toward the end of April 2019, A.C. was taken to a rheumatologist. Ex. 7 at 6. She was overall noted to be doing better, and able to go to school, with no adverse exam findings. *Id.* at 7-11. It was also noted at this time that A.C. did not display the kind of pain on muscle palpitation that would be consistent with AMPS. *Id.* at 11. A.C. was diagnosed with hypermobility syndrome, arthralgia, and Osgood-Schlatter disease⁷ in both knees, and referred for a genetic/neurology evaluation. *Id.* The neurologist made similar findings, but noted acceptance of the AMPS diagnosis, which she associated with the purportedly vaccine-caused but fully-resolved rhabdo. *Id.* at 26. The neurologist also speculated, however, that A.C. might have some psychological issues which could explain her unresolved/ongoing pain complaints, and recommended counseling for AMPS treatment. *Id.* at 26-27.

Throughout the following months, A.C. continued to receive regular treatment (including physical therapy) for the same constellation of symptoms she had experienced in the first half of 2019. Some of the records relevant to this treatment include statements that she had experienced an adverse vaccine reaction (although these statements were based more on reporting to the treaters than their own independent determinations). *See, e.g.*, Ex. 9 at 28 (June 2019 PT evaluation). Otherwise, A.C. showed improvement and eventually she stopped PT. *Id.* at 2, 4, 11. In October 2019, Dr. Moon provided a letter to Petitioner exempting A.C. from the flu vaccine in the future (and all other vaccines on the basis of a religious objection). Ex. 10 at 13. By early 2020, Dr. Moon deemed A.C. to have recovered from her rhabdo-associated AMPS entirely. *Id.* at 23, 24.

⁷ “Osgood-Schlatter disease” is a condition that causes pain and swelling below the knee joint. *Osgood-Schlatter disease*, John Hopkins Medicine, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/osgoodschlatter-disease> (last visited November 6, 2024).

II. Fact Witness – Jamie Myers

Petitioner (A.C.’s mother) was the sole fact witness to testify at the hearing. *See generally* Tr. at 4-41. She began her testimony by explaining that A.C. was in good health before the vaccination. *Id.* at 5. She was active in school sports and extracurriculars and did not have any ongoing issues. *Id.* at 5-6.

Ms. Myers then recounted the day A.C. received the flu vaccine on November 5, 2018. Tr. at 6. Ms. Myers picked A.C. up from school that afternoon for a routine appointment with A.C.’s PCP. *Id.* She mentioned that A.C. had played volleyball in P.E. class that day. *Id.* At the appointment, A.C.’s PCP examined a mole on her head and administered the flu shot to A.C. *Id.* A.C. exhibited no symptoms of illness immediately after she received the flu shot, other than some soreness in her arm that night. *Id.* at 7-8.

The next day, on November 6, 2018, A.C. went to school. Tr. at 8. When she returned home that afternoon, she complained of overall achiness and body soreness. *Id.* Ms. Myers encouraged A.C. to take a warm bath and gave her some children’s pain relief. *Id.* at 8-9. Ms. Myers testified that A.C. had attended her P.E. class again that day, and that she believed A.C. participated in a “fitness” rotation, which focused on push-ups and pull-ups. *Id.* at 9.

On the morning of November 7, 2018, A.C. told Ms. Myers, “Mom, I just don’t feel good...I can’t even lift a textbook. There’s no way I could go to school today.” Tr. at 9. A.C. stayed home from school and spent most of the day in bed, and Ms. Myers continued to give her children’s pain meds. *Id.* at 10. The next day, on November 8, 2018, A.C. was increasingly weak and sore, so she stayed home from school again. *Id.*

On Friday morning, November 8, 2018, A.C. woke up and stated she was still too weak to go to school. Tr. at 11. Ms. Myers testified that this seemed too long for a typical vaccine reaction, so she took A.C. to the ED for peace of mind. *Id.* At the ED, A.C. was diagnosed with rhabdo. *Id.* at 12. Ms. Myers explained that physicians had differing opinions about what had caused A.C.’s rhabdo. *Id.* One physician thought her P.E. class may have been extra-strenuous and caused rhabdo, while another thought maybe the vaccine caused it. *Id.* at 12-13. Ms. Myers said she thought A.C.’s P.E. participation was pretty typical – she had done it almost every day of the year. *Id.* at 13. The doctors at the ED told Ms. Myers that A.C.’s CK level was extremely high and that she needed IV fluids. *Id.* at 13. A.C. was admitted to the hospital and was “pretty miserable” during her stay. *Id.*

During A.C.’s first follow-up appointment with her PCP, on November 13, 2018, Ms. Myers shared her concerns about the fact that A.C. was still very weak and sore. Tr. at 14. Ms.

Myers testified that the treater believed the rhabdo was caused by the vaccine, and he told Ms. Myers he planned to file a report with the Government system for vaccine injuries. *Id.* at 15.

Ms. Myers also discussed their visit with a different physician on November 16, 2018. Tr. at 16. He conducted some strength tests on A.C. and ran a lot of bloodwork. Ms. Myers explained that he was looking for an infectious cause, which he found. *Id.* This treater started A.C. on antibiotics, but Petitioner claims that A.C.'s symptoms did not improve, even after two rounds. *Id.* at 16-17. Ms. Myers explained that A.C. tried physical therapy but was not ready for it because she was too weak. *Id.* at 17. During this time, A.C. stayed home from school and was tutored. *Id.* at 18.

In early 2019, A.C.'s symptoms were still present, and she started seeing a new pediatrician, Dr. Moon. Tr. at 18. At this time, A.C. was still suffering from weakness in her back and thighs and had persistent headaches. *Id.* at 19. Dr. Moon theorized that, considering the timing, the vaccine caused A.C.'s rhabdo. *Id.* Ms. Myers believed Dr. Moon also made a Government report. A.C. began water therapy and attended one counseling session around this time. *Id.* at 20.

After Dr. Moon reviewed A.C.'s medical records, she called her parents in for a family meeting and told Ms. Myers and A.C.'s father that A.C. had AMPS, which she explained was an overall muscle weakness and pain issue. Tr. at 21-22. Dr. Moon also said that she believed the rhabdo triggered the AMPS. *Id.* Ms. Myers explained that the family met with a muscle doctor in Seattle who did not have strong opinions on A.C.'s condition. *Id.* at 22. They also visited a neurologist at the local children's hospital who agreed with the AMPS diagnosis and believed the flu vaccine was the likely trigger for rhabdo. *Id.* at 22-23. Ms. Myers testified that she saw no noticeable difference between A.C.'s rhabdo and AMPS symptoms – she thought it was all the same thing. *Id.* at 23.

Eventually, A.C. transitioned from water to land therapy. Tr. at 24. After a year of therapy, A.C. was able to go back to school for her eighth-grade year. *Id.* Ms. Myers worked with the nursing staff at school to make sure A.C. had accommodations – she used the elevator, she had more time to get from class to class, and she kept pain medicine at school. *Id.* She also called home quite a bit and Ms. Myers picked her up if she wasn't feeling well. *Id.*

Ms. Myers then explained that the family had scheduled an appointment for genetic testing because A.C.'s older half-brother was diagnosed with rhabdo shortly before A.C. Tr. at 25. He had played a very strenuous football game and was diagnosed with exertional rhabdo at the E.R. a few days later. *Id.* at 25-26. He was not admitted to the hospital and was just told to drink lots of fluids. *Id.* at 26. Ms. Myers went on to testify that A.C. is doing pretty well overall – she's having a bit of ongoing kidney issues and some random headaches but “she's doing wonderful.” *Id.* at 26-27.

On cross-examination, Ms. Myers acknowledged that A.C. had been diagnosed with Klippel-Trenaunay syndrome as a child, but maintained that the diagnosis later turned out to be inaccurate. Tr. at 29. Ms. Myers also testified that A.C. had not had an adverse reaction to a vaccine previously, and confirmed that A.C. did not have cold symptoms on the day of her hospitalization. *Id.* at 32. When Respondent asked Ms. Myers if A.C. was physically active again by November 14, 2018, Ms. Myers said she was not, and was otherwise having a hard time. *Id.* at 33. Ms. Myers confirmed that Dr. Baker had been searching for an infectious cause, and she agreed that Dr. Baker opined that a mycoplasma infection may have caused A.C.'s rhabdo. *Id.* at 34-35. Ms. Myers also explained that the family switched from their former PCP to Dr. Moon after an initial evaluation with Dr. Moon in February 2019. *Id.* at 36. And Ms. Myers confirmed that Dr. Wendy Eastman, a neurologist, encouraged the family to consider anxiety or depression as the cause of A.C.'s lingering symptoms. *Id.* at 37.

III. Expert Witnesses

A. *Petitioner's Expert – Dr. M. Eric Gershwin*

Dr. Gershwin prepared two written reports and testified on behalf of Petitioner. *See generally* Tr. at 42–129; Report, dated May 23, 2022 (ECF No. 26-1) (“First Gershwin Rep.”); Report, dated April 6, 2023 (ECF No. 40-1) (“Second Gershwin Rep.”). Dr. Gershwin maintains that a combination of three factors – exercise, a rhinovirus/enteroviral infection, and the flu vaccine – contributed to the development of A.C.'s rhabdo, which in turn led A.C. to develop AMPS. First Gershwin Rep. at 2-3.

Prior to his retirement, Dr. Gershwin was a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California Davis School of Medicine. Gershwin CV, dated April 24, 2024 (ECF No. 58) (“Gershwin CV”). He also served as the Chief of the same division for nearly twenty years. Gershwin CV at 1. Dr. Gershwin received his medical degree from Stanford University and completed his residency at Tufts-New England Medical Center. *Id.* at 1-2. He is certified by the American Board of Internal Medicine in Rheumatology, and by the American Board of Allergy and Clinical Immunology. *Id.* at 2. He serves as an editor for several autoimmunity and allergy journals and has co-authored over a thousand articles. *See generally* Gershwin CV.

Dr. Gershwin began his testimony by opining that A.C. would not have developed rhabdo absent receipt of the flu vaccine. Tr. at 47. But Dr. Gershwin expressly did not opine that the flu vaccine *alone* could be, or was, causal of A.C.'s rhabdo. Instead, he maintained that it was a substantial factor in causing it, in concert with other factors. *Id.* at 57, 127; First Gershwin Rep. at 2. He acknowledged, however, that the record in this case did not suggest that A.C.'s vaccine response was aberrant. Tr. at 74.

After testifying that he has treated hundreds of patients with rhabdo, Dr. Gershwin discussed its theorized causes. Tr. at 50-51; Y. Hamel et al., *Acute Rhabdomyolysis and Inflammation*, 38 J. Inherit. Metab. Dis. 621 (2015), filed as Ex. 21 (ECF No. 28-1) (“Hamel”). As Hamel notes, rhabdo features skeletal muscle fiber breakdown, resulting in release of “potentially toxic cellular content” systemically. Hamel at 622. Known triggers include strenuous exercise or infection. Tr. at 51; Hamel at 621. Rhabdo is typically treated by hydration and administration of fluids. Tr. at 52.

Dr. Gershwin maintained that A.C. was accurately diagnosed with both rhabdo and AMPS. Tr. at 52. A.C. had exhibited typical symptoms of rhabdo – fatigue, muscle pain and weakness, and a fever. *Id.* at 53. He noted that A.C. had a CK level of 29,000 – in contrast to a normal upper limit of 240. *Id.* at 55; Ex. 8 at 4. This high CK level indicated that A.C. had a “significant amount of muscle necrosis” that had been worsening over the course of a few days. Tr. at 56. But when A.C. visited Dr. Baker on November 27, 2018, her CK levels were normal, which in Dr. Gershwin’s view indicated that the rhabdo incident had concluded by this date. *Id.* at 63; Ex. 3 at 42.

The record also provided ample evidence of a potential infectious cause for A.C.’s rhabdo, although Dr. Gershwin emphasized that it was somewhat unclear *what* specific infection was implicated. For example, A.C. had been tested for enterovirus and rhinovirus, and the results were positive. Tr. at 56. But the same PCR test for mycoplasma was negative. *Id.* at 56-57, 64; Ex. 3 at 72. Although a *later* blood test (performed post-hospitalization when A.C. saw Dr. Baker) was now positive for mycoplasma – raising the possibility that A.C. had experienced a mycoplasma infection at some point – Dr. Gershwin expressed doubt that she was so infected *at the time she was initially diagnosed* with rhabdo. Tr. at 56-57, 64. He deemed PCR “the gold standard for diagnosis of infectious disease,” giving weight to the initial negative mycoplasma result. *Id.* at 64-65. Dr. Gershwin instead was of the view that A.C. most likely had an enterovirus infection at the time of her diagnosis (but did not have an adenoviral infection or pneumonia). *Id.* at 75-76. He also acknowledged that A.C.’s diarrhea could establish that she was having an immunological response to infection, but emphasized that A.C. was not sick in this manner at the time she was hospitalized. *Id.*

Dr. Gershwin admitted that initial treaters considered weightlifting and viral illness as alternative possible causes of A.C.’s rhabdo. Tr. at 58; Ex. 8 at 8. He expressly denied, however, that her exercising had been strenuous enough alone to have triggered rhabdo. Tr. at 127. But regardless of *what* infection she had been experiencing, Dr. Gershwin insisted that it was only one aspect of a multi-causal process resulting in rhabdo, as established in Hamel. Tr. at 65. To further elaborate on this causal theory, Dr. Gershwin highlighted the immunological impact of certain factors he deemed likely to produce rhabdo. Tr. at 69. Exercise, for example, can encourage release

of pro-inflammatory cytokines. *Id.* at 69-70; First Gershwin Rep. at 4; S. Docherty et al., *The Effect of Exercise on Cytokines: Implications for Musculoskeletal Health: A Narrative Review*, 14 *BMC Sports Sci., Med. and Rehabilitation* 5 (2022), filed as Ex. 30 (ECF No. 29-2). In addition, medical science had established that pro-inflammatory cytokines rapidly increase in circulation within hours of receiving a vaccine. *Id.* at 73; G. A. Roth et al., *Designing Spatial and Temporal Control of Vaccine Response*, 7 *Nature Rev. Materials* 174 (2022), filed as Ex. 54 (ECF No. 47-4). Dr. Gershwin admitted that no record evidence suggested A.C. had experienced an aberrant response to exercise or to the flu vaccine. Tr. at 71, 74. But in his view, A.C.'s rhabdo was likely the product of a multifactorial process rather than a reaction to a one-time strong event. *Id.* at 70; First Gershwin Rep. at 2. The timing of A.C.'s vaccination, combined with her exercise (and possible infection), resulted in a "perfect storm of events" that triggered her rhabdo. Tr. at 72-73.

In support his contention that rhabdo often has co-occurring triggers, Dr. Gershwin offered some medical literature. Tr. at 76; S.P. Sayers & P.M. Clarkson, *Exercise-Induced Rhabdomyolysis*, 1 *Current Sports Med. Rep.* 59, 60 (2002), filed as Ex. 31 (ECF No. 29-3) ("Sayers") ("There are both primary and secondary factors contributing to the condition of rhabdomyolysis. A primary factor would be the exercise stress, whereas secondary factors include a variety of conditions not usually associated with muscle injury."); E. Sevetoglu et al., *Exertional Rhabdomyolysis After Influenza (H3N2) Infection in a Basketball Player*, 31 *Annals of Tropical Paediatrics* 93 (2011), filed as Ex. 24 (ECF No. 28-4) ("Sevetoglu"). Sevetoglu was a case report in which a 14-year-old professional basketball player developed rhabdo one week after he tested positive for an influenza A infection. *Id.* at 1. The authors concluded that the infection at issue may have acted "in a synergistic way and lead to rhabdo." *Id.* at 77.

Although (as discussed below) Respondent's experts emphasized that rhabdo can occur *solely* in response to an infection, Dr. Gershwin questioned that proposition's applicability to this matter. Tr. at 83. He felt, at least in the context of the facts of this case, that determining the cause of A.C.'s rhabdo required taking into account *both* A.C.'s vaccination as well as her exercise. *Id.* If A.C. had also at that time been experiencing a more active infection that could have been a sole cause, he would have expected her to exhibit actual symptoms of infection, like pneumonia, which she did not. *Id.* at 84; Second Gershwin Rep. at 1.

For evidence supporting the possibility that the flu vaccine (as opposed to a wild infection) could be causally associated with rhabdo, Dr. Gershwin offered several case studies in which patients who were also receiving statins⁸ developed rhabdo within 24 hours of vaccination. Tr. at 78-80; R. Callado et al., *Rhabdomyolysis Secondary to Influenza A H1N1 Vaccine Resulting in Acute kidney injury*, 11 *Travel Med. Infectious Disease* 130 (2013), filed as Ex. 25 (ECF No. 28-5) ("Callado"); E. Plotkin et al., *Influenza Vaccine – a Possible Trigger of Rhabdomyolysis*

⁸ Statins are prescription drugs used to lower cholesterol levels. *Statins*, Cleveland Clinic, <https://my.clevelandclinic.org/health/treatments/22282-statins> (last visited November 15, 2024).

Induced Acute Renal Failure due to the Combined use of Cerivastatin and Bezafibrate, 15 *Nephrol Dial Transplant* 740 (2000), filed as Ex. 27 (ECF No. 28-7) (“Plotkin”); Raman et al., *Influenza-Induced Rhabdomyolysis Leading to Acute Renal Transplant Dysfunction*, 21 *Nephrol Dial Transplant* 530 (2006), filed as Ex. 28 (ECF No. 28-8) (“Raman”); S.V. Shah & K. Reddy, *Rhabdomyolysis with Acute Renal Failure Triggered by Seasonal Flu Vaccination in a Patient Taking Simvastatin*, *BMJ Case Rep.* 1 (2010), filed as Ex. 55 (ECF No. 47-5) (“Shah”).

The patients in these studies were all 55+ year old men who had been taking statins at the time they received a vaccine. The 58-year-old man in Callado, for example, developed rhabdo and acute kidney failure within 24 hours of receipt of the H1N1 vaccine. Callado at 131. Although Callado’s authors acknowledged that the association between statin use and rhabdo is well established, they also noted that the subject patient was on a low dose of statin and therefore concluded that the H1N1 vaccine was “essential for rhabdomyolysis development.” Tr. at 78; Callado at 132. In Plotkin and Raman, a 68-year-old man and a 57-year-old man developed rhabdo within 24 hours of receiving the flu vaccine. The rhabdo caused both men to suffer acute renal failure. Tr. at 78-80; Plotkin at 740; Raman at 530. Dr. Gershwin agreed that statins were associated with “significant myopathies that can include some degree of myositis.” Tr. at 100.

A.C.’s AMPS diagnosis, Dr. Gershwin opined, also had evidentiary support – and was a likely by-product of her resolved rhabdo. Tr. at 65. AMPS’s etiology is generally unknown, but most episodes seem to be causally related to injury, illness, or psychological factors. Tr. at 52; D.D. Sherry, *An Overview of Amplified Musculoskeletal Pain Syndromes*, 58 *J. of Rheumatology Suppl.* 44 (2000), filed as Ex. 51 (ECF No. 47-1) (“Sherry”). Treatment of AMPS is dependent on the individual and can include counseling, physical therapy, antidepressants, and familial support. *Id.* at 53; Sherry at 48. A.C.’s PCP, Dr. Moon, had offered the view in February 2019 that the flu vaccine A.C. received was likely the cause of A.C.’s development of rhabdo and subsequent medical issues. *Id.* at 68; Ex. 1 at 93. And Dr. Eastman agreed with A.C.’s AMPS diagnosis and this causal theory. Tr. at 68; Ex. 7 at 26.

On cross examination, Dr. Gershwin agreed that even if the respiratory PCR test A.C. received initially had been negative for mycoplasma, a subsequent blood test performed on November 27, 2018, confirmed its presence. Tr. at 90, 126. He also acknowledged (as explicitly stated in Hamel) that a febrile illness (likely attributable to an infection) is the most frequent trigger associated with rhabdo, although he maintained that this did not mean rhabdo could not also be multifactorial. *Id.* at 93; Hamel at 621 (“[r]habdomyolysis [is] frequently precipitated by febrile illness or exercise”). Dr. Gershwin admitted again that A.C. had apparently had a normal cytokine response to exercise on the day of, and the day after, her vaccination. Tr. at 96. Nevertheless, he maintained that an individual’s susceptibility to injury meant that a vaccine could still be causal of an injury even in the absence of evidence that they had in fact experienced an aberrant response. *Id.* at 97.

Dr. Gershwin further acknowledged that the case reports he offered of (flu) vaccine-induced rhabdo involved patients who were taking statins – and that none of the reports provided a specific causal mechanism to explain how the vaccine interacted with the statin regime. Tr. at 108. He also admitted that he had offered case reports where infections alone caused rhabdo. *See e.g.*, T. Oishi et al., *Rhabdomyolysis Associated with Antimicrobial Drug-Resistant Mycoplasma Pneumoniae*, 18 Emerging Infectious Diseases 849 (2012), filed as Ex. 40 (ECF No. 43-6). But he deemed such case reports to reflect more acute clinical infections, while A.C. exhibited “no sign[s] of clinical infection” at the time of her diagnosis. Tr. at 109, 113 (patients whose rhabdo is infectious in origin are “usually a lot sicker than [A.C.] was”). Finally, Dr. Gershwin acknowledged that after resolution of her rhabdo, A.C. may have experienced pain attributable to some of her comorbid conditions, like Osgood-Schlatter disease, but maintained that this kind of pain was distinguishable from the muscle pain she was experiencing as a result of AMPS. *Id.* at 124.

B. *Respondent’s Expert – Dr. Hayley Gans*

Dr. Gans, a pediatric infectious disease specialist, authored one report and testified on behalf of Respondent. *See generally* Tr. at 130–229; Report, dated December 8, 2022 (ECF No. 34-1) (“Gans Rep.”). Dr. Gans opined that A.C. suffered from an infection (either mycoplasma or enterovirus or both) which led to the development of her short-lived rhabdo. Gans Rep. at 6.

Dr. Gans is a Clinical Professor in the Department of Pediatrics and Division of Pediatric Infectious Disease at Stanford University. Gans CV, dated December 8, 2022 (ECF No. 34-2) (“Gans CV”). Dr. Gans received her medical degree from SUNY at Syracuse and completed her residency and fellowship at Stanford University. Gans CV at 1. She is board certified in both Pediatrics and Pediatric Infectious Diseases. *Id.* at 2. In her clinical capacity Dr. Gans has cared for hundreds of infants and children with infections and has been involved with disease prevention through mitigation and immunizations. Gans Rep at 1. She currently conducts immunology research in the field of infectious diseases and studies vaccine responses in several populations including normal hosts, HIV-infected children, premature children, children who have received organ transplants, and children with autoimmune diseases. *Id.* Dr. Gans serves on several regulatory boards overseeing the safety of vaccines and is involved with case adjudication for vaccine studies. *Id.*

Dr. Gans agreed that A.C. had been correctly diagnosed with rhabdo, which she described as a “necrotic condition of the muscles.” Tr. at 169. She noted in her report that although “[t]he mechanism and pathophysiology” for rhabdo is unknown, “there is evidence for direct viral or bacterial invasion of the muscle causing cell death or necrosis” when onset is associated with an infection (thus corroborating the infection’s role). Gans Rep. at 4. In particular, biopsies have

revealed immune cell infiltration, “which suggests viral invasion.” *Id.*; U. Singh & W.M. Scheld, *Infectious Etiologies of Rhabdomyolysis: Three Case Reports and Review*, 22 *Clinical Infectious Diseases* 642, 644 (1996), filed as Ex. A-5 (ECF No. 45-5) (“Singh”). Bacterial infectious causes could be evidenced, she added, by findings of toxins in muscle biopsies. *Id.*

Dr. Gans proposed that there are many different possible causes of rhabdo, including trauma and infection. Tr. at 170; Gans Rep. at 4. Infection is in fact one of its most common explanations in children – and Dr. Gans offered medical literature to support this contention. Tr. at 171; J.R. Blanco et al., *Rhabdomyolysis of Infectious and Noninfectious Causes*, 95 *South Med. J.* 542 (2002), filed as Ex. A-1 (ECF No. 45-1) (“Blanco”). In Blanco, several different causes of rhabdo were identified, but the most common cause (in 31% of patients) was infection. Tr. at 172; Blanco at 1. A mycoplasma infection has also been specifically associated with rhabdo (as evidenced by a number of case reports). Tr. at 173; M. Gulenay et al., *Rhabdomyolysis: A Case Report of an Extrapulmonary Presentation of Mycoplasma Pneumoniae*, 5 *Clinical Pract. Cases Emergency Med.* 194 (2021), filed as Ex. A-2 (ECF No. 45-2); F.Y. Khan & H. Syed, *Rhabdomyolysis Associated with Mycoplasma Pneumoniae Pneumonia*, 18 *Hong Kong Med J.* 247 (2012), filed as Ex. A-3 (ECF No. 45-3); B. Sertogullarindan, et al., *Rhabdomyolysis Associated with Mycoplasma Pneumoniae Infection*, 123 *Polish Archives of Internal Med.* 66 (2013), filed as Ex. A-4 (ECF No. 45-4); K. Minami et al., *Rhabdomyolysis Associated with Mycoplasma Pneumoniae Infection*, 22 *Pediatric Infectious Disease J.* 291 (2003), filed as Ex. A-8 (ECF No. 45-8).

Dr. Gans opined that A.C.’s nontraumatic (meaning not due to direct muscle injury, especially since her level of exercise had not been strenuous) rhabdo was most likely attributable to an infection. Tr. at 153, 171. In support, she offered various facts gleaned from A.C.’s medical history. At A.C.’s visit to the ED on Nov 9, 2018, for example, A.C.’s CK levels were elevated, which indicated existing muscle breakdown occurring at that time. Tr. at 147-48; Ex. 8 at 37. But there was no evidence from these records suggesting that A.C. was then experiencing excessive inflammation either. Tr. at 150, 154.⁹ A.C. also initially tested positive for enterovirus and rhinovirus, although her PCR test was negative for mycoplasma. *Id.* at 150-52.

⁹ Petitioner objected to this line of testimony, arguing that it expressed opinions not contained in Dr. Gans’s report. *See generally* Tr at 154-61. In reaction, Respondent contended that Dr. Gans was merely addressing Dr. Gershwin’s supplemental report, in which he proposed that cytokine upregulation prompted by three factors (exercise, vaccination, and an unspecified infection) had harmed A.C.’s muscle due to a damaging inflammatory process. *See, e.g.*, Second Gershwin Rep. at 7 (discussing how viral myositis could be caused by a “cytokine driven” process – meaning inflammatory).

I allowed the questioning over Petitioner’s objection, and do not find it caused Petitioner any prejudice. Dr. Gans was not permitted a supplemental report, and therefore had to respond to Dr. Gershwin’s final report at hearing, and Dr. Gershwin in turn had the opportunity to respond in kind during Petitioner’s rebuttal case. *See* Tr. at 222-24. And in any event, Dr. Gans cited no record evidence corroborating her point – nor is there *other* record evidence supporting the conclusion that A.C. was experiencing a significant inflammatory process upon hospitalization *independent* of her

Later in November 2018 (and after A.C.'s initial rhabdo treatments), A.C. tested positive for mycoplasma infection. Tr. at 161, 163; Ex. 3 at 72. In particular, A.C.'s IgG and IgM¹⁰ levels were elevated – and Dr. Gans deemed the elevated IgG levels particularly significant, since they are a biomarker for the existence of a prior infectious process. Tr. at 164. Thus, Dr. Gans surmised, A.C. had likely experienced an active mycoplasma infection a couple of weeks earlier, making it logical to link that infection to the rhabdo she manifested in early November 2018. *Id.*; Gans Rep. at 5. Other evidence from the time of A.C.'s initial ED presentation and hospitalization provided additional circumstantial support for this contention, in Dr. Gans's view. For example, A.C.'s GI symptoms of reported diarrhea were consistent with an extrapulmonary mycoplasma infection (since such symptoms are seen in about 25 percent of children with mycoplasma). *Id.* at 176, 210; Gans Rep. at 4; K.B. Waites et al., *Mycoplasma Pneumoniae from the Respiratory Tract and Beyond*, 30 *Clinical Microbiology Rev.* 747, 763 (2017), filed as Ex. A-10 (ECF No. 45-10) ("Waites").¹¹ In addition, rhabdo is highly associated with renal failure, but rhabdo attributable to a mycoplasma infection rarely progresses to the point where dialysis is called for – and A.C. never experienced such significant kidney-associated symptoms. Tr. at 186-87; Gans Rep. at 5. At the same time, Dr. Gans admitted, A.C. had not initially presented with a fever, which she acknowledged to be a "really discerning feature" of infectious rhabdo, but A.C. did have a fever on November 10th (suggesting to Dr. Gans that medication A.C. received had masked or ameliorated any initial fever). Tr. at 178-79.

In identifying a mycoplasma infection as potentially explanatory for A.C.'s rhabdo, Dr. Gans attempted to contend with A.C.'s negative PCR test result. Dr. Gans maintained that a blood serology test is the primary way to diagnose mycoplasma, deeming the diagnostic value of the PCR test, by contrast, to be "very variable." Tr. at 164, 167. Although the PCR test is more accurate when someone has a respiratory disease, A.C. was exhibiting *extrapulmonary* symptoms of a mycoplasma infection, and therefore the PCR test would not have been expected to reveal the infection. *Id.* at 168. Dr. Gans later attempted to show that a serologic test would have extra reliability with respect to mycoplasma. *Id.* at 212; Waites at 768. But on cross, it was demonstrated

rhabdo-related symptoms. (And as noted above, Dr. Gershwin *agreed* A.C.'s vaccination did not produce an aberrant response in any event).

¹⁰ IgG and IgM are types of immunoglobulins, which are also referred to as antibodies. Antibodies are proteins that the immune system makes to fight germs. IgG antibodies, which are present in all body fluids, are very important for fighting bacteria and viruses. The body keeps a "blueprint" of all the IgG antibodies that have been created so if a person is exposed to the same germs again, the immune system can quickly make more antibodies. IgM antibodies, which are found in the blood and lymph fluid, are the first antibodies the body makes after it is exposed to germs. They provide short-term protection while the body makes other antibodies. *Immunoglobulins Blood Test*, Medline Plus, <https://medlineplus.gov/lab-tests/immunoglobulins-blood-test/> (last visited November 25, 2024).

¹¹ Dr. Gans did admit on cross-examination, however, that something besides mycoplasma could cause a single episode of diarrhea. Tr. at 211.

that Waites specifically states that “molecular-based methods have superior analytical and clinical sensitivity in most instances over indirect methods such as serology.” Waites at 771.

Another possible explanatory infection for A.C.’s rhabdo, in Dr. Gans’s view, was the enterovirus, which A.C. had tested positive for at the start of her hospitalization. In support, Dr. Gans referenced a study in which an outbreak of acute myalgia and rhabdomyolysis in Brazil was found to be associated with echovirus 30, a type of enterovirus. Tr. at 180-81; I.P. Sousa et al., *Echovirus 30 Detection in an Outbreak of Acute Myalgia and Rhabdomyolysis, Brazil 2016-2017*, 25 *Clinical Microbiology and Infection* 252.e5 (2019), filed as Ex. A-6 (ECF No. 45-6). Another article discussed the association between viral infections and skeletal muscle damage characteristic of rhabdo. Tr. at 181-82; Singh at 643 (“Influenza is the most common viral etiology, followed by HIV infection and enteroviral infection.”).

Dr. Gans nevertheless favored mycoplasma as most likely causal, since “mycoplasma has a longer incubation period than enteroviruses typically do,” making the timing of A.C.’s mycoplasma symptomology (her abdominal pain) consistent with when her rhabdo manifested. Tr. at 183, 184; Gans Rep. at 4. And she deemed a mycoplasma infection more sound as a casual explanation than the multifactorial explanation Dr. Gershwin favored. Tr. at 201-02. But she also acknowledged that she would have a different opinion about causation if A.C. could be shown not to have had a mycoplasma infection at the time of her hospitalization for rhabdo. *Id.* at 216.

Dr. Gans disputed the reliability of Dr. Gershwin’s cytokine-dependent mechanistic theory. Although she acknowledged that vaccines upregulate proinflammatory cytokines, and that “cytokines have a multitude of effects in the body and can cause inflammation and can cause tissue damage . . . there’s not a lot of support in the current case” for that having occurred. Tr. at 189, 207-08. In addition, Dr. Gans contended that Dr. Gershwin had offered little independent evidence to reliably establish that an overall inflammatory systemic response can result in the actual muscle fiber damage characteristic of rhabdo. *Id.* at 202. And even if this were the case, A.C. had a very normal response to the vaccine, with no evidence suggestive of damaging cytokine levels resulting in excessive inflammation, so there was no reason to conclude that A.C.’s rhabdo reflected such a cytokine-driven process. *Id.* at 202-3.

Moreover, the articles that Dr. Gershwin submitted to show a vaccine-rhabdo connection were largely case reports all involving elderly individuals with multiple comorbid conditions, who were also receiving multiple medications including statins (which are well-understood by the medical community to be associated with rhabdo). Tr. at 191-92, 194-95. A.C., by contrast, was not on a statin therapy, and was also not receiving any other medication that could mimic a statin’s impact on the body. *Id.* at 197. Dr. Gans further emphasized, contra Dr. Gershwin, that rhabdo can be caused by a single factor, and therefore co-occurring factors are not necessary to trigger it. *Id.* at 204.

IV. Procedural History

As noted, this case was initiated in the spring of 2021. A year later, Respondent filed his Rule 4(c) Report contesting entitlement. (ECF No. 20). Petitioner filed her first expert report from Dr. Gershwin in May 2022, and by April 2023, expert discovery was complete. After the trial in May 2024, the parties offered post-hearing briefs. *See* Respondent’s Post-Hearing Brief, dated August 7, 2024 (ECF No. 65) (“R. Brief”); Petitioner’s Post-Hearing Brief, dated August 7, 2024 (ECF No. 66) (“P. Brief”); Petitioner’s Reply, dated August 19, 2024 (ECF No. 67). The matter is now fully ripe for resolution.

V. Applicable Legal Standards

A. *Petitioner’s Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).¹² There is no Table claim for the injury of rhabdo.

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “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*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. V. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions;

¹² Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d* 104 F. App’x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): “(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 proximate temporal relationship between vaccination and injury.”

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory’s scientific or medical *plausibility*. See *Kalajdzic v. Sec’y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments “for a less than preponderance standard” deemed “plainly inconsistent with our precedent” (citing *Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also *Howard v. Sec’y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) (“[t]he standard has been preponderance for nearly four decades”), *aff’d*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*

v. United States, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec’y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *De Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. Den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*,

503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11I(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner’s testimony and his contemporaneous medical records, the special master’s decision to rely on petitioner’s medical records was rational and consistent with applicable law”), *aff’d*, *Rickett v. Sec’y of Health & Hum. Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec’y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff’d*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter’s symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528;

see also *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den’d*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the

factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). See *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec’y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. See, e.g., *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); see also *Isaac v. Sec’y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den’d*, 108 Fed. Cl. 743 (2013), *aff’d*, 540 F. App’x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”);

see also Porter v. Sec’y of Health & Hum. Servs., 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner’s case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec’y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision”) (citation omitted); *see also Paterek v. Sec’y of Health & Hum. Servs.*, 527 F. App’x 875, 884 (Fed. Cir. 2013) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

ANALYSIS

I. **Overview of Rhabdomyolysis**

The parties agree that A.C. was properly diagnosed with rhabdo, and that it resolved within a month or two of onset. P. Brief at 6; R. Brief at 23. Some of the constituent aspects of the condition should be highlighted, for purposes of analysis. Rhabdo is a syndrome that results from “the rapid breakdown of skeletal muscle fibers, which leads to leakage of potentially toxic cellular content into the system circulation.” Hamel at 622. The exact pathology of rhabdo is unclear, but its final phases involve either direct muscle injury or a failure of energy supply within muscle cells. P. Torres et al., *Rhabdomyolysis: Pathogenesis, Diagnosis, and Treatment*, 15 *The Ochsner J.* 58, 59 (2015), filed as Ex. 33 (ECF No. 29-5) (“Torres”). When muscle injury or energy depletion occurs, the result is an excessive intracellular influx of sodium and calcium ions, which ultimately causes the necrosis of muscle fibers found with rhabdo. Torres at 59.

Rhabdo is characterized by elevated levels of CK activity. Hamel at 622. Accepted causes of rhabdo include febrile illness, exercise, and most commonly, infections. *Id.* at 621, 623; Blanco at 543. Exercise-induced rhabdo usually develops as the result of “prolonged and high intensity exercise (e.g., marathon, triathlon, soccer, body-building, or CrossFit).” J. Kim et al., *Exercise-Induced Rhabdomyolysis Mechanisms and Prevention: A Literature Review*, 5 *J. of Sport and Health Sci.* 324, 326-27 (2016), filed as Ex. 22 (ECF No. 28-2). Nothing has been offered in this case, by contrast, to establish that *light* exercise would be enough to trigger rhabdo – and Dr.

Gershwin acknowledged that the level of exercise A.C. had engaged in prior to her onset was not strenuous enough to be deemed a primary cause. Tr. at 127.

I am only aware of one other instance in which a special master considered whether rhabdo could be vaccine-caused – and the determination was not favorable to the relevant petitioner. *See generally D.G. v. Sec’y of Health & Hum. Servs.*, No. 11-577V, 2019 WL 2511769 (Fed. Cl. Spec. Mstr. May 24, 2019). In *D.G.*, the petitioner’s expert opined that the flu vaccine had caused petitioner’s rhabdo via the mechanism of molecular mimicry (resulting in inflammation of the myelin in portions of the autonomic nervous system, which triggered the rhabdo). *D.G.*, 2019 WL 2511769, at *186. The special master did not find this theory persuasive, however, and was equally unconvinced by the two case reports the petitioner filed that theorized rhabdo might be caused by vaccines. *Id.* at 193. Ultimately, the special master found that respondent’s proposed cause – a combination of a viral infection and vigorous exercise – was much more likely. *Id.*

II. Petitioner Has Not Preponderantly Established that the Flu Vaccine Can Cause Rhabdomyolysis, or Did So to Her Specifically¹³

Althen Prong One

The first *Althen* prong requires a claimant to provide a “persuasive medical theory” demonstrating that the vaccine at issue can cause or significantly aggravate the type of injury alleged. *Althen*, 418 F.3d at 1278. Here, Petitioner does not contend that the flu vaccine *alone* could cause rhabdo (and I would not be able to find on this record that this had been accomplished, even if it had been her goal). Tr. at 57; First Gershwin Rep. at 2. Rather, Petitioner focuses intently on the concept that rhabdo could be multifactorial in origin, through interacting, contemporaneous triggers, including the flu vaccine as well as exercise and an intercurrent infection. Tr. at 76; Sayers at 60. But this theory also lacks preponderant, reliable support.

The evidence and expert testimony in this case favors the conclusion that in *most* cases rhabdo is likely attributable to a single occurrence: infection alone, for example, or a bout of excessive/inordinately strenuous exercise. *See, e.g.*, Torres at 59-64 (“[T]heoretically, any form of

¹³ The failure to establish just one of the three *Althen* prongs of the causation test is sufficient grounds for dismissal. *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). Therefore, I need not discuss Petitioner’s success or failure in establishing the third prong, since I have determined the first and second prongs are unmet.

My determination renders moot the need to evaluate the relationship between A.C.’s AMPS diagnosis and her rhabdo. Petitioner does not allege that A.C.’s AMPS was directly vaccine-caused, but rather that it was a rhabdo sequelae. Accordingly, because I am finding that the purported cause of AMPS in this case- A.C.’s rhabdo - was not *itself* vaccine-caused, my analysis ends there. (In any event, AMPS’s significance to this case was largely attributable to the fact that because A.C.’s rhabdo was short-lived, some kind of proof of sequelae was needed to meet the Vaccine Act’s six-months “severity requirement.” Vaccine Act, 42 U.S.C.A. § 300aa-11(c)(1)(D). (Petitioner did, however, offer reasonable support for both the AMPS diagnosis and its association with A.C.’s rhabdo).

muscle damage and, by extension, any entity that leads to or causes muscle damage, can initiate rhabdomyolysis. Common causes include trauma, statins, infection, exercise, high temperatures, and oxygen deprivation.”). Thus, there is usually no need for a confluence of factors to produce rhabdo – and nothing has been offered (beyond Dr. Gershwin’s say-so) to substantiate the contention that a vaccine would be such a necessary coincident factor.

Of course, Program petitioners are not required to offer direct proof of causation – a class of evidence understood to be in short supply when it comes to determining if a vaccine can cause an injury. And thus, the lack of reliable independent evidence directly considering a vaccine as a component in a tri-partite cause of rhabdo is not grounds for rejecting the proposed theory. But even the circumstantial and indirect proof offered in this case does not, when viewed in totality, amount to a preponderant showing that the flu vaccine likely could cause rhabdo, even via a proposed multifactorial process. Rather, the theory offered appears reverse-engineered to fit A.C.’s circumstances (i.e., that she received a vaccine, then developed rhabdo a few days later, and after attending gym class, with some evidence that she might also at that time have been experiencing some kind of infection).

For example, Petitioner relies on a number of case reports – a class of evidence usually given limited weight in Program cases, since case reports do not stand as reliable proof of a causal relationship between a vaccine and a given injury. *See W.C. v. Sec’y of Health & Human Servs.*, No. 07-456V, 2011 WL 4537887, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) (“[c]ase reports are generally weak evidence of causation because case reports cannot distinguish a temporal relationship from a causal relationship”), *mot. for review den’d*, 100 Fed. Cl. 440 (2011), *aff’d*, 704 F.3d 1352 (Fed. Cir. 2013). This type of proof does not deserve significant weight.

But even beyond this point, the specific case reports filed in this matter are factually distinguishable. *See Callado, Plotkin, Raman, Shah*. Not only did almost all involve adults, but adults *who were receiving statin* treatments. Unlike vaccines, statins *are* well-associated with rhabdo. Shah at 2 (“[s]tatins are well-recognized to be associated with muscle syndromes such as myalgia, myositis and myopathy”); Plotkin at 740 (“[r]habdomyolysis has most often been reported with a statin/gemfibrozil combination”). At best, then, these case reports might support an alternative theory: that vaccination *in the context of* receipt of a statin could promote rhabdo. Shah at 2 (“[i]nfluenza vaccination may rarely trigger rhabdomyolysis *in similar patients being treated with a statin*”) (emphasis added). The fact that these reports support a multifactorial cause for rhabdo *when a statin is involved* does not mean that other multifactorial settings are equally likely, since the statin itself seems to be the “x factor” in those cases. (And here, there is no comparable factor, like strenuous exercise or an obviously acute infection).

These case reports also do not implicate *light* exercise as a contributory factor, in concert with cytokine-driven inflammation attributable to an existing infection and/or vaccination. It is not

disputed that A.C. had not been engaged in the kind of strenuous exercise usually associated with rhabdo. But as Respondent pointed out, Dr. Gershwin does not even sufficiently explain why lighter exercise would trigger rhabdo in concert with an infection *plus* a vaccination. R. Brief at 35.

Dr. Gershwin's likely answer to the foregoing could be summarized by a single word: "cytokines." And indeed, Petitioner's theory seems to be that all three factors (a putative intercurrent infection, plus vaccination and light exercise) could lead to upregulation of proinflammatory cytokines – meaning that even if each alone could not cause rhabdo, they become pathologic in combination. Tr. at 70-74; First Gershwin Rep. at 6. But it has not been shown that even the known direct causes of rhabdo are propagated primarily through a cytokine-driven mechanism (as opposed to the direct effect of either a live viral/bacterial infection, or trauma to a muscle). *See* Torres at 59-64; Blanco at 1. Certainly no rhabdo-specific items of literature filed in this case establish that rhabdo is more likely under such circumstances.

Moreover, this causation theory relies on an oft-asserted but rarely-accepted contention: that inflammatory harm attributable to *expected* vaccine-encouraged cytokine production likely drives disease. Claimants, however, cannot establish causation simply by noting that vaccines generally cause cytokine upregulation. While this is scientifically accurate, "[it] amounts to nothing more than an explanation of how vaccines generally are expected to function...[i]t does not explain how the initial innate response becomes pathologic." *McClellan v. Sec'y of Health & Hum. Servs.*, No. 14-714V, 2019 WL 4072130, at *27 (Fed. Cl. Spec. Mstr. July 23, 2019). This is especially so given that the flu vaccine itself (which is not adjuvanted, and contains inactivated viral particles rather than a live virus) does not generate a strong immune response to begin with. *See Velasquez v. Sec'y of Health & Hum. Servs.*, No. 19-1703V, 2024 WL 829599, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2024). Nor was it shown why the cytokine upregulation deemed to be harmful would cause muscle damage, or how. As Dr. Gans noted in her report, the muscle fiber damage reflected in rhabdo may be more attributable to a direct, live viral/bacterial pathogenic invasion (or actual physical trauma to the muscle). Gans Rep. at 4.

Finally, Petitioner's theory was dependent on Dr. Gershwin's professional embrace of, and explanation for, the theory. But although he is generally qualified in the areas of rheumatology and immunology, and while he has (at least by his own account) treated patients with rhabdo, he lacks demonstrated expertise specific to the study of rhabdo and its causal factors. *See generally* Gershwin CV; Tr. at 50. He could not breathe life into the theory by invoking personal experience evaluating the condition, and the theory offered possessed a very generalized quality that would seem potentially applicable to *all* covered vaccines in the Program.

I readily acknowledge that when "viewed from ten-thousand feet" there remains a sheen of the barest plausibility to Dr. Gershwin's causation theory. Vaccines *do* cause temporary

upregulation of cytokines, which can result in transient post-vaccination malaise. Physical over-exertion (a known trigger for rhabdo), coupled with an infection, *could* theoretically interact with each other and vaccination, all combining into a pathologic process. It is not an utterly far-fetched proposition that a flu vaccine could cause rhabdo in the manner outlined by Dr. Gershwin.¹⁴

Plausibility, however, is *not* the evidentiary standard applicable to *any* of the three *Althen* prongs. *Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018) (“[t]o demonstrate causation, the petitioner’s ‘burden is to show by preponderant evidence’ *each* of the requirements set forth in *Althen* . . .”) (emphasis added) (quoting *Althen*, 418 F.3d at 1278); *Moberly*, 592 F.3d at 1322. And this is properly the case. For if Vaccine Act claims could succeed on such an easy-to-meet standard, it is hard to envision (absent strong direct proof *refuting* causation) circumstances in which *any* vaccine could not be found capable of *plausibly* causing an injury (especially if the injury involves or is mediated by the immune system). Under such circumstances, “post hoc ergo propter hoc” would become the governing principle of the Vaccine Program, and petitioners would *only* lose in cases where some medical record fact made vaccination unlikely to explain the injury, or where an alternative cause had been preponderantly established.

The Program is not intended to compensate post-vaccination injuries simply due to the temporal relationship between injury and vaccination. Rather, claimants must do the “heavy lifting” of marshaling preponderant evidence that a given vaccine can *likely* cause the injury at issue. *Hodges v. Sec'y of Dep't of Health & Hum. Servs.*, 9 F.3d 958, at *961 (Fed. Cir. 1993). When this is not accomplished, the first *Althen* prong is not satisfied.

Althen Prong Two

Although Petitioner can point to some record evidence in support of the “did cause” prong, the evidence tips against finding that this *Althen* prong has been satisfied. One fact deserving of weight is that the record does *not* establish that A.C. had engaged in an unusual or heightened amount of exertion when she developed rhabdo. On the contrary: A.C. had attended a routine gym class the day of and the day after vaccination. P. Brief at 1-2; Tr. at 9. As Petitioner noted during her testimony, A.C.’s activity level in the gym class was “pretty typical – what [A.C.] had done every day of the year that year, and probably every year previously.” Tr. at 13. Dr. Gershwin also agreed the record did not establish that A.C. had an aberrant response to exercise. Tr. at 71. And A.C.’s providers doubted that her limited exercise was contributory. *See, e.g.*, Ex. 3 at 4-5 (“I do not think that this is related whatsoever to her physical education class, as she did not workout

¹⁴ I also allow that a better-substantiated theory could meet the preponderant level of proof – especially in the context of a person who had *excessively* worked out before symptoms onset, or who demonstrated obvious clinical signs of acute infection at the time of vaccination. The contention that a vaccine “could cause” rhabdo is by no means an exhausted Program concept, and thus could potentially be provable in other cases if stronger evidence is offered sufficient to cross the preponderant “line.”

hard enough to cause any significant issues...She did not have any overexertion or any other theoretical cause that would have triggered exertional rhabdomyolysis.”).

Because of the above, Petitioner can only cite to the *fact* of A.C.’s pre-onset exercise as a causal co-factor. But she cannot establish that it met the level of strenuousness believed necessary to cause rhabdo. Sevketoglu at 93 (“Exertional rhabdomyolysis is muscle damage caused by *over-exertion* and has rarely been reported in children.”) (emphasis added). It is therefore highly unlikely that A.C.’s gym exercises could have been a co-factor sufficient to spark her brief rhabdo, or something that the vaccine could have interacted with.

In addition, there are other aspects of A.C.’s presentation that do not corroborate the causal theory proposed. For example, other than some possible post-vaccination malaise, it is not evident from A.C.’s initial treatment encounters in November 2018 that she was experiencing unusual levels of inflammation, as Dr. Gershwin allowed. Tr. at 74. And Dr. Gershwin’s attempts to mitigate this evidence (by maintaining that a lack of biomarker evidence of inflammation does not necessarily mean it was not in fact present)¹⁵ were unpersuasive. Thus, the record does not allow the conclusion that an aberrant vaccine reaction was underway.

And then there is the question of infection itself. As Dr. Gans explained, infection (in isolation) is a well-established cause of rhabdo, and this contention possesses ample reliable medical and scientific support. *See, e.g.*, Blanco at 2-3 (“the relationship between infectious diseases and muscular lesions has been proved...Infection is an important cause of [rhabdo]”); Singh at 2 (“the association between skeletal muscle damage and viral infections is well known”). There is clear record evidence that A.C. had multiple infections during her course of rhabdo, at various times and stages. Tr. at 172-73. In particular, she tested positive at first for enterovirus, and later for mycoplasma infection. Ex. 8 at 12; Ex. 3 at 72. Thus, the evidence of an infectious cause is supported by the record.

Admittedly, it cannot be ascertained from this record *which* infection was most likely causal, and I do not purport to make that determination. As Petitioner accurately observes, A.C. did not test positive for mycoplasma at the time of her rhabdo onset. Ex. 8 at 12. Dr. Gans attempted to interpret the record to support the conclusion that not all individuals suffering from a mycoplasma infection exhibit respiratory symptoms (*see generally* Tr. at 175-76), but she was not able to persuasively diminish the evidentiary value of the initial negative PCR test. Yet A.C. still tested positive for two other infections at the time of her ED presentation, with some symptoms (GI issues, vomiting, diarrhea) consistent with an enterovirus. And Dr. Gershwin seemed to accept not only that A.C. was experiencing some kind of infection, but that it had to have played *some*

¹⁵ Applying the same logic, it could be argued that tests for infection that come back negative do *not necessarily* preclude the existence of the infection – and yet Petitioner asks me to accept the validity of the initial PCR test that did not find a mycoplasma infection when A.C. was first hospitalized.

role in her resulting rhabdo. First Gershwin Rep. at 2; Tr. at 74-75. It is more likely that an infection *explains* A.C.’s rhabdo (given what medical science knows about that causal trigger) than vaccination.

I thus cannot find that the flu vaccine likely played any role in A.C.’s rhabdo. Even when a vaccine is received in the context of an individual experiencing an active infection, it is not presumed that the vaccine still had to have played some contributory role in any resulting disease or injury. *See, e.g., K.A. v. Sec’y of Health & Hum. Servs.*, No. 16-989V, 2022 WL 20213037 (Fed. Cl. Spec. Mstr. Apr. 18, 2022) (Tdap vaccine not causal of Guillain-Barré syndrome; petitioner had been experiencing active upper respiratory infection more likely causal), *mot. for review den’d*, 164 Fed. Cl. 98 (2022), *aff’d*, No. 2023-1315, 2024 WL 2012526 (Fed. Cir. 2024). Rather (and as I noted in *K.A.*), “[t]he vaccine does not deserve greater weight simply because it is “known” whereas the precise nature of the infection is not.” *K.A.*, WL 20213037, at *31. *See also Randolph v. Sec’y of Health & Hum. Servs.*, No. 15-146V, 2021 WL 5816271, at *21 (Fed. Cl. Spec. Mstr. Nov. 12, 2021) (“Causation claims do not succeed merely because Respondent cannot prove with certainty what *was* causal.”).¹⁶

I acknowledge the existence of evidence of *some* treater support for a vaccine association, such as the letter offered by Dr. Moon. *See* Ex. 1 at 93. But that evidence has an equivocal quality, especially when Dr. Moon’s other comments are taken into account and was also generated well after A.C.’s initial presentation. At the same time, other treaters expressed doubt about the putative vaccine association, or seemed to acknowledge vaccination and injury had only a temporal relationship, without offering a reasoned view that vaccines can cause rhabdo. *See, e.g.,* Ex. 3 at 42; Ex. 2 at 5; Ex. 8 at 11. And regardless, “there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.” *Snyder v. Sec’y of Health & Human Servs.*, 88 Fed.Cl. 706, 746 n.67 (2009). Because of the weakness of Petitioner’s prong one showing, and the absence of an explanation to be gleaned from records containing these treater views for *why* they felt the flu vaccine could have caused the rhabdo, I do not give them much weight under the circumstances.

¹⁶ I also do not deem this to be a case in which a “*Shyface* analysis” saves the claim. *Shyface* instructs special masters to find causation where two or more factors could be causal of injury, but it cannot be ascertained which predominated. Hence, causation is established as long as the vaccine was deemed a “substantial factor” – consistent with *Althen*. *See generally K.A.*, WL 20213037, at *1, *13, *31. But in this case, it is *not* established or conceded the flu vaccine could be directly causal of rhabdo – in fact, Dr. Gershwin himself expressly *disclaimed* that possibility. Tr. at 57. It was also insufficiently demonstrated that rhabdo is more likely when several factors synergistically interact (other than when a statin is involved). By contrast, a viral or bacterial infection clearly can be the sole cause of rhabdo – so since it is not disputed that A.C. was experiencing some kind of infection at the time of her rhabdo onset, this is not a situation where two equally-causal factors exist. One is preponderantly supported; the other is not.

CONCLUSION

The Myers family, and A.C. in particular, clearly experienced difficulties treating A.C. for her illnesses, and for that they have my sympathy. But it has not been preponderantly shown that A.C.'s short-lived rhabdo could have been – or was – vaccine-caused. As a result, I cannot find entitlement.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.¹⁷

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

¹⁷ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.