# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 22-86V**

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| SAMANTHA and BRANDON KLAGENBERG, on behalf of their minor child, M.K., | * | Chief Special Master Corcoran |
| Petitioners, | * | Filed: October 3, 2025 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

*John Beaulieu*, Siri & Glimstad, LLP, Louisville, KY, for Petitioner.

*Dorian Hurley*, U.S. Department of Justice, Washington, DC, Respondent.

## ENTITLEMENT DECISION[1]

On January 28, 2022, Samantha and Brandon Klagenberg filed a petition on behalf of their minor child, M.K., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program).[2] Petitioners allege that M.K. developed systemic juvenile idiopathic arthritis ("sJIA") as a result of tetanus-diphtheria-acellular pertussis ("Tdap") and meningococcal vaccines he received on June 14, 2021. Petition (ECF No. 1) at 1.

The matter went to hearing on January 27–28, 2025, in Washington, D.C., and is now ripe for resolution. For the reasons set forth in more detail below, I hereby deny entitlement.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

## I. Factual Background

*Vaccination and Initial Reaction*

M.K. received the Tdap and meningococcal vaccines on June 14, 2021, as part of a twelve-year-old well-child exam. Ex. 2 at 15, 49–51; Ex. 4 at 1. There is no contemporaneous evidence from any June 2021 records of any immediate reaction to the receipt of these vaccines (although Petitioners subsequently reported in later treater encounters that M.K. had experienced a close-in-time reaction).

Approximately three weeks later, on July 6, 2021, Mrs. Klagenberg took M.K. to Sutter Roseville Medical Center Emergency Department ("ED") in Roseville, CA, with complaints of joint pain, myalgias, and a rash on his bilateral upper extremities and right lower extremity since July 1, 2021 (approximately two weeks post-vaccination). Ex. 8 at 9, 10. Mrs. Klagenberg also reported that M.K. had developed a fever earlier that day, had experienced an episode of diarrhea the day prior, and began limping earlier in the week as well. *Id.* On exam, M.K. had a fever of 101.1 degrees, tachycardia, and "[m]acular popular rashes to the right [fore] arm and right medial calf." *Id.* at 12. He further displayed widespread joint pain/stiffness but denied severe pain in a single joint, and had full range of motion in all of his major joints. *Id.* at 14. Emergency medicine specialist Rodolfo Zaragoza, M.D., diagnosed M.K. with viral exanthem[3] and discharged him to be treated symptomatically for a viral illness. *Id.* at 14–15.

On July 9, 2021, Mrs. Klagenberg emailed M.K.'s pediatrician's office and stated that M.K. had been seen at the ED for a rash, fever, lethargy, nausea, excruciating joint pain, and that he continued to limp. Ex. 2 at 44. She assumed it was just "growing pains" until she noticed M.K.'s rash, which went away and then came back. *Id.* Ms. Klagenberg also noted that M.K. had been scratched by a cat three weeks earlier, and wondered about the possibility of cat scratch fever. *Id.* Nurse Shari Smoorenburg, RN, directed Mrs. Klagenberg to bring M.K. back to the ED if his fever persisted, and asked that she email photos of M.K.'s rash. *Id.* at 43. Spencer Peterson, D.O., reviewed the photos and was informed that while the rash was "mostly gone," M.K. continued to experience a lot of joint pain. *Id.* at 42.

Several days later (July 14, 2021), M.K. saw Dr. Peterson in person for complaints of "rash" and "joint pain." Ex. 2 at 47. Mrs. Klagenberg now reported that M.K. had developed a rash on his inner and upper thighs a few days after he received the Tdap and meningococcal vaccines, with more recent cessation of all initial symptoms reported at the ED except for the rash. Upon examination, Dr. Peterson noted that M.K. had a maculopapular rash extending from the medial

[3] "Exanthem" is defined as "a disease in which skin eruptions or rashes are a prominent manifestation. Classically, six exanthems of childhood were described that had similar rashes, and were numbered in the order in which they were reported: *first disease* was measles; *second disease* was scarlet fever; *third disease* was rubella; *fourth disease* was found to be a mild type of scarlet fever; *fifth disease* was erythema infectiosum; and *sixth disease* was exanthema subitem. Only the last two designations are still used." *Exanthem*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=17730&searchterm=exanthem (last visited Oct. 3, 2025).

upper leg to the proximal upper leg bilaterally. *Id.* at 49. He further observed that M.K. had a normal gait and did not appear to limp when walking into the exam room. *Id.* at 48. Dr. Peterson diagnosed M.K. with a rash, but deemed it difficult to say what had caused it (although he allowed it could be a vaccine reaction—as Petitioner proposed). *Id.* at 47. He told Mrs. Klagenberg to bring M.K. back in a few months if the rash persisted, but sooner if joint pain or fever returned (adding that if this were the case then JIA or another infectious, inflammatory disorder should be considered). *Id.*

*Return of Symptoms and sJIA Concern*

On July 21, 2021, Mrs. Klagenberg called the pediatrician and reported that M.K. "ha[d] been vomiting for [the] last [one and a half] weeks," and was unable to keep solid food down, although his joint pain was resolving and his rash was gone. Ex. 2 at 41. The record from a telemedicine visit conducted the next day notes that M.K. "had a preceding illness/vaccine reaction to meningococcal and Tdap shots for two weeks before the vomiting started with some joint pain and rash," however, the latter had resolved. *Id.* at 47. Dr. Peterson noted he was most concerned for "a post-viral gastroparesis" or "functional vomiting related to anxiety." *Id.* To that end, Dr. Peterson ordered testing and prescribed anti-nausea medication. M.K.'s lab test results revealed significant neutrophilia,[4] increased monocytes, an elevated white blood cell ("WBC") count, and elevated platelets. *Id.* at 82–83.

In an effort to obtain an explanation for M.K.'s elevated WBC count, Petitioners took him to the UC Davis Health ("UC Davis") ED on July 30, 2021. Ex. 7 at 385–86. At this time, Mrs. Klagenberg reported that M.K. had been experiencing four weeks of intermittent fevers, rash, and joint pain (which if correct, would place onset approximately two weeks post-vaccination). *Id.* at 386. He further complained of persistent vomiting, pain in his back, left hip, and left knee, and that he had been limping for the past three weeks. *Id.* Following an examination, M.K. was found to be afebrile with a demonstrated abnormal gait. *Id.* at 387. The initial differential diagnosis "include[d], but [was] not limited to: JIA, [multisystem inflammatory syndrome in children[5] ("MIS-C")], [L]yme, [slipped capital femoral epiphysis[6] ("SCFE")], spondyloarthropathy, other rheumatologic disease, reactive arthritis, [and] septic joint." *Id.*

[4] "Neutrophilia" is defined as "an increase in the number of neutrophils in the blood; it is the most common form of leukocytosis and can have any of numerous causes, including acute infections, intoxications, hemorrhage, and rapidly growing malignant neoplasms." *Neutrophilia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=33918&searchterm=neutrophilia (last visited Oct. 3, 2025).

[5] "Multisystem Inflammatory Syndrome in Children" is defined as "a dysregulated autoimmune-mediated illness in genetically susceptible patients following COVID-19 with an interval of 2–6 weeks. The median age of patients with MIS-C is 6–11 years. Most common manifestations are involvement of gastrointestinal tract, cardiovascular system, hematological system, and mucocutaneous system." *Multisystem Inflammatory Syndrome in Children,* National Library of Medicine, https://pmc.ncbi.nlm.nih.gov/articles/PMC9841678/ (last visited Oct. 3, 2025).

[6] "Slipped Capital Femoral Epiphysis" is defined as "posterior dislocation of the epiphysis at the superior end of the femur from its normal location in the acetabulum, causing pain on abduction or internal rotation; most commonly seen

While in the ED, M.K. developed a moderate fever (100.6 degrees), and was admitted to the hospital's pediatric service for further evaluation. Ex. 7 at 389. Based on the reported history, pediatrician James Saxton, M.D., noted that M.K.'s "polyarthralgia with increased inflammatory rash suggest[ed] a more JIA diagnosis [although] the fevers and vomiting may point more towards a reactive arthritis secondary to a gastritis." *Id.* at 408–09.

During hospitalization, on July 31, 2021, M.K. was evaluated by Angel Alberto Herrera Guerra, M.D., a pediatric infectious diseases specialist, immunologist, and rheumatologist. Ex. 7 at 411–12. Dr. Herrera Guerra received a history of M.K.'s symptoms to that point, and noted further that M.K.'s arthralgias "seemed to have been migratory," and were "particularly prominent in [the] knees and hips." *Id.* at 412. On exam, M.K. exhibited some potential swelling of his third right metacarpophalangeal joint and left knee. *Id.* at 415. Dr. Herrera Guerra noted the reported arthritic symptoms and M.K.'s history of rash and fever could be consistent with sJIA and/or Macrophage Activation Syndrome ("MAS"), which can be associated with sJIA. *Id.* at 420. M.K. was discharged on July 31, 2021, with diagnoses of "[p]olyarticular pain concerning for JIA" and "[a]norexia," prescribed Naproxen, and advised to follow up with his pediatrician and rheumatology. *Id.* 380–83.

On August 5, 2021, Dr. Herrera Guerra emailed Mrs. Klagenberg and asked that she have M.K.' s pediatrician refer him to ophthalmology for an evaluation of uveitis,[7] cardiology to rule out Kawasaki disease,[8] and rheumatology. Ex. 7 at 347–48. He further informed Ms. Klagenberg that M.K. had tested negative for cat scratch disease. *Id.* When asked if it was possible that the vaccine caused M.K.'s symptoms, Dr. Herrera Guerra stated that "I do not think it was the vaccine although I cannot rule it out. This looks like [sJIA] to me . . . We could blame the vaccine if everything goes away but after one month the inflammation is still very high." *Id.* at 310, 345 ("I doubt the vaccine was the cause of this, sometimes vaccines trigger autoimmune conditions but the timing between vaccine and symptoms was too short"). Lab work results later indicated the presence of moderate levels of inflammation, leading Dr. Herrera Guerra to embrace a diagnosis

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in adolescents between the ages of 10 and 15." *Slipped Capital Femoral Epiphysis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=73506&searchterm=slipped+capital+femoral+epiphysis (last visited Oct. 3, 2025).

[7] "Uveitis" is defined as "inflammation of part of all of the uvea, commonly involving the other tunics of the eye (i.e., sclera, cornea, and retina)." *Uveitis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52355&searchterm=uveitis (last visited Oct. 3, 2025).

[8] "Kawasaki Disease" is defined as " a syndrome of unknown etiology, usually affecting infants and young children, associated with vasculitis of the large coronary vessels and numerous other systemic signs, including fever, conjunctival injection, changes of the oropharyngeal mucosa, cervical lymphadenopathy, and maculoerythematous skin eruption that becomes confluent and bright red in a glove-and-sock distribution; the skin become indurated and edematous and often desquamates from the fingers and toes." *Kawasaki Disease*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=70488 (last visited Oct. 3, 2025).

of sJIA, and recommend that M.K. start Actemra following a heart ultrasound to rule out Kawasaki disease.[9] *Id.* at 347.

At a follow up appointment with Dr. Herrera Guerra on August 13, 2021, it was noted that M.K. "ha[d] been afebrile, without rash and without joint pain," but that he "continue[d] to have left knee swelling [and] some scant stiffness [was] still present." Ex. 7 at 266. Additionally, M.K.'s genetic panel for hypersensitivity to biologics came back positive for [three] genes," and his articular exam was abnormal, although findings of long-standing arthritis were not present." Ex. 7 at 266, 269–70. Dr. Herrera Guerra again diagnosed M.K. with "JIA, systemic onset," recommended M.K. follow up with cardiology and ophthalmology, and referred him to physical therapy ("PT"). *Id.* at 274. In subsequent communications, Dr. Herrera Guerra noted that M.K.'s "genetic testing did not come with any abnormality that needs to be followed up," and further stated that "I do not think the tdap had anything to do with this. The inflammation has persisted too long. Probably a coincidence." *Id.* at 343.

*Subsequent Treatment*

For the rest of Fall 2021, M.K. continued receiving additional treatment for symptoms he had been experiencing that summer. In late August, for example, Mrs. Klagenberg contacted Dr. Herrera Guerra and noted that both of M.K.'s knees were swollen, but that after steroids were prescribed, his knee pain abated (although the swelling did not dissipate). *See, e.g.*, Ex. 7 at 172 (documenting video visit with Dr. Herrera Guerra on September 30, 2021, and noting that M.K. complained of some swelling in his right knee, but had no evidence of fever, recent rash, or joint pain). M.K. also experienced hives around this time—as well as another rash he experienced in September—however, Dr. Herrera Guerra indicated that M.K.'s hives were likely a medication side-effect rather than the result of sJIA. *Id.* at 222, 172.

M.K. participated in a video visit with Dr. Herrera Guerra on December 2, 2021, reporting that he had been doing well since the last visit and had not again experienced a fever, rash, joint pain, or swelling, with only some transient morning stiffness that responded to medication. Ex. 7 at 132–33. A physical exam revealed questionable right knee swelling and a prominent left popliteal fossae vein. *Id.* at 136–37. Although Dr. Herrera Guerra deemed M.K. to be "doing well on clinical grounds," he proposed an ultrasound of M.K.'s right knee to rule out active arthritis, as well as a doppler of his left knee to rule out superficial vein thrombosis. *Id.* at 140.

Additional lab testing that month yielded normal WBC counts but more positive biomarkers for inflammation (which were interpreted to mean that M.K.'s prescriptions were failing to optimally control his sJIA—leading to a recommendation that he change his steroid dose). Ex. 7 at 94. Moreover, M.K.'s right knee ultrasound revealed "[p]rominent complex fluid

[9] On August 11, 2021, however, Dr. Herrera Guerra informed Mrs. Klagenberg via email that a test he had ordered "to look for genes that may cause problems with [A]ctemra" had come back positive, and therefore, he would recommend Xeljanz (tofacitinib) instead. Ex. 7 at 302.

collection in [his] suprapatellar region with suggestion for thickening of [his] synovium" and "large complex ovoid structures in [his] bilateral popliteal fossa regions, possibly representing complex fluid collection or hematoma with mass lesion also possible." Ex. 9 at 521–22. There was no evidence of deep vein thrombosis in M.K.'s left knee. *Id.* at 533–34.

*Treatment in 2022 and 2023*

On January 11, 2022, M.K. was seen by pediatric pulmonologist Shaina Willen, M.D., at UC Davis via video conference for screening for interstitial lung disease.[10] Dr. Willen's overall impression noted that M.K. was doing well without significant respiratory symptoms, and his pulmonary function testing later revealed "[e]quivocal findings for borderline bronchial wall thickening which may be related to accentuation of bronchovascular structures from atelectasis but could reflect small airways disease [which] is seen in viral/atypical infection or reactive acute disease. Otherwise, no acute cardiopulmonary abnormality is evident." Ex. 9 at 452–53, 406.

On February 7, 2022, M.K. returned to Dr. Herrera Guerra and reported that since his last visit, he "was found to have a mass in both knees with ultrasound." Ex. 9 at 278. On exam, M.K. exhibited swelling in both knees, as well as deviation of his temporomandibular joint ("TMJ"). *Id.* at 282, 284. Dr. Herrera Guerra indicated that the mass was "synovial hypertrophy/ganglion cyst [likely] secondary to [sJIA]." *Id.* at 286. He further noted that M.K.'s arthritis "seem[ed] to be active" and suspected that his current therapy regime was not working. *Id.* Therefore, Dr. Herrera Guerra recommended that M.K. receive new medications, as well as steroid injections in both knees following his MRI. *Id.* at 286–87. A left knee MRI was performed on February 13, 2022, and revealed "[m]oderate knee joint effusion with synovitis [that] extend[ed] into a popliteal cyst" and "findings suggestive of inflammatory arthropathy such as JIA," as well as "[m]ildly prominent nodes at the posterior aspect of the knee [that were] probably reactive." *Id.* at 252–53. Petitioner subsequently underwent bilateral ultrasound guided knee joint aspiration and steroid injection on February 17, 2022. *Id.* at 182.

Between May 2022 and March 2023, M.K. continued to report that he was doing well, had no fever, rash, joint pain, joint swelling, experiencing only sporadic morning stiffness. Ex. 9 at 5, 12; Ex. 14 at 180, 93. During a visit with Dr. Herrera Guerra on March 24, 2023, M.K. noted that he had a right shoulder mass, but that it was asymptomatic and appeared to not get any bigger. Ex. 14 at 93. A physical exam revealed micrognathia and a one-centimeter subcutaneous right shoulder mass. *Id.* A subsequent shoulder X-ray did not reveal any evidence of tissue calcification. *Id.* at

[10] "Interstitial Lung Disease" is defined as "a heterogeneous group of noninfectious, nonmalignant disorders of the lower respiratory tract, affecting primarily the alveolar wall structures but also often involving the small airways and blood vessels of the lung parenchyma; slowly progressing loss of alveolar-capillary units may lead to respiratory insufficiency and death." *Interstitial Lung Disease*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=70466&searchterm=interstitial+lung+disease (last visited Oct. 3, 2025).

61. Dr. Herrera Guerra intended on stopping Methotrexate and continue M.K. on Tofacitinib with the hope of potentially weaning him off should his symptoms remain inactive. *Id.*

Petitioners did not file any additional medical records for subsequent treatment relevant to the claim.

## II. Witness Testimony

### A. Fact Witnesses

#### *1. M.K.*

M.K. was the first fact witness to testify at hearing. *See generally* Tr. at 5–30. He began his testimony with a brief description of his life prior to receiving the vaccine at issue—noting that he had a very normal and active childhood, which included playing in a recreational basketball league up until his vaccination. *Id.* at 6–7. M.K. explained that up until this point in time, he never experienced any limitations physically. *Id.* at 7.

M.K. then recounted the weeks following his receipt of the Tdap and meningococcal vaccines on June 14, 2021. Tr. at 7; Ex. 2 at 15; Ex. 4 at 1. He testified that towards the end of June/early July, he began experiencing symptoms, including joint pain in his knees, ankles and arms, shakiness in his lower extremities, and a difficulty moving. Tr. at 8, 9. He did not, however, recall having any fevers or gastrointestinal symptoms at this time. *Id.* at 9. On July 4, 2021, M.K. testified that he was unable to participate fully in the holiday activities—describing a difficulty eating, vomiting, and an inability to walk up the stairs, thus causing him to "crawl" instead. *Id.* at 10, 11. The next two days M.K. described staying in bed and complaining of "unbearable" pain in his knees and continued shakiness in his lower extremities, until he was eventually taken to Sutter Roseville Medical Center Emergency Department later in the day on July 6, 2021. *Id.* at 12. M.K. testified that treaters at Sutter Health prescribed pain medication and discharged him home that same day. *Id.* at 13.

For the remainder of the summer, M.K. noted that he was unable to visit with his friends like he normally would—maintaining that he essentially remained indoors and that "the only way [he] could contact [his] friends was through video games." Tr. at 13. Moreover, following the receipt of the vaccinations in question, M.K. testified that he no longer played basketball due to the severe joint pain. *Id.* at 14.

M.K. then recalled presenting to UC Davis Health Emergency Department on July 30, 2021, due to his elevated WBC count. Tr. at 14; Ex. 7 at 385–86. He described how concerned he and his parents were and the overall emotional toll his subsequent arthritis diagnosis had on him. Tr. at 16. Following this diagnosis, M.K. was prescribed medication, which provided some symptom relief, and he was later discharged home on July 31, 2021. *Id.* at 16–17; Ex. 7 at 380–83. M.K. continued to visit treaters on a weekly basis for checkups and blood draws. Tr. at 17.

When asked about his condition after starting treatment, M.K. testified that "the medicine was really helping relieve the pain," although he continues to have bad days. Tr. at 17. On those bad days, M.K. explained that he has "a little bit of joint pain [in the morning] before [he] take[s] [his] medicine." *Id.* To this day, M.K. maintained that his ability to partake in any athletic-related activity has been greatly limited as a result of his arthritis diagnosis. *Id.* at 18. Moreover, M.K. testified to the emotional and physical effects he experienced as a result of his diagnosis and treatment course. He explained that he felt angry and disappointed in himself that he could no longer participate in basketball, and he struggled, socially, with navigating changes to his appearance as a result to the medication. *Id.* at 21.

M.K. concluded his testimony emphasizing the impact his arthritis diagnosis has had on his life overall and noting that his life has "changed drastically" and that he now must find a different career path as a result. Tr. at 22, 23.

*2. Samantha Klagenberg*

Mrs. Klagenberg, M.K.'s mother and a co-Petitioner in this case, was the second fact witness to testify at hearing. *See generally* Tr. at 31–85. She stated that prior to M.K.'s receipt of the Tdap and meningococcal vaccines on June 14, 2021, M.K. was very active, always playing basketball and riding his bicycle. *Id.* at 32, 33. In addition, she stated that M.K. did not have a significant prior medical history and had never complained of joint pain, swelling or stiffness prior to his vaccinations. *Id.* at 33. However, Mrs. Klagenberg testified that approximately one-week post-vaccination, she noticed a shift in M.K.'s health—noting that M.K. started to complain of pain in his lower extremities. *Id.* at 34. Initially, she believed the symptoms to be the result of "growing pains," but M.K.'s symptoms continued to worsen and then he developed a fever and rash around July 2, 2021. *Id.* at 35. Mrs. Klagenberg took photographs and regularly checked on M.K. to monitor any changes in his rash—nothing that the rash waxed and waned and always appeared when he developed a fever. *Id.* at 38. She further testified that M.K. only had approximately one episode of gastrointestinal symptoms around July 5, 2021, but thereafter, he did not experience any additional such symptoms. *Id.* at 39.

After M.K. finally got his blood drawn, lab tests revealed a significantly elevated WBC, and as a result, Petitioner took him to the emergency department where he was admitted. Tr. at 41. M.K. underwent multiple test and physical examinations, and he was eventually diagnosed with sJIA. *Id.* at 42. Mrs. Klagenberg testified further that following this diagnosis, several of M.K.'s treating physicians indicated the possibility of a vaccine reaction. *Id.* She recalled M.K. being discharged in early August but emphasized that M.K.'s symptoms persisted. Specifically, Mrs. Klagenberg testified that M.K.'s symptoms "have never gone away" and he continues to report experiencing flare-ups (which can include developing fever and rash, or joint pain). *Id.* Although, M.K. has officially weaned off several medications, expect for his Xeljanz twice daily, he still requires ongoing monitoring and care. *Id.* at 44.

Mrs. Klagenberg then described whether M.K.'s ability to participate in the same activities as he did prior to June 14, 2021, was impacted. She testified that M.K. is no longer able to do some of the same physical activities, such as basketball, due to the uncertainty his condition could have on his body. Tr. at 45. Mrs. Klagenberg similarly stated that M.K. is now homeschooled, and as a result does not go out as much, and it is "really hard seeing him not being able to do the things that his mind is telling him he can do." *Id*. at 45–46.

*3. Brandon Klagenberg*

Mr. Klagenberg, M.K.'s father and the other Petitioner in this matter, was the final fact witness to testify at hearing. *See generally* Tr. at 86–94. He testified that M.K.'s childhood, prior to his June 14, 2021, vaccinations, was very normal and active—emphasizing M.K.'s love for basketball and his aspirations to join the Army. *Id.* at 87. Similarly, Mr. Klagenberg noted that M.K. did not have a significant prior medical history. *Id.* at 88. However, Mr. Klagenberg explained that following the receipt of the Tdap and meningococcal vaccines on June 14, 2021, M.K.'s overall health changed. *Id.* He described M.K. complaining of being nauseous and unable to eat, shakiness in his lower extremities, and joint pain—and that these symptoms progressed overtime. *Id.*

Despite M.K.'s hospitalization and receiving treatment for his arthritis diagnosis, M.K.'s symptoms had persisted following his discharge, according to Mr. Klagenberg. Tr. at 89. He explained that M.K. continues to experience "quite a bit" of swelling in his knees, as well as shakiness and stiffness in his lower extremities. *Id*. at 89, 90. Although he noted further that approximately one year after treatment and several medication changes, M.K.'s symptoms began to subside. *Id.* at 89.

Mr. Klagenberg then briefly discussed how M.K.'s daily routine has changed since vaccination—noting that he and his wife significantly limit M.K.'s walking and participation in extracurricular activities, such as basketball, in order to preserve his body and keep it as healthy as possible. Tr. at 91. Additionally, M.K. began homeschooling following the receipt of his arthritis diagnosis, which greatly impacted M.K.'s social life, according to Mr. Klagenberg. *Id.* at 92. He stated that M.K. does not get to interact with as many of his friends outside of communicating via online video games. *Id.* at 92. Mr. Klagenberg concluded his testimony emphasizing the emotional strain M.K.'s arthritis diagnosis has cause—noting the difficulty of having to work with his wife and son to build a new way of life around M.K.'s physical limitations. *Id.* at 93.

B. Petitioner's Expert — Eric Slavin, M.D.

Dr. Slavin, a rheumatologist, offered two written reports and testified on behalf of Petitioner. *See generally* Tr. at 95–164; Report, dated Aug. 25, 2023, filed as Ex. 15 (ECF No. 35-1) ("First Slavin Rep."); Report, dated May 19, 2024, filed as Ex. 71 (ECF No. 43-1) ("Second

Slavin Rep."). Dr. Slavin opined that M.K.'s receipt of the Tdap and meningococcal vaccines on June 14, 2021, were "major causal factors in [his] development of sJIA." First Slavin Rep. at 17.

Dr. Slavin attended the University of Michigan for his undergraduate degree, and the Ohio State University College of Medicine for his medical degree. Curriculum Vitae, filed as Ex. 16 (ECF No. 35-2) ("Slavin CV") at 1; Tr. at 96. He then completed an internship, followed by his residency, in Internal Medicine at St. Vincent Hospital in Indianapolis, Indiana. *Id.* Thereafter, Dr. Slavin completed a fellowship in Rheumatology at the University of North Caroline, Chapel Hill. Slavin CV at 1; Tr. at 97. He currently is an Assistant Clinical Professor at Michigan State University, as well as a practitioner at West Michigan Rheumatology and Trinity Health St. Mary's Hospital, where he provides both outpatient and inpatient care. Slavin CV at 1; Tr. at 98. Dr. Slavin is also serves as a Fellow of the American College of Rheumatology. Slavin CV at 2. He is board certified by the American Board of Internal Medicine in both Internal Medicine and Rheumatology. Slavin CV at 2; Tr. at 97. Dr. Slavin contends that in the last decade he has diagnosed and treated approximately ten to twenty patients with adult-onset Still's disease ("AOSD") (the adult equivalent to sJIA), as well as treated and cared for dozens of patients with a history of juvenile idiopathic arthritis. First Slavin Rep. at 1.

Dr. Slavin began his testimony with a brief overview of sJIA—explaining that it is a rare, inflammatory condition that most commonly involves an individual's joints, is characterized by arthritis, and can be monophasic or chronic. Tr. at 103. While sJIA is considered idiopathic (and thus it is not fully understood why some individuals develop the condition), Dr. Slavin maintained that there are various "pathways and patterns and facets of [sJIA] that have been properly characterized—specifically, via the 2001 International League of Association of Rheumatology ("ILAR") classifications of JIA. *Id.* at 104; *see also* J. Lee et al., *A Comparison of International League of Associations for Rheumatology and Pediatric Rheumatology International Trials Organization Classification Systems for Juvenile Idiopathic Arthritis among Children in a Canadian Arthritis Cohort*, 74 Arthritis & Rheumatology 1409 (2022), filed as Ex. 41 (ECF No. 38-5).

The most common presenting feature of sJIA, according to Dr. Slavin, is fever, which is oftentimes accompanied by arthritis and a transient erythematous or bright salmon pink-colored rash. Tr. at 104; First Slavin Rep. at 7 (citing R. Gurion et al., *Systemic Arthritis in Children: A Review of Clinical Presentation and Treatment*, 2012 Int. J. of Inflammation 1, 3–4 (2012), filed as Ex. 15 (ECF No. 35-1) ("Gurion"). Some patients may also present with less frequent features, such as lymphadenopathy, hepatosplenomegaly, or serositis. Tr. at104; Gurion at 4. Like any condition, sJIA features complications—primarily, damage or the loss of function to an individual's joints. Tr. at 105. In rarer scenarios, Dr. Slavin testified, patients may sometimes experience Macrophage Activation Syndrome, which has been "well established in conjunction with sJIA in particular." *Id.*; First Slavin Rep. at 7; Gurion at 5.

Dr. Slavin then reviewed the particular facts of this case. He noted that prior to M.K.'s June 14, 2021 vaccinations, he had experienced no significant or chronic prior medical history. Tr. at 108. Dr. Slavin maintained that both vaccines M.K. received at that time, however, had the potential to stimulate the immune system, leading to the development of sJIA. *Id.* Shortly after the receipt of the vaccines at issue, approximately late June or early July 2021, M.K. reported an onset of muscle and joint pain, as well as rash. *Id.* at 109. Dr. Slavin testified that the presentation of these initial symptoms, and in conjunction with the overall evolution of M.K.'s condition, provided a basis for linking the above-mentioned symptoms with a diagnosis of sJIA. *Id.* Moreover, Dr. Slavin maintained that the medical records did not document any intervening infection between the date of vaccination and the date of onset. *Id.*

When asked about the potential causal role of a prior gastrointestinal illness, Dr. Slavin maintained that his review of the medical records suggested that the onset of M.K.'s gastrointestinal symptoms did not begin until approximately July 5, 2021, when he was evaluated in the ER. Tr. at 111. Four days elapsed from the time of M.K.'s initial onset of joint pain to the singular episode of gastrointestinal symptoms. *Id*. In Dr. Slavin's clinical experience, a single episode of gastrointestinal symptoms would not constitute a sufficient basis to subsequently diagnosis an individual with a gastrointestinal illness, although it would reasonably be taken into account in a differential. *Id.* at 112. Moreover, in Dr. Slavin's opinion and further based on his clinical experience, gastrointestinal illnesses and/or infections do not commonly present with a preceding four-day onset of joint pain. *Id.* Thus, he opined that M.K.'s initial symptoms of muscle and joint pain, along with a rash, was the result of sJIA as opposed to a viral gastrointestinal illness. *Id.* at 114.

Dr. Slavin spent some time discussing M.K.'s various post-vaccination doctor's appointments in July 2021. He emphasized M.K.'s visit with Dr. Peterson on July 14, 2021, at which time Dr. Peterson documented a concern for JIA in general, as well as listed a vaccine reaction as a potential cause. Tr. at 115; *see also* Ex. 2 at 47, 48–19. Lab results from July 27, 2021, revealed that M.K. had an "significantly elevated" WBC, leading to M.K.'s subsequent hospitalization at UC Davis. Tr. at 116. While admitted, and of significance according to Dr. Slavin, were M.K.'s fevers and documented elevated inflammatory markers. *Id.* at 117. Taken in concert with M.K.'s waxing and waning rashes and arthritis, pediatric rheumatologist, Dr. Herrera Guerra, was able to propose a more concrete diagnosis of sJIA at this time, to which Dr. Slavin agreed. *Id.* M.K.'s clinical course was thus "consistent with what [ ] would [be] expect[ed] from an inflammatory condition like sJIA" and M.K. did not meet any exclusionary criteria that would indicate another infectious disease process taking place. *Id.*

Not only was M.K.'s continued condition consistent with sJIA, but his overall clinical course was consistent with what one should expect from a patient with sJIA, according to Dr. Slavin. In his professional experience, there were times where a patient is believed to have his or her condition well controlled but will continue to suffer from some degree of disease activity. Tr. at 120. Such disease activity is oftentimes characterized by episodic flares, occurring maybe once

a month or on a daily basis. *Id.* M.K.'s course, Dr. Slavin opined, was consistent. Applying the facts of M.K.'s clinical course to that of the ILAR classification criteria, Dr. Slavin argued, M.K.'s reports of recurrent fevers in early and late July 2021, accompanied by a waxing and waning rash, reflected a "very classic finding" of sJIA. *Id.* at 122–23, 24; *see also* Second Slavin Rep.at 1 (stating that "[t]he ILAR criteria for sJIA requires at least two weeks of fever, with at least three days of fevers occurring in a quotidian (once daily) pattern"). Moreover, M.K. clearly had arthritis of one or more of his joints, according to Dr. Slavin, another criterion supportive of an sJIA diagnosis.

Dr. Slavin disagreed with the contention of Respondent's experts that M.K. had more likely suffered from reactive arthritis—noting that while "it was very understandable to list [reactive arthritis] in the differential initially," the timing of M.K.'s clinical course and how it evolved overtime was inconsistent with an infectious pathogen as the underlying cause. Tr. at 125. Instead, Dr. Slavin argued, M.K.'s symptoms were more constitutional and arthritic in nature, continuing for an extended period of time. *Id.* Reactive arthritis, by contrast, is commonly a self-limiting process in which individuals experience symptoms for weeks or months before remitting. *Id.*

Dr. Slavin then reviewed his proposed medical theory. He first explained that autoinflammatory diseases "are those that invoke pathology within the innate immune system," while autoimmune disease are those that involve the adaptive immune system. Tr. at 126, 128. The medical consensus, in Dr. Slavin's understanding, was that sJIA is currently understood as involving disruptions in *both* the innate autoinflammatory process and the adaptive autoimmune process. *Id.* at 128.

While the pathophysiology of sJIA is not well understood, Dr. Slavin stated that there are many studies analyzing cytokine signatures which have found "either directly or indirectly" that inflammatory cytokines are overly expressed in patients with sJIA. Tr. at 129. Pathogen Recognition Receptors, such as NOD-like Receptor Family, Pyrin Doman containing 3 ("NLRP3"), is an "integral" part of the inflammasome,[11] and when "[i]n its assembled and active form, [ ] generates the release of pro-inflammatory cytokines IL-1ß and IL-18, mediated through caspase-1." First Slavin Rep. at 9 (referencing K. Swanson et al., *The NLRP3 Inflammasome: Molecular Activation and Regulation to Therapeutics*, 19 Nat. Rev. Immunol. 477 (2019), filed as Ex. 62 (ECF No. 39-6) ("Swanson"). Dr. Slavin also mentioned additional aspects of innate

[11] The inflammasome is defined as "a complex of cryopyrin, caspase-1, and other proteins, found in phagocytic cells and related to the body's system of innate immunity. Assembly of the inflammasome leads to activation of caspase-1 and resultant cleavage and activation of interleukins IL-1B and IL-18 in the inflammatory response." *Inflammasome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25203&searchterm=inflammasome (last visited Oct. 3, 2025).

immune dysregulation seen in sJIA, such as evidence of elevated monocytes and neutrophils. Tr. at 132; First Slavin Rep. at 9–10.

Also relevant to sJIA's likely pathogenesis was immune "self-tolerance." Medical science, Dr. Slavin contended, recognizes that persons experiencing autoimmune and autoinflammatory conditions usually have undergone some level of loss of that self-tolerance, resulting in a portion of the adaptive immune response under-reacting to foreign stimuli. Tr. at 132–33. In the context of sJIA, the presence of elevated B-cells and T-cells (also known as lymphocytes) in JIA and sJIA is evidence of the adaptive immune system's involvement, according to Dr. Slavin. Accordingly, sJIA would also occur due to an aberrant adaptive immune response.

To bulwark his proposed medical theory, Dr. Slavin relied on the similarities between sJIA and AOSD, noting that the same inflammatory cytokines are seen in both. Tr. at 135; *see also* E. Feist et al., *Mechanisms, Biomarkers and Targets for Adult-Onset Still's Disease*, 14 Nature Rev. 1 (2018), filed as Ex. 30 (ECF No. 37-4) ("Feist"). Thus, Dr. Slavin maintained, there is "significant clinical as well as molecular overlap between the two conditions," adding that both sJIA and AOSD have been associated with a variety of infectious etiologies. Tr. at 135; Feist at 2. However, he further acknowledged that there has not yet been a single pathogen identified as a typical trigger for either condition. First Slavin Rep. at 10. Nevertheless, Dr. Slavin maintained that in M.K.'s case specifically, the medical records failed to identify a specific infectious process and there is no evidence to suggest alternative antigenic exposures—leaving the vaccinations at issue as the more likely cause. Tr. at 136.

Vaccines were reasonably considered to be a possible trigger for sJIA, Dr. Slavin maintained. The primary goal of a vaccine is to stimulate the immune system. Tr. at 137. In this case, certain specific ingredients in the relevant vaccines—polysaccharides and the alum adjuvant—likely played an important role, given their capacity to stimulate the same inflammatory pathways seen in sJIA. *Id.* at 138. He contended that "Menactra activates TLR4, that [then] generates IL-23, [which], in turn, primes NLRP3," whereas "Boostrix vaccine activates NLRP3 generating IL-Iß, [which], in turn, aids in the differentiation of T-lymphocytes" that will eventually generate IL-17. *Id.* 138–39.

Dr. Slavin relied on several items of medical literature that he believed demonstrate a scenario in which a vaccine was administered and later led to the activation of sJIA. Tr. at 139. He first referenced two case reports which involved individuals with sJIA experiencing *flare ups* of their disease following receipt of an attenuated rubella vaccination and a two-series flu vaccine. *Id.*; S. Korematsu et al., *A Relapse of Systemic Type Juvenile Idiopathic Arthritis after a Rubella Vaccination in a Patient during a Long-Term Remission Period*, 27 Vaccine 5041 (2009), filed as Ex. 38 (ECF No. 38-1) ("Korematsu"); M. Shimizu et al., *Relapse of Systemic Juvenile Idiopathic Arthritis after Influenza Vaccination in a Patient Receiving Tocilizumab*, 19 Clinical and Vaccine Immunology 1700 (2012), filed as Ex. 60 (ECF No. 39-4) ("Shimizu"). Dr. Slavin similarly offered articles relevant to AOSD. Tr. at 140; K. Yoshioka et al., *Onset of Adult-Onset Still's Disease*

*following Influenza Vaccination*, 21 Mod. Rheumatol. 432 (2011), filed as Ex. 68 (ECF No. 39-12) ("Yoshioka"); R. Roongta et al., *Two Flares of Still's Disease after Two Doses of the ChAd0x1 Vaccine*, 41 Clinical Rheumatology 1591 (2022), filed as Ex. 56 (ECF No. 40-10) ("Roongta"). The Yoshioka article discussed the case of a 61-year-old individual who developed AOSD one day post-vaccination, leading the authors to suggest there is an association with vaccination. Yoshioka at 432, 434. Roongta examined an 18-year-old patient with Still's disease for approximately three years, who (while in remission) developed two flares after receiving a COVID vaccine variant. Roongta at 1591.

Dr. Slavin maintained that these case reports were reliable items of literature demonstrating that vaccines could pathogenically stimulate sJIA-like conditions directly, or cause them to flare. Tr. at 141. Thus, the vaccines M.K. received "stimulated his immune system" and essentially activated toll-like receptor-4 and NLRP3 and resulted "in a pathogenic departure from th[e] typically short-lived inflammatory response." *Id.* at 143.

C. Respondent's Experts

*1. Mindy Lo, M.D.*

Dr. Lo, a pediatric rheumatologist, offered two written reports and testified on behalf of Respondent. *See generally* Tr. at 168–205; Report, dated Dec. 1, 2023 (ECF No. 41-1) ("First Lo Rep."); Report, dated May 29, 2024 (ECF No. 47-1) ("Second Lo Rep."). Dr. Lo opined that M.K.'s symptoms were more likely a result of a gastrointestinal infection that caused reactive arthritis, rather than sJIA. First Lo Rep. at 10.

Dr. Lo attended Johns Hopkins University for her undergraduate degree, and Washington University in St. Louis, Missouri, for her medical degree and Ph.D. in Molecular Microbiology and Microbial Pathogenesis. Curriculum Vitae, filed as Ex. B (ECF No. 41-31) ("Lo CV") at 1. She then completed her internship and residency in Pediatrics and Pediatric Rheumatology at the Boston Combined Residency in Pediatrics at Boston Children's Hospital and Boston Medical Center. *Id.*; Tr. at 168. Currently, Dr. Lo is an Assistant Professor of Pediatrics at Harvard Medical School and an Attending Physician in Rheumatology at Boston Children's Hospital. *Id.* She also serves as the director of the Pediatric Rheumatology Fellowship Training Program at Boston Children's Hospital. Lo CV at 2; First Lo Rep. at 1. Dr. Lo is board certified by the American Board of Pediatrics in General Pediatrics and Pediatric Rheumatology. Lo CV at 8; Tr. at 169. Dr. Lo estimates that she personally treats and cares for approximately five to seven children with sJIA per year. First Lo Rep. at 1.

Dr. Lo agreed with Dr. Slavin that sJIA is a highly inflammatory condition. Tr. at 175. As a pediatric rheumatologist, Dr. Lo acknowledged the challenges that come with diagnosing rheumatologic conditions such as sJIA, but emphasized the importance of referring to established guidelines and criteria. *Id.* In so testifying, Dr. Lo allowed that both the ILAR criteria and the

Childhood Arthritis and Rheumatology Research Alliance ("CARRA") criteria "were designed for research, for distinguishing sJIA from other types of JIA for the purposes of research and not truly intended for diagnostic purposes." *Id.* at 176. But she nevertheless contended that these criteria had diagnostic value. *Id.*

Under the ILAR criteria, sJIA is typically not a subtle diagnosis but is instead "clearcut," as children will generally present as very sick. Tr. at 176. M.K.'s case, however, was not so acute at onset. Accordingly, Dr. Lo deemed it important to evaluate the record for patterns in inflammatory markers, such as soluble IL-2 receptor, ferritin, D-dimer, and IL-18 (which has more recently been identified as an additional diagnostic marker). *Id.* at 177. Dr. Lo emphasized that such lab workup evidence is not by itself enough to meet the criteria for an sJIA diagnosis, adding that it is uncommon to identify what underlying trigger caused its development. *Id*. at 178, 179.

Based on a review of the medical records in this case, Dr. Lo opined that a diagnosis of reactive arthritis following a viral infection leading to joint inflammation was a more appropriate characterization of M.K.'s condition, rather than sJIA. Tr. at 187. She particularly highlighted the lack of persistent fever over time in the record, deeming it "really the cardinal sign of sJIA." *Id.* Similarly, M.K.'s reported rash was inconsistent with the kind of more prominent rash that would usually be seen with sJIA. *Id.* at 188.

Dr. Lo, acknowledged, however, that her opinion as to the extent of rash was based only on the filed photographs. More significantly, she noted that based on Petitioners' testimony, there may have been "more fever going on than what was reported and that symptoms are still going on." Tr. at 192. That testimony "certainly would push [her] more towards an sJIA diagnosis." *Id.* Nevertheless, Dr. Lo emphasized that she would defer to M.K.'s treating physicians at the time (who heard Petitioners' reports of M.K.'s symptoms contemporaneously with his treatment), but ultimately expressed some uncertainty as to whether she would have embraced the proposed sJIA diagnosis had she been treating M.K. at that time.

Dr. Lo next pointed out the lack of lab evidence supportive of an sJIA diagnosis. While M.K.'s lab results did reveal an elevated WBC, other inflammatory markers (D-dimer, ferritin, or soluble IL-2 receptor) are deemed to be more specific for sJIA-associated inflammation. Tr. at 189. But the medical records in this case established that testing M.K. underwent for these specific inflammatory markers yielded normal results, inconsistent with the conclusion that M.K. suffered from sJIA. *Id.* And Dr. Lo would have expected M.K.'s inflammatory markers to trend together in response to his taking anti-inflammatory therapies, but that also did not occur. *Id*. at 189–91.

Dr. Lo also addressed Dr. Slavin's causation theory. She maintained that medical science had yet to identify a cause for sJIA—and she denied awareness of any independent medical literature establishing that sJIA might be caused by either of the vaccines at issue. Tr. at 179, 180. Dr. Lo specifically criticized Dr. Slavin's heavy reliance on case reports, which she as deemed indirect and weak causal proof. *Id.* at 180. And many of those offered were not relevant to the

vaccines at issue, or were distinguishable on other grounds. *Id.* at 181–82; Korematsu (involving a live attenuated rubella vaccine and a patient with pre-existing sJIA); Roongta (studying the case of an 18-year-old patient with Still's disease for the last three years and developed multiple flares following two doses of the COVID-19 vaccine). P. Winichakoon et al., *Adult-Onset Still's Disease-like Syndrome following COVID-19 Vaccination: A Case Report and Review of the Literature*, 10 Vaccines 1 (2022), filed as Ex. 66 (ECF No. 39-10) ("Winichakoon") (involving COVID-19 vaccine).

Dr. Lo also stressed that even if the sJIA diagnosis were correct, her opinion regarding causation was unchanged, with Petitioners only able to establish a temporal association with vaccination. Tr. at 193, 194. M.K.'s sJIA would be idiopathic in nature—meaning there was no identified underlying trigger for its development. *Id.* at 205.

*2. Christine McCusker, M.D.*

Dr. McCusker, a clinical allergist/immunologist, offered two written reports and testified on behalf of Respondent. *See generally* Tr. at 206–314; Report, dated Nov. 27, 2023 (ECF NO. 41-32) ("First McCusker Rep."); Report, dated May 29, 2025, (ECF No. 47-2) ("Second McCusker Rep."). Dr. McCusker opines that the timing of onset and the prolonged disease progression over the course of weeks in M.K.'s case "would argue against a specific antigen or adjuvant driven pathology," and thus it is unlikely that either of the two vaccines he received were causative in his development of alleged sJIA. First McCusker Rep. at 9–10.

Dr. McCusker attended the University of Toronto for her undergraduate degree, and McMaster University for her Master of Science Degree, her Ph.D. in Immunology, and medical degree. Curriculum Vitae, filed as Ex. D (ECF No. 41-51) ("McCusker CV") at 1; Tr. at 206–07. She then completed a research fellowship in Immunology, a residency in Pediatrics, and clinical fellowship in Allergy and Immunology at McGill University. McCusker CV at 2; Tr. at 207. Currently, Dr. McCusker is Full Professor in Pediatric Allergy and Immunology at McGill University and the Division Director of Pediatric Allergy, Immunology and Dermatology at Montreal Children's Hospital. McCusker CV at 2–3; Tr. at 207. She is board certified in General Pediatrics by the American Board of Pediatrics and holds the Canadian equivalent certification through the Royal College of Physicians in Surgeons in Pediatrics, Allergy and Clinical Immunology. McCusker CV at 2; Tr. at 207. Her main research domain centers around the area of developmental immunology. Tr. at 209.

Dr. McCusker began her testimony expressing her disagreement with Dr. Slavin's proposed medical theory. In Dr. McCusker's understanding of the immune process, "innate immunity classically has a quick activation but a very rapid shutdown," and "in the disease states that are known where that quick shutdown does [not] occur, you have signs and symptoms rapidly." Tr. at 213. Thus, somewhere between 90 minutes to six hours after exposure to an environmental stimulus, signs and symptoms of dysregulated inflammatory activation would be

expected to appear—but that did not occur here. *Id.* Rather, M.K. did not experience any symptoms for a least two weeks post-vaccination, and therefore Dr. McCusker took issue with associating the Tdap and meningococcal vaccines as possible triggers for his immune dysregulation. *Id.* at 213–14. Even if she considered the role of T-cell-mediated immune dysregulation sufficient to cause disease, fourteen to fifteen days is too short a timeframe to place the receipt of the vaccinations at issue as etiologic explanations. *Id.* at 214.

Dr. McCusker then addressed Dr. Slavin's testimony regarding the specific vaccine ingredients—the alum adjuvant in the Tdap vaccine and polysaccharides in the meningococcal vaccine—that he proposed could have caused an inflammatory cascade. Tr. at 219. Dr. McCusker agreed that these components can activate inflammation, deeming that part of their "job" as a vaccine component. But she did not consider that to be their primary role. *Id*. at 221. Thus, while alum has a role in upregulating inflammation, its main role as a vaccine ingredient is to strengthen "the immunological synapse between the dendritic cell and T-cell, which then increases the synapse between the T-cell and the B-cell, ultimately resulting in better antibody production." *Id.*; First McCusker Rep. at 6-7; S. Awate et al., *Mechanisms of Action of Adjuvants,* 4 Front. Immunol. 114:1 (2013), filed as Ex. C Tab 11 (ECF No. 41-43), at 5–6. And polysaccharides contained in the meningococcal vaccine's antigenic components, Dr. McCusker noted, are very poor immunogens on their own—but when coupled with proteins (diphtheria or tetanus toxoids), their immunogenicity increases and allows the structure to be recognized by the T-cell, which in turn will activate a humoral immune response or the production of antibodies by the B-cells. Tr. at 222–23.

Dr. McCusker also emphasized that M.K. had previously received vaccines containing both alum and polysaccharides without any adverse reactions. Thus, Dr. Slavin's assertion that M.K. possessed some genetic predisposition to hyperinflammatory response to a specific series of stimuli resulting in the alleged adverse events was unlikely. For if he had carried such an unknown susceptibility, his previous exposure to that same series of stimuli should also have resulted in adverse reactions. *Id.* at 224.

Regarding causation, Dr. McCusker (like Dr. Lo) denied awareness of any reliable evidence supporting an association between sJIA and the Tdap or meningococcal vaccines, let alone *any* vaccine. Tr. at 225. Studies in fact had attempted to identify, via epidemiologic studies, what possible etiologic explanations might exist for sJIA—but had not reached conclusions consistent with Petitioners' causation arguments. *See, e.g.*, J. Nossent et al., *Systemic Juvenile Idiopathic Arthritis: Frequency and Long-Term Outcome in Western Australia,* 43 Rheum. Int'l 1357–62 (2023), filed as Ex. C Tab 1 (ECF No. 41-33) ("Nossent"). Nossent conducted a "population-level observational study" for all children in Western Australia over a 15-year period who were diagnosed with sJIA, ultimately only identifying 46 patients (consistent with the overall rarity of the disease). Nossent at 1358. Although Dr. McCusker allowed for the fact that there might be questions with the study as to matters of diagnosis, she emphasized its finding that there was no associated infectious explanation for any of the identified cases, when compared to the

overall population incidence of sJIA. Tr. at 250, 251 ("infection was really not a key element in onset of this disease"); Nossent at 1359 Table 1, 1360.

By contrast, many, if not all, the items of medical literature cited by Dr. Slavin to support causation discussed conditions and vaccinations not at issue herein. *See, e.g.*, Tr. at 236–38 (noting that Winichakoon involved AOSD-like conditions and the COVID-10 vaccination). Feist had examined patients with AOSD (considered by many to be part of the continuum of disease with sJIA) and suggests that a broad variety of infections have been identified as preceding onset of the disease. Tr. at 229; First McCusker Rep. at 6 (referencing Feist at 2). But Feist's authors had not identified vaccination as a link to AOSD onset. Tr. at 230; First McCusker Rep. at 6. Dr. McCusker also criticized Dr. Slavin's reliance on case reports to demonstrate an association between vaccination and sJIA—arguing that the problem with case reports was that they discussed a singular event in most cases, and thus their observations were not significant enough—not only to determine whether an association or causation exists, but whether they had relevance to a larger population.

Dr. McCusker concluded her testimony by reviewing some of the articles offered by Petitioner but previously discussed by Dr. Lo, deeming them inapposite (because they involved different vaccines, relapses in the context of preexisting AOSD/sJIA, or were case reports that did not robustly support causation). Tr. at 241-45 (discussing Roongta (Tr. at 241-42), Shimizu (Tr. at 243-44), and Korematsu (Tr. at 245-47)).

On cross, Dr. McCusker briefly emphasized that the medical literature did not support either infection or vaccination as the cause of sJIA. Investigations examining the role of infections in sJIA not only failed to find any association, but found few instances even where infections preceded sJIA onset. Tr. at 264 (discussing Nossent (*Id.* at 265–69). And the several articles she discussed in her report and at hearing as evidence of "extensive investigations [into] sJIA onset triggers" were used more to demonstrate an overall lack in medical literature supporting the notion that sJIA is a disease that is triggered by an infectious agent or vaccine. Tr. at 282; *see also* Nossent; M. Batthish & R. Schneider, *Systemic Juvenile Idiopathic Arthritis*, *in* 11 Handbook of Systemic Autoimmune Diseases 53–84 (R. Cimaz & T. Lehman T, eds., Elsevier; 2016) ("Batthish & Schneider") (discussing disease pathogenesis, and contrasting infection with sJIA as proper diagnosis, hence underscoring that infection not known as etiologic explanation for sJIA).

## III. Procedural History

The matter was initiated in the early winter of 2022. On April 24, 2023, Respondent filed his Rule 4(c) Report contesting entitlement. *See* Report, dated Apr. 24, 2023 (ECF No. 33). Thereafter, the parties each filed expert reports offering opinions on causation, as discussed above. I issued a pre-trial scheduling order, and a two-day Entitlement Hearing took place on in January 2025, in Washington, D.C. The parties requested post-hearing briefs, and that briefing was completed at the end of March 2025. The matter is now fully ripe for resolution.

## IV. Applicable Law

### 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*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] There is no Table claim for sJIA.

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; 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 & 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 of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the

[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. Appx. 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).

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 even a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (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.

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 Cerrone v. Sec'y of Health & Hum. Servs.,* 146 F.4th 1113, 1122 (Fed. Cir. 2025)*; 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.*, 704 F.3d at 1356 (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 a 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 11(c)(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 numerous items of 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 in this case, 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. Program Treatment of sJIA

The experts largely agreed as to the diagnostic characteristics of sJIA. Program case law has distinguished between two subtypes of JIA—"systemic" (sJIA) versus "oligoarticular." *See, e.g.*, *Putman v. Sec'y of Health & Hum. Servs.,* No. 19-1921V, 2022 WL 600417, at *19 (Fed. Cl. Spec. Mstr. Jan. 31, 2022). Oligoarticular JIA tends to be asymmetrical, impacts fewer joints, and involves the lower limbs, clinically presenting with joint swelling and limping rather than pain. It does not involve the kinds of systemic manifestations ("fever, rash, or other constitutional symptoms") seen with systemic JIA. *Putman,* 2022 WL 600417, at *19. Importantly, sJIA usually begins with a "unique pattern" of a spiking fever (once or twice a day) that subsides quickly the same day but reoccurs the next, along with a rash that itself will precede arthritic symptoms (which manifest within three months of onset). Batthish & Schneider at 56, 57, 59.

Some special masters have found vaccines capable of causing sJIA. *Putman,* 2022 WL 600417, at *19 (discussing cases). Evidence that a child not only was *diagnosed* with systemic JIA, but had experienced fever and rash before rheumatologic symptoms were clinically evident, has been deemed supportive of a vaccine causal relationship. *See Jimenez v. Sec'y of Health & Hum. Servs.,* No. 17-1190V, 2021 WL 3179643, at *26 (Fed. Cl. Spec. Mstr. June 23, 2021) (hepatitis A and HPV vaccines found causal of systemic JIA; rash developed within one week of vaccination).

### II. Petitioner Has Preponderantly Established M.K.'s Proposed sJIA Diagnosis

At hearing, Respondent's primary diagnostic expert, Dr. Lo, seemed to dispute the sJIA diagnosis—but then wavered somewhat after hearing testimony from Petitioners and M.K. himself. Tr. at 192. Ultimately, I find sufficient preponderant evidence exists to support that diagnosis. Admittedly, the evidence of relatively high fever early on in M.K.'s course is sparse (perhaps explaining why Dr. Lo felt there was an absence of the kind of "clear-cut" evidence of sJIA usually needed for the diagnosis). A persistent spiking fever clearly is an important element of sJIA. A. Martini et al., *Toward New Classification Criteria for Juvenile Idiopathic Arthritis: First Steps, Pediatric Rheumatology International Trials Organization International Consensus,* 46 J. Rheum. 2:190 (2019), filed as Ex. A Tab 2 (ECF No. 41-3), at 193; Batthish & Schneider at 56–57.

While fever was reported at M.K.'s first medical encounter on July 6, 2021, it was inconsistently observed, and arguably not always to the level or extent expected by diagnostic

criteria. However, the many *other* symptoms M.K. displayed throughout July and then thereafter (joint pain, myalgias, and a rash) do meet the diagnosis.[13] And treaters overall—in particular, Dr. Herrera Guerra—seemed to have accepted it as accurate. Ex. 7 at 344–46, 420–21. Accordingly, I deem the alleged sJIA injury to have been established, leaving only the question of whether the vaccines M.K. received in mid-June 2021 were likely causal of it.

## III. Petitioners Have Not Met the *Althen* Prongs

Petitioners have failed to carry their burden of preponderantly establishing that M.K.'s mid-June 2021 vaccinations "did cause" his M.K.—or that they could cause it. *See Althen*, 418 F.3d at 1281. This is a sufficient basis for denying entitlement, since all three *Althen* prongs must be established. *Dobrydnev v. Sec'y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). (And for this reason, I include no discussion of Petitioner's success in meeting the third prong).

*Althen* Prong Two

M.K.'s medical record does not support the conclusion that his receipt of two vaccines in mid-June 2021 likely had something to so with the subsequent onset of sJIA symptoms a bit more than two weeks later. M.K. was asymptomatic during that interval, as Petitioners' experts and witnesses admitted. *See, e.g.*, Tr. at 8, 109; Ex. 1 at ¶¶ 4–7; Ex. 8 at 9–10. But Dr. Slavin's theory invoked a response from the innate immune system, in which one would expect to see signs and symptoms of dysregulated inflammatory activation within minutes or hours of vaccination if it were occurring. Tr. at 213–14; *see also* First McCusker Rep. at 7, 9. Thus, Dr. Slavin characterized his theory as relying upon the contention that the Tdap and meningococcal vaccines could trigger an amplified systemic inflammatory response resulting in sJIA's physical symptoms, and that the innate immune response would mount a fast reaction to foreign antigens - yet M.K. never reported any such symptoms reflective of a systemic inflammatory response. *See* Tr. at 156–57.

In addition, even if M.K.'s treating physicians at times considered vaccination as a potential cause of his condition, they ultimately did not *conclude* that the vaccines he received were causal. Thus, pediatric rheumatologist Dr. Herrera Guerra (who diagnosed M.K. with sJIA) firmly expressed the view that the vaccines had nothing to do with sJIA, adding "that onset of M.K.'s symptoms was "[p]robably a coincidence," and explicitly stating: "I do not think this is a vaccine reaction." Ex. 7 at 343, 345–346; *see also* Tr. at 65, 69 (Mrs. Klagenberg testifying that she asked Dr. Herrera Guerra multiple times whether the vaccines caused M.K.'s sJIA, and that Dr. Herrera Guerra told her that it "probably wasn't related to the vaccine"). Such treater views, while not sacrosanct, merit some degree of deference. *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony" of treating physicians can be "probative," because

[13] While the gastrointestinal symptoms M.K. displayed are not notably characteristic of sJIA, they have been recognized as a less common kind of clinical manifestation. Batthish & Schneider at 61.

"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").

Admittedly, Dr. Peterson allowed for the possibility that M.K.'s rash was a vaccine reaction, but he so speculated *before* the sJIA diagnosis was confirmed, and also seemed to mistakenly have assumed that M.K. had received vaccinations roughly two weeks prior, with rash onset "a few days later"—not the actual two weeks that separated vaccination from onset of the rash. Ex. 2 at 47. I thus give less weight to those views than to the views of other treaters, like Dr. Herrera Guerra, which appear to have been based upon a better overall understanding of M.K.'s medical record. *Hibbard*, 100 Fed. Cl. 742, at 749; *see also Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 136 (Fed. Cl. 2011).

Otherwise, to meet the second *Althen* prong Petitioners mostly rely on the naked fact that M.K.'s June 14, 2021 vaccinations literally preceded onset of his sJIA symptoms. *See, e.g.*, First Slavin Rep. at 16 (Dr. Slavin noting that the "timeline of the development of M.K.'s signs and symptoms fit well with the administration of the vaccines"); Tr. at 136–47. But the gap between vaccination and when M.K. was first taken to see treaters on July 6, 2021—for symptoms that had begun no sooner than two weeks after the June 14th vaccinations—is inconsistent with Petitioners' causation theory.[14] The theory, as sketched by Dr. Slavin, would involve a cytokine-driven, innate response leading to immune dysfunction—something that Dr. McCusker persuasively noted should have been evident close-in-time to vaccination, but is not on this record. Moreover, the case reports Dr. Slavin invoked consistently identified *shorter* onsets, even when possibly triggered by distinguishable vaccines. *See, e.g.*, Yoshioka at 434 (onset the day after vaccination); Shimizu at 1701 (sJIA relapse seven days after vaccination). And even those Program cases that have found vaccine-caused sJIA involved more obvious symptoms onset closer-in-time to vaccine administration. *Jimenez,* 2021 WL 3179643, at *26 (rash onset reported to have begun within a week of vaccination).

*Althen* Prong One

Petitioners did not, through Dr. Slavin, preponderantly established the likelihood that the two vaccines received by M.K. can cause sJIA. They could muster no direct evidence (certainly *not* a Vaccine Act requirement, as circumstantial evidence can be relied upon to meet the three *Althen* prongs), and instead attempted to knit together a causation theory with a number of items

[14] I note that my consideration of this timing issue overlaps somewhat with prong three's analysis. To some extent, that is an "occupational hazard" in any Program case, since the question of whether an injury onset occurred in a timeframe that can be shown to have been "medically acceptable," measured from the vaccination date, is part of evaluating whether the vaccine "did cause" the alleged injury. I nevertheless am including this in my prong two analysis, since I deem prong three to require a more fulsome consideration of scientifically *possible* onset timeframes in light of a claimant's theory. Here, timing of onset is an additional factor suggesting the vaccines M.K. received did not likely cause his sJIA—and thus even if he could show a two- to three-week onset was medically acceptable writ large, the timing in which his sJIA *actually began* undermines the conclusion the vaccines did likely cause it.

of more indirect proof. But while some of those elements had indicia of reliability, overall the theory as presented was insufficient to cross the preponderant "line."

At the outset, it should be emphasized that *it has not been shown* that the wild antigenic analogs for the components of the Tdap or meningococcal vaccines are themselves associated with sJIA. Indeed, it does not appear that medical science recognizes *any* infectious etiology for sJIA. *See, e.g.*, Batthish & Schneider at 54, 55 (discussing role of genetic polymorphism as potentially best explaining sJIA pathogenesis). Dr. McCusker (relying on Nossent) persuasively demonstrated that studies looking for such a connection had not identified infections as an explanation for sJIA. First McCusker Rep. at 4–10; Tr. at 214, 249. And she successfully rebutted articles offered by Petitioner to the contrary. Tr. at 226–32; First McCusker Rep. at 4, 6.

However, sJIA *has* been associated with overproduction of certain proinflammatory cytokines, stemming from "a dysregulation of the innate immune system." Batthish & Schneider at 54. To that end, Dr. Slavin proposed that components of the vaccines at issue could have produced an autoinflammatory cascade, setting up the circumstances for development of sJIA. First Slavin Rep. at 13–14. This would be enough, he contended, in a susceptible person to trigger the condition. Tr. at 143–44. But this theory breaks down in several respects.

First, Petitioners' causation theory assumes, without reliable support, that vaccination could set up the conditions for immune dysregulation that would nevertheless not manifest with any outward symptoms for several days (important to the actual facts of this case, since M.K. evidenced no initial reaction or symptoms). But as Dr. McCusker noted, there is a "mechanistic gap" in Dr. Slavin's theory that fails to provide an explanation for how an individual's cells could remain "quiescent" but then go into action two weeks later, without an identifiable second environmental trigger. Tr. at 255–56. This, she persuasively established, was both too long for an innate immune response but too short for the start of the secondary, adaptive response. *Id.* at 213–14. Cytokine upregulation would occur in a short timeframe close to vaccination, but then fall off—while macrophage development associated with vaccine activation was not persuasively established by Dr. Slavin to have the capacity to "provide continued inflammatory signals for days to weeks," as he contended, with Dr. McCusker persuasively showing that this contention was ultimately speculative. Tr. at 147, 217–18; First McCusker Rep. at 7–9. Nor was the concept that sJIA could occur due to vaccine-induced *adaptive* response immune dysregulation well substantiated, since the timeframe for adaptive responses would likely occur over more than two weeks. Tr. at 214. Thus, the concept that both branches of the immune system might work cooperatively in sJIA's vaccine-induced pathogenesis was ultimately an unreliable contention.

Second, Dr. Slavin unsuccessfully identified components in either vaccine as capable of instigating an initial, aberrant innate response to vaccination. Tr. at 219–23. He contended, for example, that the alum adjuvant component in the Tdap vaccine could activate the inflammasome immune pathway, leading to excessive upregulation of proinflammatory cytokines. Tr. at 137–39; First Slavin Rep. at 13–17. But Dr. McCusker rebutted that argument, noting that this

mischaracterized what the alum adjuvant primarily accomplishes when confronting the immune system. Tr. at 220–21; First McCusker Rep. at 6-7. Moreover, generalized contentions about the immune-dysregulating dangers of vaccine adjuvants come dangerously close to advocating a causation theory that the Program has deemed lacks any indicia of independent scientific reliability. *Garris v. Sec'y of Health & Hum. Servs.*, No. 22-1354V, 2025 WL 2401999, at *13 n.11 (Fed. Cl. Spec. Mstr. June 20, 2025) ("[t]he Program has uniformly rejected ASIA [autoimmune/inflammatory syndrome induced by adjuvants] as a scientifically-*unreliable* causation theory. *See, e.g.*, *Rowan v. Sec'y of Health & Hum. Servs*., No. 10-272V, 2014 WL 7465661, at *12 (Fed. Cl Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory because it "is not a proven theory" and no "persuasive or reliable evidence" supports it), *mot. for review den'd,* 2015 WL 3562409 (Fed. Cl. 2015)"). Nothing offered in this case suggests that my reasoned but negative reaction to such a theory warrants reevaluation.

Dr. Slavin's identification of the polysaccharide components in the meningococcal vaccine fared no better. He proposed that bacterial polysaccharides in the meningococcal vaccine might also promote cytokine upregulation early on. Tr. at 137–39; First Slavin Rep. at 13–17. But as Dr. McCusker established, polysaccharides are poor immunogens, and thus are not good at driving the kind of immune response necessary to cause overproduction of inflammatory cytokines. Tr. at 222–23. This argument too was mostly speculative, and untethered to either sJIA specifically or the likely impact of receipt of a meningococcal vaccine.

Petitioners' other evidence offered to support a vaccine association was primarily in the form of case reports—a kind of evidence typically given limited weight on the question of causation. *Porter v. Sec'y of Health & Hum. Servs.*, 663 F. 3d 1242, 1253-54 (Fed. Cir. 2011) (single case studies "d[o]not contain any meaningful analysis about causation"); *Campbell v. Sec'y of Health & Hum. Servs*., 97 Fed. Cl. 650, 668 (2011) ("[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value compared particularly to formal epidemiological studies"); *Martinez v. Sec'y of Health & Hum. Servs.*, No. 16-738V, 2022 WL 4844923, at *29 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) ("case reports ... as a general rule do[] not receive great weight when assessing causation"), *mot. for review den'd,* 165 Fed. Cl. 76 (2023).

Moreover, the specific case reports offered (as Dr. Slavin largely admitted)[15] were almost consistently distinguishable—either because they involved a different vaccine, relapse in the context of existing sJIA/AOSD, or a distinguishable injury. *See, e.g.*, Korematsu (sJIA relapse after flu vaccine), Roongta (AOSD flares after COVID vaccine); Shimizu (sJIA flare after flu

[15] Dr. Slavin did not cite any case reports that discuss the Tdap or meningococcal vaccines and new onset of sJIA. Tr. at 225–26. And he admitted he could find nothing specific to Tdap. *Id.* at 162–63. At best, Petitioners referenced on case report at hearing specific to the meningococcal vaccine. *See* U. Walker et al., *Flare of a Cryopyrin-Associated Periodic Syndrome Following Vaccination with Neisseria Meningitidis Polysaccharides,* 45 J. Rheum. 6:878-79, filed as Ex. 80 (ECF No. 64-1) ("Walker"). But Walker involved a patient who experienced what appeared to be flare of symptoms of what Dr. Slavin acknowledged to be a "different disease process" than sJIA. Tr. at 145, 163.

vaccine), Winichakoon (AOSD after flu vaccine), and Yoshioka (AOSD after flu vaccine). Case reports specific to AOSD are not reasonable substitutes for sJIA-specific literature, despite the overlap between the two conditions (as Dr. McCusker pointed out). Tr. at 229; *Smith v. Secy' of Health & Hum. Servs.,* No. 14-848V, 2018 WL 3991386, at *25 (Fed. Cl. Spec. Mstr. July 5, 2018) (diseases are "not simply interchangeable within a causation theory"). And the fact a vaccine could cause a flare-up in the context of existing disease is not evidence the vaccine could also cause that disease from the start. Tr. at 242–43. Dr. Lo (who has diagnosed children with sJIA) expressed no awareness of any concerns about vaccines causing flares in such a population. *Id.* at 184-85, 199.

Thus, the "can cause" element of the *Althen* test was not at all satisfied. Dr. Slavin's theory was conclusory. It seemed designed mainly to fit the facts of this case—where two specific vaccines were received two weeks prior to illness onset – by crafting a theory with vaguely-substantiated science about the speculative roles of vaccines in a disease not otherwise associated with vaccination, let alone infection. It was not based on reliable medical or scientific evidence suggesting that either vaccine can likely cause sJIA.

## CONCLUSION

I am sorry not to be able to award damages in this case. I enjoyed hearing from the Petitioners (and their notably-articulate son, M.K.), and I sympathize with their medical ordeal in caring for him. But a Program entitlement award is only appropriate for claims supported by preponderant evidence in favor of causation. Here, Petitioners have not made such a showing.

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.[16]

**IT IS SO ORDERED.**

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

[16] 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.