In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1608V

PAUL PELLEGRINO, *as parent and natural guardian of A.P., a minor*,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: July 25, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Madelyn Weeks, U.S. Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION[1]

On July 23, 2021, Paul Pellegrino filed this matter on behalf of his minor child, A.P., under the National Childhood Vaccine Injury Act (the "Vaccine Program").[2] Petition (ECF No. 1). Petitioner originally alleged that A.P. experienced oligoarticular juvenile rheumatoid arthritis due to receipt of diphtheria-tetanus-acellular pertussis ("DTaP") and haemophilus b ("Hib") vaccines on July 26, 2018, with aggravation of her arthritis after receipt of hepatitis A and influenza ("flu") vaccines on November 1, 2018, but later restricted his causation theory to the contention that the flu vaccine was the cause of A.P.'s injury.

[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 Ruling will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National 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) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I determined that this matter could be reasonably resolved based on the evidentiary record, and the parties filed briefs in support of their respective positions. *See* Petitioner's Motion for Ruling on the Record, dated Dec. 13, 2024 (ECF No. 57) ("Mot."); Respondent's Opposition, dated Jan. 30, 2025 (ECF No. 58) ("Opp."); Petitioner's Reply, dated Feb. 14, 2025 (ECF No. 59) ("Reply"). Now, after review of the record, including expert input, I deny entitlement. The theory that the November vaccinations caused A.P.'s subsequently-diagnosed oligoarticular juvenile idiopathic arthritis ("JIA") is inconsistent with record evidence that A.P.'s symptoms most likely manifested before that time. I also do not find it has been established (despite due opportunity) that the vaccinations worsened A.P.'s condition.

I. Fact Summary

July 2018 Vaccinations

A.P. was born on April 23, 2017, without complications. Ex. 1 (ECF No. 1-2) at 2.[3] She had normal health and development during her first year of life, and received routine childhood vaccines without any adverse events. *See, e.g.,* Ex. 7(ECF No. 36-1) at 625–27, 593–94, 584, 588, 589, 590.[4]

July 2018 Vaccinations

On July 26, 2018, A.P. had her fifteen-month well-child visit. Ex. 2 (ECF No. 1-3) at 2. Her exam was normal, and she was administered DTaP and Hib vaccines. *Id.* There is no record evidence of any reaction to the receipt of these vaccines.

Approximately one month later, on August 29, 2018, A.P. saw pediatrician George Manousos, M.D., at Charlotte Pediatrics, for "increased fussiness." Ex. 7 (ECF No. 36-1) at 411. The pediatrician was informed that two weeks before, A.P. had experienced upper respiratory symptoms and a low-grade fever for three days that had since resolved, but she thereafter developed a rash on her hands and feet which was deemed by Dr. Manousos to be "presumably coxsackievirus." *Id*. A.P. had also recently developed a runny nose and difficulty with bowel movements. *Id*. Dr. Manousos noted, however, that A.P. appeared to be moving all extremities normally, and her family did not report any bruising or swelling. *Id*. Dr. Manousos's initial

[3] This case was initiated as a *pro se* matter, and Petitioner filed some exhibits at the start of the case. *See generally* ECF Nos. 1-2 to 1-7). But after counsel appeared, many primary medical exhibits were refiled, but (confusingly) repeating the same numbering scheme, while not also seeking to strike the first-filed exhibits. I will therefore be compelled herein to identify the ECF number for each medical record exhibit, to avoid confusion.

[4] The pre-vaccination records do reveal some concern for an eye issue later diagnosed as physiologic anisocoria. Ex. 1 (ECF No. 24-1) at 162–63. But it does not appear from a review of the totality of the records filed in this case that these concerns bear on A.P.'s subsequently-diagnosed oligoarticular JIA, and therefore I do not further address them.

impression was cystitis, but he felt that teething, nasal congestion, or eustachian tube pressure could also be contributing to A.P.'s symptoms. *Id*. at 412.

For the next two months, there is no record evidence of any intervening treatment for A.P. particularly relevant to this claim. *See, e.g.*, Ex. 4 (ECF No. 31-1) at 251. However, Petitioner's first affidavit filed in this matter (filed after he obtained counsel) suggests that symptoms began to manifest in the wake of the July vaccinations. *See, e.g.*, Petitioner's Affidavit, dated May 13, 2022, filed as Ex. 6 (ECF No. 33-1) at 1¶ 4 ("[f]ollowing the receipt of vaccinations on July 26, 2018, A.P. began to limp and developed swelling in her left knee").

Second Vaccination Event and Growing Evidence of Oligoarticular JIA

On November 1, 2018, A.P. returned to Dr. Manousos for her eighteen-month well-child visit. Ex. 3 (ECF No. 1-4) at 2. At this time, her parents informed Dr. Manousos that her constipation had improved, that she enjoyed having her teeth brushed, and was trying to count and saying a few letters. *Id*. They did not, however, report noticing any joint swelling or difficulty walking. A.P.'s exam was normal, and she received her first dose of the flu vaccine and her second dose of the hepatitis A vaccine. *Id*. at 3–4.

Almost two months later, A.P.'s parents first had her evaluated for the kinds of symptoms at issue in this case, taking her to see Virginia Casey, M.D., at OrthoCarolina, on December 31, 2018. At this time, Petitioner and his wife informed Dr. Casey that "following vaccinations at the end of 7/2018," they had observed A.P. "locking of her left knee and limping." Ex. 1 (ECF No. 24-1) at 239. (This record does not, however, identify a precise onset—and as noted from the prior evidence, no earlier reports of comparable symptoms were ever provided to other treaters). Although at first the limping had been "intermittent," it was now occurring every morning and sometimes going into the day, coupled with more recent evidence of left ankle swelling. *Id.* A family history of adult onset arthritis was also noted. *Id.*

On exam, Dr. Casey observed that A.P. had noticeable swelling and reduced range of motion in her left knee, with a slight effusion in the joint, plus observable left ankle swelling. Ex. 1 (ECF No. 24-1) at 239. Dr. Casey's assessment was probable JIA. *Id*. at 240. She recommended ibuprofen and gentle motion exercises, and referred A.P. to rheumatology. *Id*.

In early January 2019, A.P. was taken back to Dr. Manousos. Ex. 7 (ECF No. 36-1) at 353. He was informed that A.P.'s parents "first began having concerns *at the end of July* following [A.P.'s] 15-month vaccines." *Id.* (emphasis added). Over time thereafter, Dr. Manousos was informed, A.P.'s parent observed (a) left knee locking during diaper changes, (b) unsteadiness and limping movement in the mornings, which was becoming more evident on a daily basis, and (c) ankle swelling. *Id*. Dr. Manousos's exam revealed that A.P. had an antalgic gait and obvious

swelling of her left ankle. *Id*. at 354. He agreed with the JIA assessment and ordered additional laboratory work, including repeat inflammatory markers. *Id*. A.P. also around this time in early January saw an ophthalmologist for follow-up of A.P.'s pupil size issue, and they reported first seeing walking difficulty at the start of December. Ex. 4 (ECF No. 31-1) at 246, 248. Upon exam, A.P.'s left pupil was still larger than her right, but the treater did not observe any iritis or uveitis that might arguably be associated with JIA. *Id*. at 246–47.

On January 9, 2019, A.P. was evaluated by Thomas Griffin, M.D., a rheumatologist at Levine Children's Specialty Center. Ex. 1 (ECF No. 24-1) at 249. Dr. Griffin's history specified the end of July 2018 as the start of A.P.'s intermittent limping, which was then deemed to have become more common by December, and with evidence of the left knee remaining bent, morning stiffness, and a hesitance to put her left heel down when walking. *Id.* Dr. Griffin examined A.P. and diagnosed her with oligoarticular JIA. *Id*. at 251, 254. He recommended that A.P. return soon for arthrocentesis and steroid injections of her left ankle and both knees (and these treatments were provided on January 16, 2019). *Id*. at 254, 294. Subsequent lab work was positive for ANA[5] consistent with JIA. *Id*. at 298.

After that, A.P. received additional treatment for oligoarticular JIA. A.P.'s parents have also recounted to treaters a history in which her symptoms began sometime after she turned one and/or after her July 2018 vaccinations (although they have also maintained the severity of her left leg sensitivity/limping and joint swelling increased by December). *See, e.g.*, Ex. 3 (ECF No. 28-1) at 58, 60 (documenting June 19, 2019, pediatric rheumatology consultation with Ashley Naughton, M.D., and Heather Van Mater, M.D., at Duke University Health Systems, for a pediatric rheumatology consultation for evaluation of JIA and rashes).[6] She has been approved to receive other vaccines, despite concerns articulated in this case about an immune reaction. *See, e.g.*, Ex. 3 (ECF No. 28-1) at 142; Ex. 10 (ECF No. 42-1) at 40; Ex. 3 (ECF No. 28-1) at 152, 160, 177, 185.

[5] "Antinuclear Antibodies" are defined as "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjogren syndrome, and mixed connective tissue disease. Antinuclear antibodies may be detected by immunofluorescent staining. Serologic tests are also used to determine antibody titers against specific antigens." *Antinuclear Antibodies*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=56804&searchterm=antinuclear+antibodies (last visited July 25, 2025).

[6] Other treaters have been informed of an even later onset. *See, e.g.*, Ex. 3 (ECF No. 28-1) at 110, 112 (pediatric immunologist treating A.P. for urticaria informed in August 2019 that her rash symptoms began in April 2019—as well as her joint issues).

II. Expert Reports

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

Dr. Gershwin is a rheumatologist and immunologist, and he prepared three expert reports on Petitioner's behalf. Reported, dated July 22, 2023, filed as Ex. 12 (ECF No. 47-1) ("First Gershwin Rep."); Report, dated Mar. 9, 2024, filed as Ex. 24 (ECF No. 51-1) ("Second Gershwin Rep."); Report, dated July 14, 2024, filed as Ex. 28 (ECF No. 54-1) ("Third Gershwin Rep.").

Prior to his retirement, Dr. Gershwin was a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California Davis School of Medicine. First Gershwin Rep. at 1. He also served as the Chief of the same division for nearly forty years. *Id.* Dr. Gershwin received his medical degree from Standford University, and then completed his residency at Tufts-New England Medical Center thereafter. *Id.* He is certified by the American Board of Internal Medical in Rheumatology, and by the American Board of Allergy and Clinical Immunology. *Id.* Dr. Gershwin serves as an editor for several autoimmunity and allergy journals and has co-authored over a thousand peer-reviewed articles. *Id.* 1–2.

First Report

Dr. Gershwin began his report with an overview of A.P.'s history, and he agreed with the diagnosis of oligoarticular JIA. First Gershwin Rep. at 2. He defined JIA as a "complex autoimmune disease" effecting children and involving chronic joint inflammation. *Id.* at 3, 4–5. Its etiology remains incompletely understood—but its autoimmune character means that its occurrence is likely attributable to a combination of personal genetics, environmental exposures, and immune mechanisms. *Id.* at 4. Dr. Gershwin proposed that the nature of the immune cells observed in affected joints for patients with JIA suggested it had similarities in its progression to "delayed-type hypersensitivity reactions." *Id.* at 5.

JIA has several subtypes, including "systemic" JIA (in which a spiking fever is followed by a number of initial clinical features, such as rash and lymphadenopathy[7]). First Gershwin Rep. at 3. Oligoarticular JIA, by contrast, features symptoms occurring in a single joint, and is evidenced by "a high number of autoreactive T cells" in the relevant joint, along with a pathogenesis involving "antigen-drive activation of the adaptive immune system" (unlike systemic JIA, which he posited occurs due to "an uncontrolled activation of the innate immune system"). *Id.; see also Id.* at 2, 7 (summarizing kinds of T cells and cytokines characteristic of this form of JIA). Thus, systemic JIA is "markedly distinct" from the subtype at issue in this case in terms of both

[7] "Lymphadenopathy" is defined as a "disease of the lymph nodes, usually with swelling; called also adenopathy." *Lympadenopathy*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28980&searchterm=lymphadenopathy (last visited July 25, 2025).

"pathogenesis and immunologic abnormalities." *Id.* at 3. Dr. Gershwin noted, however, that medical science has not yet identified the autoantigen likely responsible for driving the disease process at issue for oligoarticular JIA. *Id.* at 2.

Dr. Gershwin forthrightly acknowledged the extent to which the opinion he offered was unsupportive of the theory Petitioner had originally proposed at the outset of the claim's filing. In particular, he maintained that the July 2019 vaccinations had not likely "played any role" in A.P.'s illness. First Gershwin Rep. at 2. He opined, based on his own review of the record, that before the November 1, 2018 vaccinations A.P. had not likely experienced any JIA symptoms (or any other autoimmune disease for that matter). *Id.*

At the same time, however, Dr. Gershwin disclaimed the ability to identify from the medical record *when* A.P. first experienced the kind of joint swelling (here in the ankle) that would reflect oligoarticular JIA onset. First Gershwin Rep. at 2. At best, he noted that A.P.'s mother had stated in a witness statement that swelling in A.P.'s ankle was noted over Thanksgiving 2018—and therefore "[i]f the special masters accepts the onset of AP's symptoms as stated in this affidavit, then I can express an [sic] favorable opinion on this case." *Id.*

Relying on such an onset, Dr. Gershwin proposed that the flu vaccine could have been causal of A.P.'s oligoarticular JIA. First Gershwin Rep. at 2. He opined that the vaccine would initially stimulate the innate immune response, leading to a "dysregulated immune response characterized by autoreactive T cells that perpetuate the disease." *Id.* This would in particular occur via promotion of the production of pro-inflammatory cytokines, triggering the disease process in a person (like A.P.) who was likely "genetically susceptible to immune dysregulation." *Id.* at 3. None of the items of literature offered by Dr. Gershwin at this time, however, shed light on how any vaccine, let alone the flu vaccine, would cause this specific kind of disease process.

The timeframe in which A.P.'s symptoms first manifested were also consistent with a flu vaccine trigger, Dr. Gershwin maintained. First Gershwin Rep. at 2. He proposed that onset could have occurred within six weeks of the November 1st vaccination (assuming again that contentions about symptoms observed in November were deemed accurate). *Id.* Although the initial innate response to vaccination would be swift (with activation "within hours to a few days"), the adaptive response driving oligoarticular JIA would take longer to produce identifiable clinical symptoms (although Dr. Gershwin did not opine it could occur in a longer timeframe than six weeks). *Id.* at 7. And here that had occurred.

Second Report

Dr. Gershwin's second report responded to the expert report filed by Respondent's rheumatologist, Dr. Carlos Rose. First, he disagreed with Dr. Rose's opinion (which he noted

seemed more rooted in personal experience than any independent evidence) that leg or knee "locking during diaper changes" could be evidence of oligoarticular JIA at its early stages, and was so here (before the November 1, 2018 vaccinations). Second Gershwin Rep. at 1. Dr. Gershwin maintained that he had been unable to identify medical support for this contention, and noted (as Dr. Rose seemed to grant) that there was not clear medical record evidence of onset prior to vaccination.

By contrast, Dr. Gershwin noted, the evidence did reveal "a dramatic and clinically significant change in disease activity" toward the end of November 2018 (reiterating that his own opinion required a fact determination that this was the most likely onset for A.P.'s JIA). Second Gershwin Rep. at 1. If so, it was just as likely that the cytokine-stimulating immune response due to the November 1st vaccination could have aggravated A.P.'s illness as an intercurrent infection, given the extent to which vaccines "attempt to mimic infection." *Id.*

Second (and somewhat in response to Dr. Rose's contention that A.P.'s JIA could not have manifested close in time to her July 2018 vaccinations) Dr. Gershwin contended that an autoimmune disease could develop within five days of an environmental trigger. Second Gershwin Rep. at 1–3. He noted that an innate immune response would be expected to begin in "days, sometimes hours," of a stimulus, and that this process would in turn initiate and aid in the following adaptive phase. *Id.* at 3.[8] Presumably, then, Dr. Gershwin believed A.P.'s JIA could have begun close-in-time to the earlier July vaccinations—although he does not say so in this report (and in fact squarely states elsewhere that his opinion depends upon a fact finding of onset in November 2018). Dr. Gershwin concludes this report with a repetition of the main elements of his theory, as set forth in his original report. *Id.* at 3–4.

Third Report

Dr. Gershwin prepared a final, short response to the contentions of Respondent's immunologic expert, Dr. Andrew MacGinnitie. Among other things, Dr. Gershwin objected to Dr. MacGinnitie's suggestions that medical and scientific evidence was unsupportive of a relationship between the flu vaccine and oligoarticular JIA, noting that an absence of epidemiologic proof in support of causation was irrelevant, since such studies could never identify causation for the rare event of a vaccine injury. Second Gershwin Rep. at 1.[9] He similarly argued that although it was

[8] Dr. Gershwin supported this argument with a page-sized chart taken from an independent source, and also offered some additional literature to explain it. I do not, however, reference these items, for the simple reason that their general contentions are not disputed, and that the idea of the speed of an immune response is not the fulcrum of my decision in this case.

[9] Dr. Gershwin offered one article to support this contention. D. Salmon et al., *Funding Post=Authorization Vaccine-Safety* Science, 391 New Eng. J. Med. 102 (2024), filed as Ex. 59 (ECF No. 56-1). But as Respondent has noted, Salmon does not stand for the proposition for which it has been cited. Opp. at 25. Instead, *Salmon* focuses on the need for more post-authorization vaccine-safety research to aid in the reduction of vaccine reactions. *Id.* at 3. The authors

likely A.P. had some genetic susceptibility to the autoimmune process leading to JIA, there was no existing legitimate way to test for that predisposition, let alone screen off from vaccination those who possessed the genetic predisposition. *Id.* That susceptibility, he proposed, was evident in the fact that A.P. later developed what could (in December 2018) be diagnosed as JIA—but in so maintaining he admitted to an absence of evidence of "abnormal inflammation" experienced by A.P. post-vaccination. *Id.*

Otherwise, Dr. Gershwin contended that what might be tenable about the impact of one version of the flu vaccine would not be true of different versions, since the vaccine is reformulated annually. Second Gershwin Rep. at 2. And he stressed the difference between "induction of disease and the perpetuation of disease," adding that studies suggesting vaccination was safe for existing JIA patients involved sample groups too small to deem evidentiarily significant. *Id.*

B. *Respondent's Experts*

1. Dr. Carlos Rose – Dr. Rose is a pediatric rheumatologist, and he prepared two written reports in this case for Respondent. *See* Report, dated Oct. 6, 2023, filed as Ex. A (ECF No. 48-1) ("First Rose Rep."); Report, dated Apr. 10, 2024, filed as Ex. E) (ECF No. 52-13) ("Second Rose Rep.").

Dr. Rose attended the University of Buenos Aires School of Medicine for his medical degree. Curriculum Vitae, filed as Ex. B (ECF No. 48-8) ("Rose CV"). He then completed post-graduate training at the University of Buenos Aires, Hospital "Jose de San Martin," where he became Chief Resident of Internal Medicine. *Id.* at 4. Thereafter, he pursued an internship in Pediatrics at the Medical Center of Delaware, followed by several fellowships in Adult and Pediatric Rheumatology. *Id.*; First Rose Rep. at 2. Prior to his recent retirement, Dr. Rose was a full-time Rheumatologist at Nemours/Alfred I. duPont Hospital for Children, in Wilmington, Delaware, where he practiced for over forty years. First Rep. at 1. Throughout his career, Dr. Rose has treated and cared for children and adult patients with rheumatic diseases. *Id.* at 1–2. He is board certified by the American Board of Pediatrics in Pediatrics with a sub-specialty certificate in Pediatric Rheumatology. *Id.*; CV at 5. Dr. Rose has published over 100 peer-reviewed articles and lectured in both a national and international setting. First Rep. at 2.

First Report

Dr. Rose provided a detailed overview of A.P.'s medical history, from birth in 2017 through 2021. First Rose Rep. at 3–12. In his review of these records, he emphasized several points. First, he noted that even though the medical record does not detail complaints from

propose allocating a portion of the funding from the Vaccine Injury Compensation Progrm to pursue such vaccine-safety research and monitoring. *Id.*

Petitioner or his spouse about any JIA-like symptoms in the summer of 2018 (after the July vaccinations), Petitioner *did* report to treaters not too long thereafter (beginning at the end of December 2018) that this was when such symptoms were first observed. *See, e.g.*, *Id.* at 4–5. There was record proof that Petitioner informed treaters of worsening in December as well—but they consistently also identified the end of July as the start for gait abnormality concerns. *Id.* at 5–6, 7. Thus (as Dr. Rose emphasized later in his first report), onset of A.P.'s oligoarticular JIA likely occurred well before the November 1st vaccinations, regardless of when her JIA was *diagnosed.* *Id.* at 19.

Dr. Rose expanded on his views about onset in other sections of his first report. *See generally* First Rose Rep. at 13–17. Oligoarticular JIA, he maintained, often presents in infants with knee "locking" (seen when diapers are changed) and subsequent limping. *Id.* at 14. In response to their legs being lifted from the feet in order to place a diaper, babies with oligoarticular JIA may (in the presence of "mild knee synovitis") contract their legs to avoid the pain associated with the parent movement, making the knees appear "locked" (and then producing what appear to be an abnormal limping gait after). *Id.* But this process would be transitory, at least in the "early phase" of the illness. *Id.* In this case, Dr. Rose argued, the record was consistent with a process that first manifested at the end of July 2018 as knee locking and subsequent limping. *Id.* at 15. But the evidence of knee swelling and difficulty walking/leg weakness was evident much later, in the late fall of 2018. *Id.* at 15–16.

Second, Dr. Rose discerned from the medical record evidence that A.P. had likely been experiencing some kind of viral infection "concomitant with the aggravation of the arthritic symptoms" in December 2018. First Rose Rep. at 8. Testing was ordered after A.P. was brought to the orthopedist at the end of December, and in Dr. Rose's estimation it revealed neutropenia (low white blood cell count), with the lowest value as of the end of December 2018. *Id.* at 7. Dr. Rose deemed this to confirm the existence of an "ongoing viral infection." *Id.* In addition, A.P. was observed at an early January 2019 visit to Dr. Manousos to have nasal drainage and a puffy appearance around her eyes—and then at an additional visit with a treater around this time for fever and the aforementioned joint swelling, testing revealed biomarkers for ongoing inflammation. *Id.* at 6–7.

From this evidence, Dr. Rose opined that the recurrence of more evident JIA symptoms was likely the product of reactivation due to an intercurrent infection. First Rose Rep. at 17. (He also observed subsequent symptoms flares he believed were attributable to infection. *See, e.g.*, *Id.* at 11 (discussing flare in January 2020)). Indeed, given how often infants experienced infections, it was highly likely that a child with oligoarticular JIA would experience onset coincidentally with an existing infection. But otherwise it was consistent with JIA that transient infections would cause flares in symptoms. The same proinflammatory cytokines produced in response to an infection would activate synovial macrophage immune cells, causing obvious exacerbations. *Id.* at 17–18.

A.P.'s infection-like symptoms in late December 2018-early January 2019 likely explained why she appeared worse at these times. *Id.* at 18.

Next, Dr. Rose provided his view on the nature of oligoarticular JIA (which he agreed the record establishes to be A.P.'s proper diagnosis), and what is understood to drive the disease pathologically, contrasting this with Dr. Gershwin's contentions about the role a vaccine could play in that process. Dr. Rose agreed that the cytokine response elicited by a vaccine would "play a pivotal role in driving the immune response," but disputed that these cytokines would in turn trigger a disease process leading to JIA. First Rose Rep. at 20. In fact, even if it were accepted (as Dr. Gershwin contended) that A.P.'s JIA post-dated the November 1, 2018 vaccinations, she did not even display symptoms of JIA until late December 2018—inconsistent with a cytokine-driven innate response (which would have to occur much closer in time to the vaccination event). *Id.*

Otherwise, Dr. Rose maintained, Dr. Gershwin had offered literature that accurately explained what is known about JIA's pathogenesis (*see* A. Grom, *Juvenile Idiopathic Arthritis: Epidemiology and Immunopathogenesis*, UpToDate 2022, https://www.uptodate.com/contents/juvenile-idiopathic-arthritis-epidemiology-and-immunopathogenesis (last visited July 25, 2025), filed as Ex. 15 (ECF No. 47-4)), but it did not "offer any specific clues for a potential role of the flu vaccine" in triggering JIA. First Rose Rep. at 20. Dr. Rose stressed that JIA was deemed idiopathic in origin, with only genetics known to be a causal factor for it. *Id.* at 21. Dr. Rose also denied that the medical record established aggravation of Petitioner's JIA based on receipt of the flu vaccine in early November 2018. Rather, that record establishes that any symptoms flares (beginning at the end of November 2018) were attributable to intercurrent viral infections—and consistent with a disease course that was by that time underway for several months. *Id.*

Second Report

Dr. Rose emphasized in his second report the extent to which Dr. Gershwin's causation theory was "contingent on the establishment . . . that disease onset was around the Thanksgiving weekend of 2018 and is limited to the causal effect of the flu vaccination" from November 1st of that same year. Second Rose Rep. at 1. Yet A.P.'s parents had reported to treaters on several occasions that they had observed left knee "locking" and limping not long after the July 26th vaccinations. *Id.* at 1–3. Treaters had concluded an onset of July–August 2018 as a result. *Id.* at 3. And A.P.'s parents made statements about such an onset in witness statements. *Id.* at 2. To Dr. Rose, this was consistent with a "knee flexion contracture" that would reflect a response to inflammation—as confirmed by a later physical exam in January 2019. *Id.* at 2. Onset was therefore most likely well before the administration of the flu vaccine to A.P. in November 2018, since by that time "autoimmunity had already been developed." *Id.* at 4.

Dr. Rose further disputed the "pathogenic aspects" of Dr. Gershwin's opinion. For example, Dr. Gershwin seemed to propose that the flu vaccine could have the same aggravating impact on existing JIA as an intercurrent infection. Second Rose Rep. at 3–4. Dr. Rose noted his agreement with Dr. Gershwin that vaccination would provoke an immediate triggering of an innate immune response, but contended that this response (and its concurrent production of cytokines) would subside not long thereafter. *Id.* at 4. As a result, A.P.'s innate response to receipt of the flu vaccine on November 1, 2018, would have died down well before Thanksgiving that same year (when A.P.'s mother had reportedly observed ankle swelling and an unbalanced gait). *Id.* at 4, 5. This would thus reflect at best "disease progression," but not likely onset due to the November vaccination's impact on the innate response. *Id.*; K. Talaat et al., *Rapid Changes in Serum Cytokines and Chemokines in Response to Inactivated Influenza Vaccination*, 12 Influenza Other Respiratory Viruses 202 (2018), filed as Ex. E-1 (ECF No. 52-14).

The medical record did, in Dr. Rose's view, suggest "some degree of disease progression" in the later parts of November 2018, culminating in the decision by A.P.'s parents to seek more urgent treatment at the end of December. Second Rose Rep. at 5. But by this time, she was also experiencing a viral infection "that likely put [A.P.] over the top and made her disease obvious to all caretakers and doctors." *Id.* This allowed for subsequent treaters to make a full diagnosis of oligoarticular JIA. *Id.* at 6. But a "cytokine-mediated disease aggravation" arising from the November 1st vaccination was "biologically impossible." *Id.*

2. Dr. Andrew MacGinnitie – Dr. MacGinnitie is a pediatric allergist/immunologist, and he prepared a single written report on Respondent's behalf. Report, dated May 30, 2024, filed as Ex. C (ECF No. 52-1) ("MacGinnitie Rep.").

Dr. MacGinnitie received his medical degree from the University of Chicago Pritzker School of Medicine, graduating with both an M.D. and a Ph.D. from the Department of Pathology. Curriculum Vitae, filed as Ex. D (ECF No. 52-12) ("MacGinnitie CV"). Thereafter he completed a residency in Pediatrics in the Boston Combined Residency Program, training at Boston Children's Hospital and Boston Medical Center, followed by an Allergy/Immunology fellowship at Boston Children's Hospital. MacGinnitie CV at 2. He is a Professor of Pediatrics at the Medical College of Wisconsin, as well as an attending physician at Children's Wisconsin. *Id.* Dr. MacGinnitie maintains an active clinical practice and has extensive experience in caring for children and adults with a variety of immunologic diseases, including reactions to vaccines. *Id.* He is board certified in both Allergy/Immunology and Pediatrics and is a Fellow of the American Academy of Allergy, Asthma and Immunology. *Id.* Additionally, he performs research and has published articles in several areas related to immunology, including proposed vaccine reactions and primary immunodeficiency. *Id.*

After a review of the medical facts, Dr. MacGinnitie summarized Dr. Gershwin's theory, noting that it relied on cytokine production and immune cells due to "activation of the innate immune system," initiating (as a result of some genetic predisposition) "autoimmunity targeted at A.P.'s joints." MacGinnitie Rep. at 8. But Dr. MacGinnitie deemed the theory lacking in substantiation, for several reasons.

First, Dr. MacGinnitie criticized the theory as vague, noting that it relied on generalities about the vaccine-induced innate immune response but without specific corroborative evidence. MacGinnitie Rep. at 9. There are many kinds of cytokines that perform different functions—and without specifying what cytokines were at issue, how the flu vaccine could promote their production, how long this would take, and how they would encourage a pathogenic process, the theory was too general to be tested. *Id.* The generality inherent in Dr. Gershwin's arguments was evident in his contentions about the timing ("onset could take somewhere between a few days and six weeks to develop") for vaccine-induced JIA. *Id.* at 8–9.

Second, Dr. MacGinnitie highlighted record evidence that was unsupportive of the conclusion that the flu vaccine was responsible for A.P.'s oligoarticular JIA. For example, the record did not establish that she had experienced an unusual amount of inflammation, or any other concerning response, after receiving the vaccine on November 1, 2018—in the form of a fever or evidence of joint swelling. MacGinnitie Rep. at 10. In addition, that same record seemed to establish that A.P.'s symptoms predated vaccination, as established by witness statements and history reports provided by A.P.'s parents to treaters. *Id*. at 9. This made it impossible for the flu vaccine to have caused A.P.'s oligoarticular JIA. And A.P.'s treaters never proposed a causal relationship between the flu vaccine and A.P.'s illness, at most observing only a temporal association, but also recommending future vaccination. *Id.* at 11–12.

Dr. MacGinnitie further noted the lack of substantiation for any association between the flu vaccine and JIA. As a general matter, vaccination does not initiate a strong immune stimulus. MacGinnitie Rep. at 10. Vaccines are encountered by the human immune system far less often than a myriad of other environmental stimuli, including wild infections (which are far more likely to result in illness). There is no epidemiologic evidence that the flu vaccine can cause JIA—while there were studies suggesting that vaccination was not likely to *worsen* existing JIA. *Id.* at 10–11; C. Silva et al., *Vaccinations in Juvenile Chronic Inflammatory Diseases: An* Update, 9 Nat. Rev. Rheumatology 532 (2013), filed as Ex. C-9 (ECF No. 52-10); N. Alfayadh et al., *Vaccinations do not Increase Arthritis Flares in Juvenile Idiopathic Arthritis: A Study of the Relationship between Routine Childhood Vaccinations on the Australian Immunisation Schedule and Arthritis Activity in Children with Juvenile Idiopathic* Arthritis, 2020 Int. J. Rheumatology 1 (2020), filed as Ex. C-10 (ECF No. 52-11). At most, vaccines with live-attenuated components (such as measles-mumps-rubella ("MMR")) might be contraindicated for existing JIA patients—but A.P. was not as of November 2018 receiving immunosuppressive treatments. MacGinnitie Rep. at 11. And A.P. had

never before experienced a reaction to the flu vaccine—inconsistent with the contention that she possessed a susceptibility that was likely to be triggered. *Id.*

Dr. MacGinnitie concluded by observing that the "I" in JIA stood for "idiopathic"—meaning without an identified cause/trigger. MacGinnitie Rep. at 12. Although Dr. Gershwin found it significant that no other alternative explanation for A.P.'s injury existed, "no trigger is found in the majority of JIA patients." *Id.*

III. Procedural History

This case was initiated in July 2021 as a *pro se* matter and reassigned to me a few months later. Existing counsel appeared for Petitioner at the end of 2021, and then began the process of completing filing of medical record evidence. Respondent offered his Rule 4(c) Report challenging entitlement in January 2023, and thereafter both sides filed the aforementioned expert reports, with the final such report filed in August 2024. I subsequently determined that I would resolve the claim via ruling on the record, and the parties briefed their respective positions as noted above.

IV. Parties' Arguments

Petitioner

Petitioner argues he has met his burden of proof to establish causation-in-fact under the test set by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005). Mot. at 21–26. He first maintains that the evidence preponderates in favor of the conclusion that the flu vaccine "can cause" oligoarticular JIA. For support, he offers Dr. Gershwin's expert reports, relying on nearly two pages of block quotes taken directly from them. *Id.* at 21–23. He also notes that there is no dispute that JIA is autoimmune-mediated (evidenced in part by the identification of autoreactive T cells in joint synovial fluid), adding that "[t]his shows that the adaptive immune system drives this autoimmune disorder" (although Dr. Gershwin's theory as discussed above seemed more focused on the vaccine's impact on the *innate,* initial immune response. *Id.* at 23. He also reiterates that its occurrence can involve both a genetic susceptibility and environmental trigger. *Id.* at 23. He thus contends that this showing meets the first prong's requirement, adding that "[t]o require more is to require scientific certainty." *Id.* at 24.[10]

[10] In connection with this seemingly off-handed contention, Petitioner devoted several pages of his brief to a lengthy exegesis on the law governing the first *Althen* prong, maintaining something many petitioners contend: that plausibility is the proper standard applied to the theory presented, and that contrary interpretations of the standard erroneously conflate *what* a Petitioner must prove with the level of evidence needed to do so. Mot. at 14–20. This view has, however, been soundly rejected by several recent Circuit decisions (as discussed below)—and simply reflects the desire of some Program counsel to live in a world where the most bare-bones *Althen* prong one showing would suffice.

Next, Petitioner posits that he has shown the flu vaccine was likely responsible for A.P.'s injury. Mot. at 24–25. He again references (via long block quotes) Dr. Gershwin's opinion in support. *Id.* at 24. In essence, he relies on the fact that A.P. had not experienced, or been diagnosed with, JIA before November 1, 2018, invoking Dr. Gershwin's theory to explain how the vaccine resulted in her injury (although without reference to medical record evidence corroborating the theory's functioning in "real time"). He also asks for the "opportunity to present evidence and brief the question of significant aggravation" if it is determined that A.P.'s onset predated vaccination—although he does not in this opening brief make any reference to the legal standards relevant to such a claim, or explain why he could have attempted such a showing at this time (especially since the possibility that A.P.'s injury related to her July 2018 vaccinations was *expressly included* in the original Petition). *See* Petition (ECF No. 1) at 3 ¶¶ 8 ("A.P.'s Arthritis and other injuries were caused by her July 26, 2108 vaccinations," and "A.P.'s Arthritis and other injuries were significantly aggravated by her November 1, 2018 vaccination").

Finally, Petitioner maintains that the timeframe of A.P.'s onset was medically acceptable. Mot. at 25–26. In addition to again offering another long block quote from Dr. Gershwin's reports, Petitioner (deeming Mrs. Pellegrino's witness statements to be reliable) contends that A.P.'s onset was evidenced by ankle swelling from 2018 Thanksgiving weekend—within the six weeks for onset proposed by Dr. Gershwin. *Id.* at 26.

On reply, Petitioner makes a number of points in an attempt to bulwark his causation showing. He again contends that A.P.'s ankle swelling was observed in late November 2018—stressing that prior medical records between July and November 1st did not reveal any evidence of arthritis or complaints about it. Reply at 1–2. He deems later instances from 2019 treatment encounters (in which he or his wife informed treaters that they had observed knee locking in A.P. that prior summer) to be non-contemporaneous and/or not reflective of objective treater views (even though, in effect, Petitioner is urging that *his own* statements to treaters, or those of his wife's, about onset effectively be disregarded). *Id.* at 2–3.

Petitioner also maintains that Dr. Rose's speculation about the import of knee locking or leg straightening during diaper changes has no independent medical support. Reply at 3. And he repeats the view that the relevant standard for the first *Althen* prong is not medical certainty, but instead only requires him to "present a biologically plausible theory, supported by sound and reliable evidence." *Id.* at 4.

Respondent

Respondent argues the *Althen* prongs have not been met in this case. He emphasizes that Dr. Gershwin's theory is limited to the contention that the flu vaccine A.P. received on November 1, 2018, caused her to develop oligoarticular JIA—abandoning the originally-alleged theory that

the July 2018 vaccinations had any connection with the injury. Opp. at 16. But even the theory Dr. Gershwin embraces has not been preponderantly substantiated (and Respondent emphasizes that merely attempting to establish that it is *plausible* the vaccine could cause an autoimmune injury is not enough). *Id.* at 22–23.

First, Petitioner has not established it likely the flu vaccine can cause oligoarticular JIA. *Id.* at 23–26. Respondent notes that Dr. Gershwin's theory is broad and too unspecific to persuasively link the flu vaccine to the injury, ignoring reliable evidence that vaccination does not lead to JIA flares or is otherwise a risk factor. *Id.*

Second, Respondent maintains that the "did cause" *Althen* prong is unsatisfied. Opp. at 26–28. A.P.'s treaters, for example, did not implicate the flu vaccine in her disease's etiology, and in fact recommended she receive vaccines in the future. *Id.* at 26–27. And there was no record evidence that A.P. was in fact genetically predisposed to experience an autoimmune injury, or that she had experienced some unusual inflammatory response to receipt of the vaccine (let alone in prior instances in the past). *Id.* at 27–28. Finally, Respondent contends the third prong is unmet, noting that Dr. Gershwin's proposed six-week interval for onset due to vaccination had no independent support, especially since he relied on the transient effect of immunization in stimulating the innate/initial immune response (in the absence of evidence A.P. *did* experience such a response anytime in the days after the November 1st vaccination). *Id.* at 28–30.

Respondent also applies a significant aggravation analysis to Petitioner's claim (despite the fact that Petitioner has not affirmatively attempted to do so in his briefing). *See generally* Opp. at 14–16, 17–29. Just as Petitioner did not establish that the flu vaccine caused A.P. oligoarticular JIA, he did not preponderantly show that this vaccination worsened existing JIA.

V. Applicable Legal Standards

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

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

[11] 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

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,* 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Distinguishing between "preponderant evidence" and "medical certainty"

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concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

is important because special masters must take care not to impose an evidentiary burden that is too high. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed.Cir.1991) ("The standard of proof required by the [Vaccine] Act is simple preponderance of evidence; not scientific certainty.... [I]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the court meet the standards of the laboratorian.") (citations and internal quotation marks omitted).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Demore v. Sec'y of Health & Hum. Servs.*, No. 20-1265V, 2024 WL 4542934 (Fed. Cl. Spec. Mstr. Sept. 26, 2024), *aff'd*, No. 20-1265V, 2025 WL 868902, at *4 (Fed. Cl. Mar. 20, 2025) (rejecting the argument that a petitioner's burden is to prove that a causation theory is *plausible* and instead requiring petitioner to prove the theory by a preponderance of the evidence) (emphasis added). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates

that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *De Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. Den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

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

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

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

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

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

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

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

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

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of

expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

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

E. *Determination of Entitlement on Basis of Written Record*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Oligoarticular JIA and Program Treatment

The parties and their experts agree that A.P. was properly diagnosed with oligoarticular JIA—and that this condition is distinguishable from the *systemic* form of JIA. Mot. at 1; Opp. a 17; First Gershwin Rep. at 2; First Rose Rep. at 13. As I noted in *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.

Some special masters have found vaccines capable of causing *systemic* JIA, but the same is not true for oligoarticular JIA (which involves one joint, and does not feature pre-clinical symptoms evidence of systemic inflammation). *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). But in *Putman* (which admittedly involved the MMR rather than the flu vaccine) I did not find the same reasoning persuasive when applied to the context of oligoarticular JIA, since the theory was vague, relying too much upon an elision between the impact of the innate and adaptive immune responses to meld into an autoimmune process, but without proof the vaccine could initiate it. *Putman,* 2022 WL 600417, at *21–23. (Notably, *Putman* and *Jimenez* both

involved expert opinions offered by Drs. Gershwin and Rose, with Dr. MacGinnitie also preparing a report in *Putman*).

II. Petitioner did not Carry his *Althen* Burden of Proof

Petitioner has embraced a single causal theory: that the flu vaccine A.P. received on November 1, 2018, was the cause of her JIA. *See* First Gershwin Rep. at 2. But he did not carry his burden of proof under *Althen*. I address below only the prongs most significant to my analysis (and because the failure to establish *any one* prong is fatal to a causation claim, I do not evaluate his success with respect to all three prongs).[12]

Prong Two

A significant obstacle to the finding that the flu vaccine "did cause" A.P.'s oligoarticular JIA is the fact that Petitioner and his wife consistently informed treaters that A.P.'s symptoms *predated* her receipt of the flu vaccine. *See, e.g.*, Ex. 7 (ECF No. 36-1) at 353 (January 2019 treatment occasion). While A.P. may not have been diagnosed with JIA before the November 1st vaccination, the date of diagnosis is not the same as the date of onset, as Program case law recognizes. *Huntoon v. Sec'y of Health & Hum. Servs.*, No. 21-1965V, 2023 WL 2231842, at *4 (Fed. Cl. Spec. Mstr. Feb. 27, 2023), *mot. for review* denied, 167 Fed. Cl. 93 (2023) (stating that "[i]n Program cases, onset is measured from first manifestation of symptom, regardless of whether it is understood in that manner—or whether additional symptoms progression confirming the diagnosis occur later in sequence") (citing Section 16(a)(2); *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1335,1340 (Fed. Cir. 2011)). Petitioner thus cannot establish the flu vaccine caused an injury that already existed.

In response, Petitioner makes a curious, somewhat self-defeating argument. In effect, he asks that his statements to treaters (as evidenced in contemporaneous records) about a pre-November onset be given low evidentiary weight. *See, e.g.*, Mot. at 25. In so arguing, he notes the fact that many treatment records from before the November 1st vaccination date make no mention of any symptoms that could be deemed to be JIA-associated—as if that evidence diminishes the truth of statements made to treaters at later times.

Program claimants frequently urge special masters to give no weight to records that do *not* mention symptoms they otherwise maintain were occurring—either because they contest the accuracy/completeness of the record, or (more persuasively) because controlling case law notes that omission of a report of a symptom from a medical record does not necessarily establish its absence. *Synder v. Sec'y of Dep't of Health & Hum. Servs.*, No. 01-162V, 2009 WL 332044, at

[12] *Dobrydnev v. Sec'y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014) (stressing that all three *Althen* prongs must be satisfied).

*148 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (stating "the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame."). Here, Petitioner turns that reasoning on its head, asking me to *accept* as most probative those records that omit complaints of initial JIA-like behaviors by A.P., while ignoring statements he or his wife later made to treaters about when they first observed A.P. actually displaying those kinds of symptoms/behaviors.

I am not inclined to accept Petitioner's invitation to weigh the proof in that manner. It is true that treatment records from between the end of July to the end of October 2018 (approximately three months) make no mention of any JIA-like symptoms reported to A.P.'s pediatric care providers—and such contemporaneous medical records deserve evidentiary weight. But later on, Petitioner and his wife *clearly told* treaters—in other records contemporaneous with when they actually sought care for A.P.—that they had observed such nascent symptoms earlier (although they may not have understood them at the time to be serious). *See,* e.g., Ex. 3 (ECF No. 28-1) at 192 (documenting MyChart message to Dr. Sleasman on June 25, 201, indicating that A.P.'s "arthritis started shortly after [her] 15-month vaccines" which were administered in July 2018). It is reasonable, in weighing the totality of this evidence, to conclude that Petitioner and his wife truthfully reported symptoms they had observed prior in time. All of the above is also consistent with a slowly-progressing disease process that took time to manifest in a more obvious clinical manner.[13]

Moreover, even if there was no evidence anywhere in the record of a pre-November 1st onset, I would still find that the causation was not established, due to Petitioners' inability to demonstrate the November vaccination "did cause" A.P.'s oligoarticular JIA, under the second *Althen* prong. The record does not establish any initial, inflammatory-in-nature reaction to the flu vaccine, as would be expected if a cytokine-driven innate-oriented immune response triggered by vaccination was initiating an aberrant process. There is simply the Thanksgiving weekend observation of ankle swelling, followed by difficulty walking, that A.P.'s parents reporter to treaters at the end of December 2018/early January 2019. And no treaters ever embraced a flu vaccine-associated cause either. The sole evidence of a "logical sequence of cause and effect" is the fact that A.P. developed more alarming symptoms in the weeks after vaccination, and then was later properly diagnosed with oligoarticular JIA. This is not enough to meet the preponderant standard for the second *Althen* prong.

[13] I give less weight to Dr. Rose's explanation for A.P.'s reported behaviors during diaper changes, which he construed as consistent with a nascent, developing oligoarticular JIA. Dr. Rose is a pediatric rheumatologist, and therefore his interpretation of such reports from A.P.'s parents have some expertise-derived validity. But Petitioner is correct that Respondent has not corroborated this aspect of Dr. Rose's opinion with independent scientific or medical evidence standing for the proposition that this is how oligoarticular JIA commonly manifests in an infant.

Prong One

Petitioner's inability to establish that the flu vaccine "can cause" oligoarticular JIA is another sound basis for denial of entitlement (although my determination that the second prong was not met is by itself dispositive). Dr. Gershwin's theory was too broad in nature, implicating both the innate and adaptive arms of the immune process and the impact of vaccination upon them generally, but without the necessary independent evidentiary corroboration (which could have been derived from either his own direct experience researching this condition or independent research supporting a causal likelihood). Dr. MacGinnitie, by contrast, persuasively highlighted the overly-general nature of Dr. Gershwin's theory, along with the fact that the flu vaccine itself is not known to be particularly immunogenic in the first place.

Otherwise (and although this case involves a different vaccine), the reasoning employed in *Putman* supplies useful guidance herein for why causation has not been demonstrated under *Althen* prong one. There, I noted that a similar theory proposed by Dr. Gershwin to demonstrate how vaccination could result in oligoarticular JIA never rose "above a bare form of reasoned speculation." *Putman,* 2022 WL 600417, at *23. The same is true here. Dr. Gershwin's theory presumes the flu vaccine's interference with almost all aspects of the immune process, but with little in the way of ballast that would allow me to so conclude. And I noted in *Putman* that reasoning about the impact of a vaccine-instigated, aberrant immune response worked "better" in the context of systemic JIA, where a child's rheumatic symptoms are preceded by certain kinds of seemingly-nonspecific symptoms (fever, rash) that could more reliably be associated with an aberrant vaccine reaction. *Id.* at *20. No better showing was made in this case.

I also make one additional comment regarding the first *Althen* prong. As set forth in the section of this Decision discussing the legal standards applicable to the case, the Federal Circuit has clearly embraced *preponderance* as the applicable evidentiary standard. *See, e.g.*, *Kalajdzic*, 2024 WL 3064398, at *2. This means that even if claimants need not prove *with certainty* a vaccine can cause the injury at issue—and they of course are *never* called upon to do so - they still have to substantiate their theory with enough reliable and trustworthy evidence to tilt the scales in their favor, however slightly. By contrast, arguments for a plausibility standard aim to *lower* the evidentiary bar, as the Circuit has recognized. *See, e.g.*, *Sheller v. Sec'y of Health & Hum. Servs.,* 121 F.4th 1301, 1308 (Fed. Cir. 2024) (noting that "[a] plausible theory . . . resides somewhat 'lower than the preponderant evidence standard required to prove entitlement to compensation'") (*citation omitted*).

Admittedly, there are a few older decisions (many from the Court rather than the Circuit) where the term plausibility has been employed loosely, as if it is congruent with preponderance — and Petitioner has noted cases that embrace such logic, in an effort to enshrine plausibility as the correct standard. *See generally* Mot. at 14–18. But it is *these decisions* that are incorrect, especially

to the extent they posit that plausibility can carry the day as long as enough *individually-reliable* items of evidence are offered. Plausibility is simply not equivalent to "more likely than not."

In *Boatmon,* the Federal Circuit could not have been clearer in explaining itself on this point:

> We have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard. *Moberly*, 592 F.3d at 1322 (rejecting a "more relaxed standard" of whether the condition was "likely caused" by the vaccine and reiterating that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury ... is not the statutory standard"); *see also LaLonde*, 746 F.3d at 1339 ("However, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (quoting *Moberly*, 592 F.3d at 1322)).

Boatmon, 941 F.3d at 1360.[14]

III. Petitioner Has Not Established A.P.'s Oligoarticular JIA was Significantly Aggravated by her November 1, 2018 Vaccinations

Dr. Gershwin squarely (and in abandonment of Petitioner's initial filings) maintains that A.P.'s oligoarticular JIA *did not begin* prior to the November 1, 2018 vaccinations. *See, e.g.*, First Gershwin Rep. at 2. And Petitioner does not attempt to argue otherwise in the alternative—despite clearly having been provided the opportunity to do so (and despite record evidence of instances in which A.P.'s parents so informed treaters).

As a result, there is *no pending significant aggravation claim left in this case to address.*[15] However—even if Petitioner *had* attempted to prove such a claim, the record evidence would not support it.

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[14] This case typifies why claimants often loudly bang the plausibility "drum." Petitioner cannot marshal much in the way of reliable scientific or medical evidence that the flu vaccine can cause oligoarticular JIA—as Dr. Gershwin's bare-bones theory illustrates. That theory relies on broad generalities about the immune system and how vaccines interact with it—defending the absence of corroborative proof with the argument that it is somehow grossly improper or unfair for a Court to evaluate this absence in the first place. This is not a reasonable view of the burdens placed on Program claimants—a burden that does not rise to the level of certainty, and yet still requires a petitioner to substantiate the claim. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed. Cir. 1993) (in causation-in-fact cases, "the heavy lifting must be done by the petitioner, and it is heavy indeed").

[15] Petitioner's brief passively suggests that he is "prepared" to address significant aggravation if I had deemed it necessary. Mot. at 25. But this amounts to an untenable attempt to hold such a claim "in reserve"—when Petitioner has now had a full and fair opportunity to affirmatively assert that theory as an alternative basis for recovery. For this

Where a petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

As noted, the record in this case could be read to establish A.P.'s onset in late July 2018, if her parents' statements to treaters are given weight (as is reasonable, since Petitioner and his wife told treaters this on several occasions). Thus, A.P.'s oligoarticular JIA likely preceded her November 1st receipt of the flu vaccine (which Dr. Gershwin has focused on). And there is stronger evidence that A.P.'s collective symptoms *did* worsen in the late fall—enough to impel her parents to seek treatment, and which later lead to the formal diagnosis based on a combination of clinical and lab testing evidence. These facts would support findings in favor of Petitioner on the first three *Loving* prongs.

But it has not been preponderantly shown that the flu vaccine *could worsen* oligoarticular JIA, or did so here. Thus, a putative significant aggravation claim fails, largely along the same lines that Petitioner did not meet the *Althen* Prongs (which track *Loving* prongs four to six). It was not preponderantly shown by Dr. Gershwin that receipt of the flu vaccine could worsen JIA symptoms, for example—while reliable epidemiologic studies filed by Respondent suggest vaccination in fact would not lead to new symptomatic flares in individuals already diagnosed with JIA. The medical record also does not support the conclusion that the flu vaccine *did* likely worsen

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reason, my analysis of significant aggravation is succinct, and justifiably so. Special masters are not required to anticipatorily analyze (especially in great detail) *potential* claims arising from a record that a claimant does not affirmatively seek to prove, even after having the opportunity to do so.

A.P.'s illness—even if she did reveal symptoms in its wake that lead her parents to more actively seek treatment (which in turn lead to the provision of the diagnosis). Again, the record does not establish any close-in-time reaction to the flu vaccine that would be consistent with vaccine stimulation of the innate immune system leading to an aberrant autoimmune process.

III. This Matter was Appropriately Resolved Without a Hearing

In ruling on the record, I am choosing not to hold a hearing. Determining how best to resolve a case is a matter that lies generally within my discretion, but I shall nevertheless explain why a hearing was not required.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[ ] each party a full and fair opportunity to present its case." *Hovey,* 38 Fed. Cl. at 400-01 (1997) (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id.* And such a record *can* be created based solely on the filings in the case (which are more often than not voluminous, including medical record documents, expert reports, and attorney brief filings). Accordingly, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to resolve disputes of fact or law, is not *itself* grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—so long as a party has been given the proper "full and fair" chance to prove their claim.

Petitioner, who initiated the case *pro se,* unquestionably was aided by obtaining experienced counsel capable of structuring the claim in a more ordered fashion, and allowing its evaluation in the best light possible. But even with the aid of a qualified expert like Dr. Gershwin, the evidence in the case *on its face* ruled out one of Petitioner's arguments: that the November 1, 2018 vaccinations were the start of A.P.'s arthritic issues, given the number of times her parents reported symptoms starting not long after the July vaccinations. Dr. Gershwin focused only on the symptoms *after* the second round of relevant vaccinations, and did not attempt to offer an opinion about the causality of the first (or that the second round aggravated an existing disease process). And I could evaluate the theory offered based on the written record and exhibits, requiring no live expert testimony to understand it. No trial of this claim was required for its fair resolution.

CONCLUSION

Petitioner has not met his burden of proof. 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.